

**International Assistance and Cooperation in
Access to Essential Medicines:
A Study of the Issues in Governance and Implementation**

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ABSTRACT

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International assistance and cooperation for access to essential medicines can be established as an obligation of developed countries based on international human rights law and an array of authoritative guidance. The research aim of this thesis was to understand how developed countries can be influenced to meet this obligation under the current international order with a view to the improvement of international governance over this issue.

To address this aim, this thesis conducted an analysis based on three sub-questions: (1) what is the current international order governing access to essential medicines, (2) what are the processes and mechanisms that the international order has used to influence developed countries and how have the countries responded, and (3) is there an alternative model to the current governance structure that could lead to improved implementation of international assistance and cooperation by developed countries.

The analysis of the international order involved a study of the World Health Organization and its interactions with the World Trade Organization and the development-related institutions involved in access to medicines (i.e. the World Bank, UNAIDS, and the Global Fund). The lack of leadership by the WHO in governing access to essential medicines has led to significant tensions between the institutions in the form of conflicts, overlaps, and other issues.

The thesis proceeds with a country case study to understand how states interact with the international order and how they can be influenced towards norm implementation. It was determined that the international order possesses an influential array of 'socialization' methods that have been successful in inducing states toward norm compliance (when backed by the support of international NGO networks and domestic pressure). However, the level of disarray that remains in the international order continues to have a negative effect on international assistance and cooperation.

The thesis concludes with an analysis of emerging changes to the current system of governance over access to essential medicines and considers whether these changes might bring an improvement to developed country support of access to essential medicines.

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TABLE OF ABBREVIATIONS

Abbreviation	Full Name
AEM	Access to Essential Medicines
ARV	Antiretroviral
CESCR	Committee on Economic, Social and Cultural Rights
DFID	U.K. Department for International Development
DSB	WTO Dispute Settlement Body
EC	European Commission
ETH	WHO Department of Ethics, Trade, Human Rights and Health Law
FCTC	Framework Convention on Tobacco Control
FTA	Free Trade Agreement
GSP	Generalized System of Preferences
GTH	Globalization, Trade and Health team
GTT	Global Task Team
HNP	Health, Nutrition and Population
IAC	International Assistance and Cooperation
ICESCR	International Covenant on Economic, Social and Cultural Rights
IGO	Intergovernmental Organization
IGWG	WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
IHR	International Health Regulations
INGO	International Nongovernmental Organization
IP	Intellectual Property
ITAC	Industry Trade Advisory Committee
MDG	Millennium Development Goals
OHCHR	Office of the High Commissioner for Human Rights
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHI	Secretariat for Public Health, Innovation and Intellectual Property
TNC	Trans-national Corporation
TPAA	Trade Promotion Authority Act
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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International Covenant on Economic, Social and Cultural Rights (adopted on 16 December 1966, entered into force 3 January 1976) GA Res 2200A (XXI) (ICESR)

UN Commission on Human Rights, 'Effective Functioning of Human Rights Mechanisms: Treaty Bodies' (9 March 2000) UN Doc E/CN.4/2000/98/Add.1

UN Commission on Human Rights, Report of the Special Rapporteur, Paul Hunt, Submitted in Accordance with Commission Resolution 2002/31' (2003) UN Doc E/CN.4/2003/58

Access to Medications in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria, UNCHR Res 2003/29 (22 April 2003) UN Doc E/CN.4/RES/2003/29

UNCHR, 'Report to the Economic and Social Council on the Fifty-Ninth Session of the Commission' (23 April 2003) UN Doc E/CN.4/2003/L.11/Add.3

Optional Protocol to the International Covenant on Economic, Social and Cultural Rights GA Res 63/117 (10 December 2008) UN Doc A/RES/63/117

UNGA, 'Compilation of Guidelines on the Form and Content of Reports to be Submitted by States Parties to the International Human Rights Treaties' (2009) UN Doc HRI/GEN/2/Rev.6

UN Human Rights Council, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (2009) UN Doc A/HRC/11/12

UN Economic and Social Council (ECOSOC)

ECOSOC Res 1985/17 (28 May 1985) UN Doc E/RES/1985/17
'General Comment 1' in 'Reporting by States Parties' (24 February 1989) UN Doc E/1989/22

'General Comment 3' in 'The Nature of States Parties' Obligations' (14 December 1990) UN Doc E/1991/23

‘Revised General Guidelines Regarding the Form and Contents of Reports to be Submitted by States Parties under Articles 16 and 17 of the International Covenant on Economic, Social and Cultural Rights’ (17 June 1991) UN Doc E/C.12/1991/1

‘Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights’ in ‘CESCR General Comment 14 –The right to the highest attainable standard of health’ (11 August 2000) UN Doc E/C.12/2000/4

‘Report on the Twenty-Fifth, Twenty-Sixth and Twenty-Seventh Sessions (Supplement No. 2)’ (2002) UN Doc E/2002/22

‘Report on the Twenty-Eighth and Twenty-Ninth Sessions (Supplement No. 2)’ (2003) UN Doc E/2003/22

‘Fifth Periodic Reports Submitted by States Parties under Articles 16 and 17 of the Covenant: United Kingdom of Great Britain and Northern Ireland’ (31 January 2008) UN Doc E/C.12/GBR/5

World Health Organization (WHO)

Constitution of the World Health Organization (adopted 22 July 1946, entered into force 7 April 1948).

International Health Regulations (adopted on 25 July 1969, amended 23 May 1973, adopted on 20 May 1981, entered into force on 1 Jan 1982)

International Health Regulations (adopted on 23 May 2005, entered into force on 15 June 2007)

International Code of Marketing of Breast Milk Substitutes, WHA 34.22 (1981)

WHO Revised Drug Strategy, WHA Res 39.27 (1986)

Revised Drug Strategy, WHA Res 49.14 (1996)

Tobacco or health programme, WHA Res 49.16 (1996)

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'Report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property' (19 May 2008) WHA Sixty First Committee, Doc. A61/9

World Trade Organization (WTO)

Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994)
LT/UR/A-1C/IP/1

Declaration on the TRIPS Agreement and Public Health (14 November 2001)
WT/MIN(01)/DEC/2

Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003) WT/L/540

Amendment of the TRIPS Agreement (6 December 2005) WT/L/641

European Commission

Commission Regulation 816/2006, Compulsory Licensing of Patents relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, OJ (L 157) 1–7

South Africa

Medicines and Related Substances Control Amendment Act, No. 90 (1997)

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European Union and a Member State: Seizure of Generic Drugs in Transit—Request for Consultations by Brazil (12 May 2010) WT/DS409/1

European Union and a Member State: Seizure of Generic Drugs in Transit—Request for Consultations by India (11 May 2010) WT/DS408/1

Canada: Patent Protection of Pharmaceutical Products—Complaint by the European Communities and their Member States—Report of the Panel (17 March 2000) WT/DS114/R

South Africa

Pharmaceutical Manufacturers Association of South Africa v President of the Republic of South Africa. Case No 4183/98, filed Feb 18, 1998 (High Court of South Africa)

Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex parte President of the Republic of South Africa and Others 2000 (2) SA 674 (CC); 2000 (3) BCLR 241 (CC)

Chapter 1: INTRODUCTION

This chapter provides a background introduction to the issue of access to essential medicines (AEM) and the alleged need for developed countries to implement their international assistance and cooperation duty so that greater AEM can be realized in developing countries. First, the chapter provides a background discussion and definition for ‘access to essential medicines’ and highlights the critical role of developed country involvement in overcoming the current hurdles to AEM through international assistance and cooperation. The chapter proceeds with a summary of several key ethical and legal arguments recognizing a duty for international assistance and cooperation (IAC). This is followed by a list of international assistance and cooperation standards for access to essential medicines, which was drawn from various international agreements, declarations, and guidance. The chapter concludes with a statement on my research aim and approach as well as a summary overview of the chapters in this thesis.

The Issue of ‘Access to Essential Medicines’

According to public health proponents, the problem of access to essential medicines heavily burdens developing countries around the world. It has been estimated that ‘infectious diseases kill over 14 million people each year, nine out of ten of whom live in the developing world’.¹ Children and young adults in Africa and South-East

Asia bear a large proportion of infectious diseases, where half of the deaths among this group are due to six particular diseases – AIDS (14% of deaths), Acute Respiratory Syndrome (11%), Diarrhoeal diseases (11%), malaria (8%), Measles (6%), TB (2%).² Despite the existence of effective medicines, millions of people will continue to suffer and die from these and other life-threatening conditions because they cannot access the necessary treatments. It has been estimated that as much as one-third of the world's population (2 billion people) lacks access to such essential medicines.³

The stark inequities faced by such populations, notably those suffering from HIV/AIDS, have highlighted the acute need for international assistance and cooperation in support of their plight. Novel institutions have been established to provide assistance, such as UNAIDS; the Global Fund to Fight AIDS, Tuberculosis and Malaria; and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Bold declarations of cooperation have emerged in a variety of international policy fora. For example, World Trade Organization (WTO) member states issued a formal declaration affirming that its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health, and in particular, to promote access to medicines for all'.⁴ This includes the government option to use

¹ U.S. Government, *Trade Agreements and Access to Medications Under the Bush Administration* (United States House of Representatives Committee of Government Reform - Minority Staff Special Investigation Division 2005), p. 1-2.

² J Quick, 'Ensuring Access to Essential Medicines in Developing Countries and Least Developed Countries - Framework for Action' (2002) World Health Organization (Essential Drugs and Medicines Policy Dept.).

³ U.S. Government, p. 1-2.

⁴ Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2.

TRIPS ‘flexibilities,’ such as compulsory licensing and parallel importation, to address public health concerns. Over the past decade, dramatic increases in some medicines have been achieved; however, the general problem of access to medicines ‘for all’ still persists.⁵ This problem, in part, can be attributed to the resource constraints faced by developing countries and their inability to afford medicines. Many believe that developed countries have a critical role in access to essential medicines efforts; yet, their support and response to this issue is often weaker than needed and, in some cases, counterproductive in the policy measures taken.

Defining ‘Access to Essential Medicines’ (AEM)

The phrase ‘access to essential medicines’ has been used by developing countries, activists, intergovernmental organizations, academics and numerous others in a variety of contexts, but their use of the phrase does not always imply the same thing. For the purposes of this thesis, it is necessary to establish a clear definition of ‘essential medicines’ and ‘access’.

First of all, the term ‘essential medicines’ often refers to treatment for life-threatening diseases of critical public health need or emergency with a direct reference to the World Health Organization’s definition of ‘essential medicines’.⁶ In other instances, the phrase includes the category of ‘neglected diseases’ for which a lack of attention has been paid toward research and development for the appropriate

⁵ J Wise, ‘Access to AIDS medicines stumbles on trade rules’ (2006) 85 (5) Bulletin of the World Health Organization 342.

⁶ WHO, ‘Essential Medicines’ <http://www.who.int/medicines/services/essmedicines_def/en/index.html> (20 May 2007).

treatments.⁷ There has also been an increasing reference to treatments for the chronic diseases and conditions, such as pain management and cancer.⁸

The World Health Organization (WHO), which is the foremost authority on matters of international health, defines essential medicines as ‘those that satisfy the priority health care needs of the population’.⁹ To help guide countries in their selection and coverage of medicines under national policies, WHO develops a biennial ‘model list’ of essential medicines which selects treatments based on the criteria of: disease prevalence, efficacy and safety, and comparative cost-effectiveness.¹⁰ WHO recommends that these medicines ‘be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford’.¹¹ In recognition of differing national health needs, WHO intends for ‘the concept of essential medicines ... to be flexible and adaptable to many different situations; exactly which medicines are

⁷ P Hunt, 'Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations' (2003) [2003] 4 United Nations Health and Human Rights Working Paper Series 1.

⁸ A Thom, 'Dying in pain a reality for most Africans' (2009) Health-e <<http://www.health-e.org.za/news/article.php?uid=20032573>> (16 Nov 2009); A Taylor, L Gostin and K Pagonis, 'Ensuring Effective Pain Treatment' (2008) 299 (1) *Journal of the American Medical Association* 89; H Frankish, '15 million new cancer cases per year by 2020' (2003) 361 (9365) *The Lancet* 1278; M Aublanc, L Menning and M Aurigemma, 'Cancer treatment and care in developing countries: Experts spotlight growing crisis, Axios International' (2009) <<http://www.axios-group.com/section/89>> (2 Feb 2009).

⁹ WHO.

¹⁰ *ibid.* (It is important to note, however, that the WHO has added some medicines to its list with a statement that ‘cost was not a factor in determining the suitability of the drugs for the list’. For example, in 2002, this included a set of ten antiretroviral drugs. See B Schwartlander, I Grubb and J Perriens, 'The 10 year struggle to provide antiretroviral treatment to people with HIV in the developing world' (2006) 368 *The Lancet* 541, p. 544; E 't Hoen, 'Globalisation and Equitable Access to Essential Drugs' (2000) *Third World Network* <<http://www.twinside.org.sg/title/twr120c.htm>> (1 July 2009).)

¹¹ WHO, 'Health Topics - Essential Medicines' <http://www.who.int/topics/essential_medicines/en/> (20 May 2007).

regarded as essential medicines remains a national responsibility'.¹² This thesis adopts the WHO's definition of 'essential medicines', but with the recognition that country needs may differ and that not all essential medicines might be on the 'model list'.

'Access', in relation to essential medicines, can be defined as the ability to obtain and use a medicine.¹³ For developing countries, a major hurdle to access is the affordability of essential medicines.¹⁴ Affordability is based upon two factors – price and ability to pay. In developing countries, access to essential medicines is often obstructed due to the high prices of patented treatments and the population's low average incomes.¹⁵ The burden of trying to afford essential medicines is obvious in country statistics, which indicate that '[medicines] are the largest household and second largest public expenditure for health' in many developing countries.¹⁶ (For the remainder of this thesis, the phrase 'access to essential medicines' will be referred to in the abbreviated form of 'AEM'. Also, my application of 'access' will be limited to 'existing' medicines that are available in the market. Some groups, such as Médecins Sans Frontières, apply the term 'access' more broadly and include non-

¹² *ibid.*

¹³ K Johnson, 'Session 11: Access to Essential Medicines' (Pharmaceuticals Management for Underserved Populations, Johns Hopkins Bloomberg School of Public Health 2006). The UN has also defined 'access' as 'having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population'. See UN MDG Gap Task Force, 'Delivering on the Global Partnership for Achieving the Millennium Development Goals' (2008) United Nations <<http://www.un.org/millenniumgoals/pdf/MDG%20Gap%20Task%20Force%20Report%202008.pdf>> (1 June 2010), p. 35.

¹⁴ Other access problems may include unreliable health systems (in the procurement and distribution of medicines), poor quality in medicines due to a lack of regulation, and the irrational use (i.e. overuse, under-use, or mis-use) of medicines. These issues are primarily matters of national control, and thus beyond the scope of my present study regarding international assistance and cooperation. See J Quick, '25 Years of Essential Medicines' (2003) World Health Organization (Department of Essential Drugs and Medicines Policy) .

¹⁵ UN MDG Gap Task Force, p. 41.

¹⁶ Quick, 'Ensuring Access to Essential Medicines in Developing Countries and Least Developed Countries - Framework for Action'.

existing (or undiscovered) medicines for the treatment of conditions that have been neglected due to a lack of research and development (R&D).

In response to this problem, many developing countries have turned to the use of generic medicines as a solution to treatment affordability. Generic medicines are ‘copies of patented drugs or drugs whose patents have expired’.¹⁷ Because generics are simply copies without other major associated costs (e.g. research and development costs), they can be sold much more cheaply than their patented counterparts because they only require manufacturing costs.¹⁸ With the burgeoning generic production industries in countries such as India, Thailand and Brazil, developing countries have been able to establish a source of more affordable treatment for their populations and their neighbours.¹⁹ However, the justification for using generics to address the problem of affordability is a popular point of dispute between health advocates and the pharmaceutical industry. A common argument used by the pharmaceutical industry against the utilization of generics is that it threatens their return on investment for the research and development (R&D) of new medicines.²⁰ Proponents of generics counter that developing countries constitute ‘such a small part of the drug industry revenue’ (for example, the entire African continent accounts for just over 1%

¹⁷WTO, ‘TRIPS and Pharmaceutical Patents (Fact Sheet)’ (2006) World Trade Organization <www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.doc> (10 July 2008), p. 7.

¹⁸ In fact, the WHO estimates that ‘[t]he average potential saving in 17 lower and middle income countries by switching from branded originator products to generics range from 26 % to 88 %’. B Santoso, ‘Essential medicine system in developing countries’ (2010) World Health Organization <http://www.wpro.who.int/NR/rdonlyres/DA076EF9-BB72-4B2C-B6DE-ED02ED61AE7D/0/PPT_Budion_Essentialmedicinesystemindevelopingcountries.pdf>.

¹⁹ M Ramphele and N Stern, ‘Generic Drugs can Make the Money Last’ *New York Times* (New York 1 March 2003).

²⁰ P Danzon and E Keuffel Regulation of the Pharmaceutical Industry 2005, p. 16. See also Abbott Laboratories, ‘Global Citizenship Issues: Intellectual Property’ <http://www.abbott.com/global/url/content/en_US/40.30.40:40/general_content/General_Content_00272.htm> (20 May 2007).

in worldwide sales) and that the industry has consistently spent more in the areas of marketing and administration than on R&D.²¹ Furthermore, the World Bank has pointed out that ‘half of the current R&D expenditure worldwide, estimated at \$70-90 billion, is funded publicly’.²² This includes many of the current HIV/AIDS treatments²³ marketed by the pharmaceutical industry.²⁴ Developed countries have been heavily criticized for embracing and promoting pharmaceutical industry interests in international fora (e.g. the World Trade Organization) rather than upholding AEM.²⁵ This is unsurprising given that most, if not all, of the world’s most profitable pharmaceutical companies are based in highly industrialised countries (such as the United States, the United Kingdom, Germany, Switzerland, France, and Japan).²⁶

Another solution that has been used to address the problem of access in developing countries is the financing of drug procurement programmes or donation of drugs by developed countries. Such programmes often take the form of multilateral or bilateral initiatives, which focus on combating certain diseases and channel foreign assistance into the purchase or donation of medicines for select developing countries. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria (‘the Global

²¹ MSF, 'MSF Frequently Asked Questions' <<http://www.accessmed-msf.org/campaign/faq.shtm>> (20 April 2007); E 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A long way from Seattle to Doha' (2002) 27 *Chicago Journal of International Law* 27.

²² MSF.

²³ Examples include stavudine, zidovudine, didanosine, zalcitabine, abacavir, and ritonavir.

²⁴ D Brown, 'Group Says U.S. Should Claim AIDS Drug Patents' *Washington Post* (26 May 2004) A04. See also MSF.

²⁵ The promotion of pharmaceutical industry interests in the World Trade Organization and the establishment of the WTO Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) will be detailed later in this thesis.

²⁶ 'Global 500 2009 Pharmaceutical Industry' (2009) <<http://money.cnn.com/magazines/fortune/global500/2009/industries/21/index.html>> (2).

Fund'), the World Bank HIV/AIDS initiatives, and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) programme are a few key examples of multilateral and bilateral efforts to help developing countries attain medicines through financial support or donations. Developed countries, however, have been heavily criticized for their selective and inefficient medicines programmes in developing countries.²⁷

Another key concern about these initiatives is the lack of AEM sustainability if a financing or donation programme terminates. This is serious problem for HIV/AIDS patients because the current medicines (i.e. antiretrovirals) do not cure the condition but only help to control the disease with ongoing and regular treatments.

AEM's Normative Background and the Duty of International Assistance and Cooperation (IAC)

Over the past decade, AEM has gained widespread recognition as an international norm (as discussed later in this section).²⁸ The global HIV/AIDS crisis and the existence of effective antiretroviral treatments²⁹ helped propel the issue of AEM onto the international stage and, subsequently, prompted numerous international government agreements, declarations, and commitments to alleviate the problem of AEM faced by heavily disease-burdened countries (namely poor developing countries). International efforts to address global health and development (such as the

²⁷ These inefficiencies include redundancy, unnecessary competition, and poor coordination in the use of finances among the various initiatives.

²⁸ J Youde, 'Is Universal Access to Antiretroviral Drugs an Emerging International Norm?' (2008) 11 J of International Relations and Development 415; C Barry and K Raworth, 'Access to Medicines and the Rhetoric of Responsibility' (2002) 16 (2) Ethics & International Affairs .

²⁹ Antiretrovirals treatments do not cure HIV/AIDS, but can help extend the lifespan and quality of life of those suffering from HIV.

Millennium Development Goals and HIV/AIDS programmes) also recognize AEM as a critical component to achieving their objectives. Furthermore, the problem of AEM is widely recognized and discussed within academic, government, and activist circles. The extensive body of literature developed by these groups has greatly contributed to AEM's normative recognition.

As discussed in the previous section, developed countries hold a critical role in access to essential medicines efforts. To date, however, their support of global AEM efforts has been weak and, in some cases, counterproductive.³⁰ In order for global AEM efforts to succeed, there is a need for developed countries to recognize the criticality of AEM in developing countries and to provide the necessary international assistance and cooperation. Yet, why should states feel the need to recognize AEM as a norm and a call to action in terms of international assistance and cooperation? There are several key ethical and legal arguments that justify international assistance and cooperation by developed countries for the realization of AEM in developing countries, which are briefly reviewed in this section.

Ethical Arguments

Humanitarianism is a popular concept among industrialized country governments and corporate actors as an ethical basis for action in access to essential medicines programmes (and, more broadly, global health initiatives) as illustrated by a variety of philanthropic efforts to date.³¹ In philosophical terms, humanitarianism is a form of

³⁰ This will be elaborated upon in Chapter 5.

³¹ S Alkire and L Chen, 'Global health and moral values' (2004) 364 (9439) *The Lancet* 1069.

virtue ethics; however, it can be understood more simply as a ‘humanistic response [e.g. compassion or empathy] to evident social problems’ by helping those in need.³² The popular appeal of humanitarianism as a justification for action among the wealthy nations and corporate actors lies in its ‘voluntary’ nature as opposed to a sense of ‘duty’ or ‘obligation’, which characterises several other ethical principles (discussed later in this section).³³ This voluntary approach allows actors to determine the degree to and frequency with which they choose to subject themselves to helping others, if at all. Stephen Marks has noted, however, that humanitarianism creates two other problems for assistance and cooperation. First, it creates the ‘danger’ that developing countries will become dependent on others’ voluntary assistance and treated as ‘victims not agents’.³⁴ Second, such assistance is likely to address humanitarian ‘emergencies’ and ‘catastrophes’ rather than the ‘root causes of social problems’.³⁵ Another related ethical argument for international assistance and cooperation is the theory of enlightened self-interest, which moves beyond helping others simply based on compassion - but also to serve one’s self-interest (e.g. national security).³⁶ A concern with this approach is that it could lead to a misalignment between actual needs in developing countries and what donors prefer to support. This is an approach that has been embraced by a number of developed countries.

³² *ibid.*

³³ *ibid.*

³⁴ *ibid.*

³⁵ *ibid.*

³⁶ L Gostin, 'Meeting Basic Survival Needs of the World's Least Healthy People Toward a Framework Convention on Global Health' (2008) 96 (1) *Georgetown Law Journal* 331.

Another ethical argument for international assistance and cooperation is the emerging theory of global justice.³⁷ This theory seeks to move beyond the ‘narrowly framed’³⁸ classic theories of distributive justice, which are focused on ‘just distribution’ within a state.³⁹ Rather, in today’s society, there needs to be an approach that account for the powers of globalization as states cannot be considered self-sufficient or self-contained. (This is illustrated by the problem of AEM in terms of rapid global disease spread and international trade.) The emerging conceptions of global justice appear to embrace a cosmopolitan approach whereby ‘principles of justice apply to all individuals wherever they are in the cosmos’⁴⁰. Cosmopolitanism considers humans to be ‘the ultimate unit of moral concern, each human being of equal value for all, even those with the most remote affinity’.⁴¹ In other words, ‘the interests of all persons ... must count equally in moral deliberation, and that geographical location and citizenship make no intrinsic difference to the rights and obligations of those individuals.’⁴² Jennifer Ruger observes that this theory can vary from ‘strong demands for cooperation on a global scale to simple adherence to the no-

³⁷ P Singer, *One World* (Yale University Press, New Haven 2000); T Pogge, *World Poverty and Human Rights* (Polity Press, Cambridge, UK 2002); M Nussbaum, 'Toward Global Justice' (2000) The Fathom Archive <<http://fathom.lib.uchicago.edu/1/77777760815/>> (11 May 2009).

³⁸ Gostin.

³⁹ J Rawls, *A Theory of Justice* (Harvard University Press, Cambridge, MA 1971), p. 303; S Marks, 'Obligations to Implement the Right to Development: Political, Legal, and Philosophical Rationales' in BA Andreassen and SP Marks (eds) *Development As a Human Right: Legal, Political, and Economic Dimensions* (Harvard University Press, 2006), p. 61; Stanford, 'Distributive Justice' (2007) Stanford Encyclopedia of Philosophy <<http://plato.stanford.edu/entries/justice-distributive/>> (11 May 2009); Gostin; T Nagel, 'The Problem of Global Justice' (2005) 33 *Philosophy and Public Affairs* 113; M Walzer, *Spheres of Justice: A Defense of Pluralism and Equality* (Basic Books, New York, NY 1983).

⁴⁰ J Ruger, 'Ethics and Governance of Global Health Inequalities' (2006) 60 *Journal of Epidemiology and Community Health* 998, p. 999.

⁴¹ Marks, pg. 67.

⁴² A Kuper, 'More Than Charity: Cosmopolitan Alternatives to the “Singer Solution”' (2002) 16 (2) *Ethics & International Affairs* 107, p 108.

harm principle—that is ...international institutions and agreements may not cause harm'.⁴³

Towards a Legal Basis

In an effort to move beyond the more abstract notions for international assistance and cooperation, the concept of human rights has become a popular argument endorsed by activists, developing countries, and some international agencies supporting international action for AEM. Various scholars and health practitioners have turned to human rights in an effort to understand how greater access to medicines could be established through a rights-based approach in developing countries. A growing body of work has emerged identifying access to medicines as a derivative of the right to health, outlining its component human rights obligations, considering its relationship with the competing interests of intellectual property rights, and analyzing its justiciability in domestic courts.⁴⁴ There has been limited attention, however, to the extraterritorial obligations of developed countries on this issue. This particular issue will be addressed in greater detail later in this chapter.

⁴³ J Ruger, 'Normative Foundations of Global Health Law' (2008) 96 *Georgetown Law Journal* 423, p. 428

⁴⁴ S Marks, 'Access to Essential Medicines as a Component of the Right to Health' in A Clapham and M Robinson (eds) *Realizing the Right to Health (The Swiss Human Rights Book)* (Geneva 2009); HV Hogerzeil and others, 'Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?' (2006) 368 *The Lancet* 305–11, pp.305-311.; A Grover, 'Report to the UN General Assembly Human Rights Council, UN Doc. No. A/HRC/11/12' (2009) UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health <<http://www.unhcr.org/refworld/docid/49faf7652.html>> ; HV Hogerzeil, 'Essential medicines and human rights: what can they learn from each other?' (2006) 84 *Bulletin of the World Health Organization* 371; P Hunt and R Khosla, 'The Human Right to Medicines' (2008) 5 (8) *Sur-International Journal on Human Rights* 101; P Cullet, 'Patents and Medicines: the Relationship between TRIPS and the Human Right to Health' (2003) 79 (1) *International Affairs* 139.

The right to ‘the enjoyment of the highest attainable standard of health’ (also known as the right to health) is a fundamental human right in international law that is often cited in support of AEM.⁴⁵ The right to health was first established under the preamble to the World Health Organization (WHO) Constitution, which stated that ‘[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.’⁴⁶ The legal significance of this declaration in the WHO Constitution is noted by Brigit Toebes, who states that the ‘constitutions of international organizations are ... multilateral treaties under public international law’ and, therefore, the WHO Constitution is ‘binding upon States that are party to the WHO.’⁴⁷ As of 2006, the WHO Constitution applies to 193 member states.

Two other key international law sources also recognize the right to health. One source is the Universal Declaration of Human Rights (UDHR), which was adopted in 1948 by the UN. Though the UDHR is not technically international law *per se*,⁴⁸ it has been increasingly considered ‘customary international law’ and, thus,

⁴⁵ A Hendriks, 'The Right to Health in National and International Jurisprudence' (1998) 5 (4) *European Journal of Health Law* 389, p. 20; T Evans, 'A human right to health?' (2002) 23 (2) *Third World Quarterly* 197; H Hestermeyer, 'Access to Medicines as a Human Right' (2004) 8 *Max Planck UNYB* 101; H Hogerzeil, 'Access to essential medicines as a human right' (2003) 33 *Essential Drugs Monitor* 25; H Nygren-Krug and HV Hogerzeil, 'Human rights: a potentially powerful force for essential medicines' (2006) 84 (5) *Bulletin of the World Health Organization* 410. (There are other human rights that have been applied in support of access to medicines, such as the right to life.)

⁴⁶ WHO, Constitution of the World Health Organization (adopted 22 July 1946, entered into force 7 April 1948), Preamble.

⁴⁷ B Toebes, *The Right to Health as a Human Right in International Law* (School of Human Rights Research Series, Intersentia/Hart, Antwerpen 1999), p. 33.

⁴⁸ 'Universal Declaration of Human Rights' (1948) Office of the High Commissioner for Human Rights <<http://www.unhcr.ch/udhr/miscinfo/carta.htm>>.

alleged to be binding on States.⁴⁹ In Article 25.1 of the UDHR, it proclaims that ‘everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and *medical care*’.⁵⁰ (emphasis added) The term ‘medical care’, as used by the UDHR, is understood to include medicines – such as drugs and vaccines.⁵¹

The second key source is the International Covenant on Economic, Social and Cultural Rights (ICESCR), which was adopted by the UN in 1966. The ICESCR, a ‘cornerstone protection of the right to health in international law’,⁵² is an international treaty that is legally-binding upon the 192 member states of the UN. According to Article 12.1 of the ICESCR, States must ‘recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.’⁵³ Furthermore, in attaining the fulfilment of this right, the ICESCR’s Article 12.2 specifies that States should take the necessary steps for:

12.2 (c) ‘The prevention, *treatment* and control of epidemic, endemic, occupational and other diseases.’

12.2 (d) ‘The creation of conditions which would assure to all *medical service* and medical attention in the event of sickness.’ (emphasis added)

With explicit statements addressing ‘treatment’ and ‘medical service’, both the 12.2 (c) and 12.2(d) indicate a clear dependence on access to essential medicines in order to fulfil the right to health. Thus, as the UN Special Rapporteur on the Right to

⁴⁹ Toebe, p. 40.

⁵⁰ ‘Universal Declaration of Human Rights’, Art 25.1

⁵¹ Hunt, ‘Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations’.

⁵² UN, ‘The right of everyone to the enjoyment of the highest attainable standard of physical and mental health. E/CN.4/2003/58’ (2003) UN High Commissioner for Human Rights.

⁵³ ‘International Covenant on Economic, Social and Cultural Rights (adopted on 16 December 1966, entered into force 3 January 1976)’ G.A.Res. 2200A (XXI), Art 12.1.

Health concluded, ‘access to medicines forms an indispensable part of the right to the highest attainable standard of health’.⁵⁴

To assist States in the implementation of Article 12 (i.e. the right to the highest attainable standard of health) of the ICESCR, General Comment 14 was produced by the UN Committee on Economic, Social and Cultural Rights (CESCR) in 2000. The purpose of General Comment 14 was to clarify the ‘right to health’ in light of the changing world health situation and evolving notions of health since the ICESCR’s adoption in 1966.⁵⁵ A notable specification made by the CESCR in General Comment 14 was that the provision of ‘essential drugs, as ... defined under the WHO Action Programme on Essential Drugs’ is a *core obligation* of states under the right to health.⁵⁶ (WHO’s definition of ‘essential medicines’ was provided earlier in this chapter and will be elaborated upon in Chapter 3.)

Core obligations are the ‘most essential’ elements of a right. In other words, core obligations are the elements that ‘encompass the essence of the right’ whereby without them a right would lose its significance.⁵⁷ Brigit Toebes notes that such obligations must be guaranteed ‘immediately’ and ‘under any circumstances’.⁵⁸ This

⁵⁴ P Hunt, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health (Report to the UN General Assembly)* (A/61/338, 2006) 1-25, p. 1-25

⁵⁵ ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in ‘CESCR General Comment 14 - The right to the highest attainable standard of health’ (E/C.12/2000/4, 2000), para. 10.

⁵⁶ *ibid.*, para. 43(d) and 44 (b),(c). Also, the CESCR recognizes access to essential medicines as a core obligation because it used the primary health care components defined in the Declaration of Alma-Ata as a guide on essential elements of the right to health. See Toebes, p. 676.

⁵⁷ Toebes, p. 676.

contrasts with other non-core obligations of the right to health that are subject to ‘progressive realization’,⁵⁹ which requires ‘deliberate, concrete and targeted’ steps in an expeditious and effective manner.⁶⁰ Such non-core obligations would include the other medicines that are not considered ‘essential’ or have yet to exist (e.g. treatments for neglected diseases). Hence, as Paul Hunt and Rajat Khosla conclude, ‘while a state is required to progressively realize access to non essential medicines, it has a core obligation of immediate effect to make essential medicines available and accessible throughout its jurisdiction’.⁶¹

Fulfilling the core obligation of access to essential medicines, however, can pose a serious problem for developing countries. In such countries, the large populations of impoverished and disease-stricken individuals who lack basic necessities (such as food, water and shelter) are already causing a major strain on government resources, among other domestic economic and social concerns.⁶² In recognition of the disparate realities among countries, General Comment 14 states:

For the avoidance of any doubt, the Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide international assistance and cooperation, especially economic and

⁵⁸ *ibid.*, p. 675-676; ECOSOC., para. 30. (See also ECOSOC, para. 43. It explains that states are expected to ‘ensure the satisfaction of, at the very least, minimum essential levels’ of the core obligations to their respective national populations.)

⁵⁹ An example non-core obligation that is subject to ‘progressive realization’ provided by the UN Special Rapporteur for the Right to Health is that of research and development for new medicines. See Hunt, ‘Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations’, p. 10.

⁶⁰ ECOSOC, para 31. See also Hunt, ‘Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations’, p.10.

⁶¹ Hunt and Khosla, ‘The Human Right to Medicines’, p. 102.

⁶² B Leach, J Paluzzi and P Munderri, ‘Prescription for Healthy Living: Increasing Access to Medicines’ (2005) UN Millennium Project Task Force on HIV/AIDS, TB, Malaria and Access to Essential Medicines (Working Group on Access to Essential Medicines) <<http://www.unmillenniumproject.org/documents/TF5-medicines-Complete.pdf>> (12 July 2008), p. 114.

technical which enable developing countries to fulfil their core and other obligations.⁶³

This comment emphasizes that industrialized nations cannot ignore the current health conditions in developing countries. Instead, it has been argued that states are expected to meet their international assistance and cooperation duty to other economically disadvantaged countries by helping those countries in respecting, protecting and fulfilling their core obligations, such as access to essential medicines.⁶⁴ If an industrialized nation fails to meet this obligation, it can be considered to have neglected 'to fulfil its international legal obligations towards the right to health'.⁶⁵ This thesis focuses on the core obligation of access to essential medicines (AEM) rather than the broader concept of access to medicines, which incorporates both core and non-core obligations. Also, the duty of international assistance and cooperation will be discussed in further detail a bit later in this chapter.

Access to Essential Medicines as a Human Right

In addition to efforts to establish the legal basis of access to essential medicines in the right to health (as a derived right), there has been a growing movement to recognize access to essential medicines as a right in itself. In other words, to establish a 'right

⁶³ ECOSOC, para. 45.

⁶⁴ According to the CESCR's General Comment 14, countries hold a 'tripartite' set of obligations towards the right to health. These obligations are 'to respect, to protect and to fulfil' the right to health. See O Ferraz and J Mesquita, 'The Right to Health and the Millennium Development Goals in developing countries: A Right to International Assistance and Cooperation?' (2006) Human Rights Centre, University of Essex
<http://www.essex.ac.uk/human_rights_centre/research/rth/docs/IAC_H_final.doc> , p. 15.

⁶⁵ Hunt, 'Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations', p. 9.

to essential medicines'. Much like the movements that have transformed other 'obligations' into 'rights' in public discourse and within legal culture, there is an interest in bringing a greater sense of legal status to the issue of access to essential medicines. For example, a notable event in the 'right to essential medicines' movement occurred in 2005 at a Montreal conference titled 'Human Rights and Access to Essential Medicines: The Way Forward'. This conference brought together individuals from governments, international agencies (including WHO), non-governmental institutions and academic institutions to discuss and issue a formal statement on 'the human right to essential medicines'.⁶⁶ The Montreal Statement reaffirmed existing international standards by declaring that 'States Parties to international human-rights treaties have a core obligation to respect, protect, and fulfil the right to essential medicines' and that '[t]his core obligation requires immediate and effective measures and is not subject to progressive implementation'.⁶⁷ More importantly, it drew attention to the fact that 'despite many resolutions and statements of commitment in recent years, far too little has been accomplished toward the effective realization of ... the right to essential medicines.'⁶⁸ Though the Montreal Statement carries no legal power, it symbolizes another significant step in the recognition of access to essential medicines' importance by explicitly declaring it as a distinct right and solidifying state expectations. Furthermore, as a human right, access to essential medicines would 'become part of an effort to develop standards of achievement with respect to citizens' rights within an *international*

⁶⁶ Canadian Coalition for Global Health Research, "The "Montréal Statement on the Human Right to Essential Medicines" drafted at the University of Montreal. " (2005) Canadian Coalition for Global Health Research <http://www.ccghr.ca/default.cfm?lang=e&content=accessmeds_news&subnav=news> .

⁶⁷ *ibid.*, para. 4.

⁶⁸ *ibid.*, para. 4

community' (emphasis added), which transcends the 'principle of legitimacy within a particular national state'.⁶⁹ David Sidorsky⁷⁰ boldly argues that such processes of human rights formulation 'asserts that universal norms or standards are applicable to all human societies' and 'affirms that all individuals, solely by virtue of being human, have moral rights which no society or state should deny'.⁷¹

It is recognized that much of the rights-based discourse on access to essential medicines, as well as its related concepts (i.e. the duty of international assistance and cooperation), is still working its way through legal and policy scholarship. Whether a proclamation of a 'right to essential medicines' has legal force remains a matter of ongoing political debate, but there is growing acceptance and use of the phrase amongst members of the international community (i.e. state officials, NGOs and activists, and academics).⁷² This recognition of 'access to essential medicines' as a human right can be attributed to several persuasive arguments. First, access to essential medicines is argued to be a grave matter of 'life or death' for individuals and framing it in the terms of 'human rights' helps to elevate attention to its critical status.⁷³ Because public health increasingly relies on the existence and continuing

⁶⁹ H Steiner and P Alston, *International Human Rights in Context* (Clarendon Press, Oxford 1996), p. 327.

⁷⁰ David Sidorsky is a Professor of Philosophy at Columbia University.

⁷¹ Steiner and Alston., p. 300.

⁷² The 'right to essential medicines' (or the 'right to medicines') has been used in the writings of Dr. Hans Hogerzeil (Director of Essential Medicines and Pharmaceutical Policies at WHO), Prof. Paul Hunt (former UN Special Rapporteur on the Right to Health), Prof. Stephen Marks (Harvard University), Prof. Thomas Pogge (Yale University), Knowledge Ecology International, Médecins Sans Frontières, and others. (See also WHO, *WHO Policy Perspectives on Medicines* (No 03, 2001 - Globalization, TRIPS and Access to Pharmaceuticals 2001). In this document, the WHO states 'access to essential drugs is a human right'.)

growth of certain medicines for survival, it is believed to '[make] sense to incorporate such interventions into our concepts of basic rights'.⁷⁴ Furthermore, the expression of access to essential medicines as a human right implies 'a special importance, status, [and] priority'; thus allowing it to potentially 'trump' other competing issues such as intellectual property rights.⁷⁵ Second, stating a right to essential medicines helps to create state obligations and individual entitlements to these public goods.⁷⁶ Third, the rights-based approach to essential medicines helps to promote 'a merely ethical valorisation to be overcome in favour of the analysis of actions adopted in the framework of public health in a context of legal enforceability'.⁷⁷ Essentially, the use of a human rights framework 'provides new tools for analysis, action, accountability, alignment of policies, and advocacy' to guide states on the problem of access to essential medicines.⁷⁸ Fourth, access to essential medicines is considered a fundamental element for compliance with the human right to health (as discussed earlier in terms of core obligations).⁷⁹ Since 'most countries have acceded to at least one global or regional covenant or treaty confirming the right to health', it is argued

⁷³ B Pecoul, '25th Anniversary of the Essential Medicines List: Access to essential medicines of the future' (2002) <<http://www.accessmed-msf.org/prod/publications.asp?scntid=71120021641496&contenttype=PARA&>> .

⁷⁴ J Kahn, 'Rights and practical access to medicines (Special Theme – Intellectual Property Rights and Public Health Round Table Discussion)' (2006) 84 (5) *Bulletin of the World Health Organization* 409.

⁷⁵ Nygren-Krug and Hogerzeil, p. 410; V Leary, 'The Right to Health in International Human Rights Law' (1994) 1 (1) *Health and Human Rights: An International Journal* 24, p. 35.

⁷⁶ Hogerzeil, 'Access to essential medicines as a human right', p. 25. See also Pecoul.

⁷⁷ X Seuba, 'A human rights approach to the WHO Model List of Essential Medicines' (2006) 84 (5) *Bulletin of the World Health Organization* 405, p. 405.

⁷⁸ Nygren-Krug and Hogerzeil, p. 410.

⁷⁹ Kahn, p. 409. See also Seuba, p. 405.

that essential medicines need to be recognized as a derivative right of the well-recognized human right to health.⁸⁰

International Assistance and Cooperation according to International Human Rights Law

The state obligation to provide international assistance and cooperation has long been an area of debate among academics. While some might hold fast to the notion of state sovereignty and the idea that states hold human rights obligations only in relation to their own citizens, the impacts of globalization have led many to reassess the significance of national boundaries. In addition, some argue that state obligations of international assistance and cooperation were intended by the drafters of international human rights laws as the obligation can be found in the key documents, including: Articles 1(3), 55 and 56 of the UN Charter; Articles 22 and 28 of the UDHR; and Articles 2(1), 11(1), 11(2), 15(4), 22 and 23 of the ICESCR. Sigrun Skogly believes that, because these obligations are insufficiently recognized and have rarely been invoked, there is a need to ‘rediscover or uncover these obligations’ from the body of international human rights law.⁸¹

For example, an important source of international assistance and cooperation is found in Article 2(1) of the ICESCR, which requires ‘[e]ach State Party to the present Covenant undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its

⁸⁰ Hogerzeil, 'Essential medicines and human rights: what can they learn from each other?', p. 371.

⁸¹ S Skogly, *Beyond national borders: States' human rights obligations in international* (Intersentia, Antwerpen, Netherlands 2006), pp. 13 and 30.

available resources'.⁸² The 'elusive and complex' nature of this statement, which can be attributed to diplomatic negotiations, was noted by the CESCR and led to clarification under General Comment No. 3 on 'The nature of states parties' obligations'.⁸³ General Comment No. 3 explained that those who drafted the ICESCR intended that the statement of 'to the maximum of its available resources' apply not only to the resources within a state but also to 'those available from the international community through international cooperation and assistance'.⁸⁴ In addition, the UN Special Rapporteur on the right to health has emphasized the ICESCR's Article 2(1) in relation to the right to health and explicitly states that the right 'gives rise to responsibilities in relation to international assistance and cooperation'.⁸⁵

Yet, in what manner should developed countries assist and cooperate? To address this question, the tripartite classification of obligations (i.e. to respect, to protect, and to fulfil) has been used to elaborate on the developed country duty of international assistance and cooperation in greater detail.⁸⁶ The duty to respect, which

⁸² 'International Covenant on Economic, Social and Cultural Rights (adopted on 16 December 1966, entered into force 3 January 1976)', Art. 2(1) (1966).

⁸³ M Carmona, 'The obligations of 'international assistance and cooperation' under the International Covenant on Economic, Social and Cultural Rights: A possible entry point to a human rights based approach to Millennium Development Goal 8' (2009) 13 (1) *International Journal of Human Rights* 86., p. 88.

⁸⁴ ECOSOC, 'General Comment No. 3, The Nature of States Parties' Obligations' (1990) UN Committee on Economic, Social and Cultural Rights, UN Doc. No. E/C.12/1991/23, para. 13.

⁸⁵ P Hunt, 'The UN Special Rapporteur on the Right to Health: Key Objectives, Themes, and Interventions' (2003) 7 (1) *Health and Human Rights: An International Journal* 1, p. 4. (The UN Special Rapporteur points to an International Court of Justice judge's dissenting opinion in the Advisory Opinion on the Legality of the Use By a State of Nuclear Weapons in Armed Conflict, where the judge cited the ICESCR's article 12 and stated 'it will be noted here that the recognition by States of the right to health is in the general terms that they recognize the right of "everyone" and not merely of their own subjects. Consequently, each State is obligated to respect the right to health of all members of the international community.' See, 'Dissenting Opinion of Judge Weeramantry' (1996) ICJ Reports <<http://www.icj-cij.org/docket/files/93/7417.pdf>>, p. 144.

has been called a ‘classic’ human rights obligation, refers to the requirement that states ‘avoid measures that hinder or prevent the enjoyment of ... rights in another state’.⁸⁷ Such measures would include a state’s foreign policies and any aspects that might interfere with the realization of rights outside of the state. The duty to protect requires that states take account of human rights in their actions as members of international organizations as well as when entering into bilateral and multilateral agreements.⁸⁸ It also calls upon states to ‘take measures to prevent non-state entities under their jurisdiction from interfering with the enjoyment of the ... rights abroad’.⁸⁹ Such non-state entities include private corporations that reside within their national jurisdiction, but operate internationally or have an impact on other states, and measures to prevent them can take the form of domestic legislation to regulate their activities. The duty to fulfil has been defined as the obligation of the state to take positive steps by facilitating, providing, and promoting human rights in other states.⁹⁰ This particular duty has been considered controversial, given its emphasis on positive state action in other countries, but is gaining acceptance in the human rights community as a ‘secondary or subsidiary obligation [that] ... applies if the domestic state for reasons beyond its control fails to fulfil economic, social, and cultural rights’ and when ‘measures taken to respect and protect are not sufficient’.⁹¹

⁸⁶ Carmona, pp. 89–94; Skogly, pp. 66–72; Ferraz and Mesquita, p. 15; Hunt, 'The UN Special Rapporteur on the Right to Health: Key Objectives, Themes, and Interventions', p. 4.

⁸⁷ Skogly, p. 66; Carmona, p. 90.

⁸⁸ Carmona, p. 91.

⁸⁹ *ibid.*

⁹⁰ *ibid.*, p. 92.

⁹¹ Skogly, p. 71; W Vandenhole, 'EU obligations for development: extraterritorial obligations under the ICESCR' in M Salomon, A Tostensen and W Vandenhole (eds) *Casting the net wider: Human rights, development and new duty-bearers* (Intersentia, Antwerp 2007); W Vandenhole, 'Is there a legal obligation to cooperate internationally for development?' (2007) *Convention of the Rights of the Child*

International Assistance and Cooperation (IAC) Standards for Access to Essential Medicines

From the previous review of different ethically and legally based assertions, there are a strong series of arguments that developed countries hold obligations of international support for the norm of access to essential medicines (AEM). Yet, despite the allusions to essential medicines in international laws and its backing by different ethical arguments, there continues to be ambiguity around the specific international roles and responsibilities that should be met by states. This issue has prompted numerous authoritative, but nonbinding, interpretative statements that aim to clarify and expand upon references to essential medicines in international agreements, especially given emerging global health trends and issues. Such statements include: the UN Committee on Economic, Social and Cultural Rights General Comment 14,⁹² the UN Commission on Human Rights Resolution 2003/29,⁹³ World Health Assembly Resolution WHA55.14,⁹⁴ the WTO Doha Declaration on TRIPS and Public Health,⁹⁵

(CRC) — Report to General Day of Discussion

<<http://www.crin.org/docs/Vandenhole%20International%20Cooperation.pdf>> , p. 1.

⁹² 'The Right to the Highest Attainable Standard of Health' (Article 12 ICESCR). See , 'International Covenant on Economic, Social and Cultural Rights (adopted on 16 December 1966, entered into force 3 January 1976)' .

⁹³ UN, 'Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria (2003)' (2003) UN High Commissioner for Human Rights, E/CN.4/2003/L.11/Add.3

⁹⁴ WHO, 'Ensuring Accessibility to Essential Medicines (WHA55.14)' (2002)
<http://www.who.int/gb/ebwha/pdf_files/WHA55/ewha5514.pdf> (10 Jan 2007).

⁹⁵ WTO, 'Declaration on the TRIPS Agreement and Public Health' (2001) World Trade Organization, WT/MIN(01)/DEC/W/2 (14 Nov 2001).

the UN Millennium Development Goals,⁹⁶ Montreal Statement on Essential Medicines as a Human Right,⁹⁷ and the reports of the UN Special Rapporteur on the Right to Health.⁹⁸

The guidance offered by these sources can be synthesized to develop a single, coherent set of international standards for developed countries on access to essential medicines. The theme of international assistance and cooperation (IAC) as a duty, which was found across almost all interpretative guidance on access to essential medicines, presents a critical set of standards for industrialized nations. By applying the comprehensive guidelines listed in the CESCR's General Comment No. 14 as a foundation, the discussion below details the IAC standards that developed countries must address:

- (1) To respect access to essential medicines in other countries, and to prevent others (i.e. third parties) from violating this norm⁹⁹

This is a critical standard which obligates States 'to refrain from interfering directly or indirectly' with a developing country's efforts to achieve access to essential

⁹⁶ Two particular Millennium Development Goals (MDGs) apply to the issue of access to essential medicines. MDG #6 combats HIV/AIDS, malaria, and other diseases. In addition, MDG #8 aims to develop a global partnership for development. See , 'UN Millennium Development Goals' <<http://www.un.org/millenniumgoals/>> (10 Apr 2007).

⁹⁷ Canadian Coalition for Global Health Research; , 'Montreal Statement on Essential Medicines as a Human Right' (Human Rights and Access to Essential Medicines: The Way Forward 2005).

⁹⁸ Grover; Hunt, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health (Report to the UN General Assembly)* ; P Hunt, *UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (UN Economic and Social Council, E/CN4/2003/58 2003).

⁹⁹ ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in 'CESCR General Comment 14 - The right to the highest attainable standard of health' , para 39.

medicines.¹⁰⁰ At the same time, it asks industrialized nations to ‘protect’ access to essential medicines in developing countries by preventing third parties (such as pharmaceuticals or other countries) that may interfere with this fundamental component of the right to health.¹⁰¹ Such guidance is critical in understanding industrialized nation obligations in regards to the WTO TRIPS Agreement.

According to the Doha Declaration on TRIPS and Public Health, developing countries have the right to exercise TRIPS flexibilities in recognition of their public health needs. First, countries have ‘the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.’¹⁰² Second, countries’ ‘practices relating to parallel importation cannot be challenged under the WTO dispute settlement system [and] ... each Member is free to establish its own regime [for the use of parallel importation] ... without challenge.’¹⁰³ Hence, industrialized nations should refrain from interfering in developing country activities to apply compulsory licensing or parallel importation for access to essential medicines. For example, certain practices (such as trade watch lists or trade sanctions) would effectively pressure trading partners, especially developing countries, into acting in accordance with another country’s preferences in order to gain or maintain a favourable trading position. Furthermore, industrialized nations should prevent others (e.g. pharmaceutical companies) from interfering in such activities as well.

¹⁰⁰ *ibid*, para 33.

¹⁰¹ *ibid*.

¹⁰² WTO, 'Declaration on the TRIPS Agreement and Public Health' .

¹⁰³ *ibid*.

- (2) To facilitate access to essential medicines in other countries, whenever possible, and to provide the necessary aid in times of emergency.¹⁰⁴

In recognition of the limitations of developing countries' abilities 'to fulfil' their core obligations (e.g. access to essential medicines) to their populations, it follows that an associated IAC duty calls upon industrialized nations 'to support to fulfil' access in those countries. Furthermore, in situations of 'emergency', it is emphasized that industrialized nations have a responsibility to contribute to 'the maximum of [their] capacities'.¹⁰⁵ The CESCR notes that other countries' emergencies are a 'collective responsibility' at an international level because 'some diseases are easily transmissible beyond the frontiers of a State'.¹⁰⁶ Though General Comment 14 does not clearly define what qualifies as situations of emergency, other international guidance has stated that countries have 'the right to determine what constitutes a national emergency or other circumstances of extreme urgency' and that such cases can be understood to include 'HIV/AIDS, tuberculosis, malaria and other epidemics.'¹⁰⁷

- (3) To ensure that access to essential medicines is granted due attention in international agreements and to consider the development of further legal instruments.¹⁰⁸

¹⁰⁴ ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in 'CESCR General Comment 14 - The right to the highest attainable standard of health' ., para 39. See also UN, 'Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria (2003) ' .

¹⁰⁵ ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in 'CESCR General Comment 14 - The right to the highest attainable standard of health' , para 40.

¹⁰⁶ *ibid.*

¹⁰⁷ WTO, 'Declaration on The TRIPS Agreement and Public Health' , para. 5(c).

¹⁰⁸ ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in 'CESCR General Comment 14 - The right to the highest attainable standard of health' , para 39. See also WHO, 'Ensuring Accessibility to Essential Medicines (WHA55.14) ' ; UN, 'Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria (2003) ' .

Industrialized nations are urged ‘to develop and implement national strategies’,¹⁰⁹ including legal measures, that ‘safeguard or promote’ access to essential medicines.¹¹⁰ Though many States have acceded to numerous international agreements recognizing obligations to assist and cooperate in the provision of access to essential medicines, such agreements are often not ratified at the national level and, in consequence, ignored and often relegated to rhetoric. This is a standard that requires greater attention and evaluation.

- (4) To ensure that no international agreement or policy adversely impacts upon access to essential medicines.¹¹¹

As parties to numerous current international agreements, as well as potential future agreements, States need to ensure that no adverse measures within the agreements will hinder access to essential medicines. Furthermore, States should never apply restrictions on the supply of essential medicines to another State as a tool of political or economic pressure – such as embargoes, political or theological ideology, or other similar measures.¹¹² This has been an issue in some countries’ foreign policy and the tendency for corporate protectionism through the creation of ‘TRIPS-plus’ provisions

¹⁰⁹ UN, ‘Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria (2003)’.

¹¹⁰ *ibid.*

¹¹¹ Hunt, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health (Report to the UN General Assembly)*. See also ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in ‘CESCR General Comment 14 - The right to the highest attainable standard of health’, para 39.; UN, ‘Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria (2003)’. In Paragraph 41 of General Comment 14, the committee also notes that States should ‘refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment.’

¹¹² ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in ‘CESCR General Comment 14 - The right to the highest attainable standard of health’, para. 41.

(i.e. measures that go beyond what is required by TRIPS) in bilateral and regional trade agreements with developing countries.¹¹³

- (5) To ensure (by way of membership) that the actions of international organizations take due account of access to essential medicines.¹¹⁴

International organizations, such as the World Health Organization (WHO), the World Trade Organization (WTO) and World Bank, play critical roles in setting policy and handling international agreements that can influence access to essential medicines in developing countries. States can use their membership status within these international organizations to ensure that access to essential medicines is properly accounted for in the activities of such organizations. For instance, the WTO's activities in setting minimum standards for the protection intellectual property rights (i.e. Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS]) have a significant impact on developing countries' access to medicines. Member states have worked to ensure that TRIPS addressed the issue of access to essential medicines through a subsequent clarifying WTO statement known as the Doha Declaration on TRIPS and Public Health.

- (6) To provide an environment that facilitates the fulfilment of responsibilities in access to essential medicines by other actors.¹¹⁵

Though states possess primary accountability for the right to health, the General Comment also emphasizes that 'all members of society' possess certain

¹¹³ These issues will be discussed in Chapter 5.

¹¹⁴ ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in 'CESCR General Comment 14 - The right to the highest attainable standard of health', para 39.; UN, 'Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria (2003)' .

¹¹⁵ ECOSOC, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights* in 'CESCR General Comment 14 - The right to the highest attainable standard of health', para 42.

‘responsibilities towards the realization of the right to health’.¹¹⁶ In the case of access to essential medicines, other societal actors involved include: intergovernmental and non-governmental organizations, health professionals, civil society organizations, and private industry. The CESCR notes that in order for these actors to fulfil their responsibilities, states have an obligation to ‘provide an environment which facilitates the discharge of these responsibilities’.¹¹⁷ For example, the United Kingdom has a duty to create an equal opportunity for health professionals to participate on government advisory committees pertaining to essential medicines policies, which is a privilege that the pharmaceutical industry currently enjoys.

As a few concluding thoughts on these international standards, while IAC standards for AEM exist, the wide array of authoritative documents from which they had to be drawn could make it difficult for states to notice and acknowledge with them. A review of the various aforementioned documents revealed a general consistency in IAC expectations, which are addressed most comprehensively by the CESCR’s General Comment No. 14. However, for the purposes of state implementation, it would be best to present a single, coherent set of standards from which states can report on or be criticized against.

The array of authoritative guidance indicates a deliberate movement by the international order to crystallize the elusive commitments of industrialized nations. The acceptance of these international standards, however, still faces significant challenges due to its heavy basis on socio-economic rights. As the former UN Special

¹¹⁶ *ibid.*

¹¹⁷ *ibid.*

Rapporteur notes, '[a]lthough the right to health is [a] fundamental human right, with the same international legal status as freedom of religion or the right to a fair trial, [it] is not as widely recognized as these other civil and political rights.'¹¹⁸ In addition, other conflicting or competing foreign policy concerns (e.g. international trade and development) may be granted special preference over AEM because of their impact on national economic or security interests. Chapter 5 will illustrate how this issue is dealt with through the processes of socialization and other institutional mechanisms.

Research Aims & Approach

AEM has become a well-recognized norm with a solidifying set of international standards for assistance and cooperation by developed countries. IAC standards for AEM can be derived from a broad set of ethical arguments and a progressive interpretation of international human rights pertaining to health and HIV/AIDS. The problem, however, is that current efforts and initiatives by developed countries are not meeting the critical 'access' needs of developing countries as indicated earlier.

Given the widespread recognition of AEM as an international norm and the significant body of research literature that has emerged in recent years justifying IAC for AEM, the academic focus on AEM is now shifting from discussing 'points of principle' to the issue of practical implementation.¹¹⁹ In recent research on the implementation of AEM, much of the focus has been on the national constitutions and

¹¹⁸ Hunt, *UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, para. 38.

¹¹⁹ Hogerzeil, 'Essential medicines and human rights: what can they learn from each other?', p. 371.

laws of developing countries¹²⁰ and the technical intellectual property issues¹²¹ they face under the international trade agreements.¹²² While the study of these issues is critical, the general body of implementation literature is incomplete because of the gap in research addressing the critical problem of weak and inconsistent international support (i.e. international assistance and cooperation) for implementation by developed countries. Much of the national implementation research mentions access to essential medicines as a 'core component',¹²³ but the lack of adequate resources and international cooperation makes it difficult for developing countries to address the obligation immediately - or anytime in the near future.¹²⁴ Numerous international commitments have been made by developed countries, but the follow-through has been considered 'abysmal' and many of the statements are now viewed as largely rhetoric.¹²⁵ Furthermore, there have been cases where developing states are hindered in addressing access to essential medicines due to the actions or policies (e.g. bilateral trade agreements and politically-motivated foreign assistance programmes) of

¹²⁰ Hunt, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health (Report to the UN General Assembly)*. See also Hogerzeil and others, 'Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?'

¹²¹ These technical issues include the use of compulsory licensing and parallel importation of medicines.

¹²² E Ghanotakis, 'How the U.S. Interpretation of Flexibilities Inherent in TRIPS Affects Access to Medicines for Developing Countries' (2004) 7 (4) *Journal of World Intellectual Property* 563. See also D Matthews, 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' (2004) 7 (1) *J Intl Economic L* 73.

¹²³ Core components must be provided 'immediately', and are not subject to 'progressive realization'.

¹²⁴ WHO, *WHO Policy Perspectives on Medicines*.

¹²⁵ International Treatment Preparedness Coalition, 'Missing the Target #3: Stagnation in AIDS treatment scale up puts millions of lives at risk. (Second six-month update to ITPC's AIDS treatment report from the frontlines, Report ITPC website)' (2006) <http://www.aidstreatmentaccess.org/mtt3_final.pdf> (1 Feb 2009); E Rosenthal, 'Efforts to Treat AIDS Falling Short in Poor Countries, Report Says' *New York Times* (New York City Nov 29, 2006); Barry and Raworth.

developed countries. Hence, these issues reveal a critical research gap where there is a need to consider the problem of developed countries' implementation of international assistance and cooperation for AEM in developing countries.¹²⁶

The research aim of this thesis is to understand how developed countries may be influenced to implement IAC standards for AEM with a view to the improvement of international governance over this issue. This involves the analysis of three sub-questions. First, what is the current international order governing access to essential medicines? Second, what are the processes and mechanisms that the international order has used to influence developed countries and how have the countries responded? Third, is there an alternative approach to the current governance structure that could lead to improved implementation of international assistance and cooperation by developed countries?

Thesis Overview

My thesis seeks to address these research questions through a socio-legal analysis of the IAC implementation for AEM. To address the first question about the current international order, I present my theoretical framework (in Chapter 2) which serves to help me understand and assess the components and characteristics of the international order for AEM and how it influences states in their implementation. This framework guides the course of my analysis in the following chapters, which discuss the main institutions found in the current international order for access to essential medicines

¹²⁶ It is noted that my use of the term 'developed countries' is applied to the category of highly-industrialized nations, such as the United States, United Kingdom, Switzerland, Japan, Germany and France. I limit the use of the term to these countries because of their high level of economic prosperity and the large size of their pharmaceutical industries. This term will be used interchangeably with 'industrialized nations' throughout this thesis.

and their interactions with each other, states, and other associated actors (i.e. nongovernmental organizations and businesses). The framework draws upon relevant literature and research from the social sciences, which include the concepts of: norm implementation, international orders and global governance; institutions (and their component factors); and institutional interactions and conflicts (e.g. overlap and parallelism).

For my empirical research, I analyze the main international institutions involved in access to essential medicines - specifically medicines for HIV/AIDS (antiretrovirals).¹²⁷ These institutions include the World Health Organization (WHO), the World Trade Organization (WTO), and three development-related agencies (i.e. first the World Bank and then the Joint United Nations Programme on HIV/AIDS¹²⁸ and the Global Fund for HIV/AIDS, Tuberculosis and Malaria¹²⁹). I consider the involvement of these main institutions individually as well as their interactions with each other. My discussion of the WHO, which is covered in Chapter 3 (The International Institution for Health), analyzes the WHO as an institution and attempts to understand the reasons behind its lack of leadership in the realm of global health. Through a review of its current mandate, legal powers (and other unofficial mechanisms) to influence states, and the historical use of these powers, this chapter assesses the internal and external challenges faced by the WHO as an international institution for health and in its involvement over access to essential medicines.

¹²⁷ It was determined that tracing IAC for AEM in terms of governance and implementation would require a particular focus for the purposes of my empirical research. Access to medicines for HIV/AIDS (i.e. antiretrovirals) provides a fitting area for study given its extensive history of activity at the international and national levels as well as its recent institutional and state-level developments.

¹²⁸ It is also known as 'UNAIDS'.

¹²⁹ It is also referred to as 'the Global Fund'.

In Chapter 4 (Conflicting International Regimes over AEM), I discuss how the lack of leadership by the WHO has permitted other major international institutions to enter the realm of global health and dominate the governance of access to essential medicines. These include the institutions for international trade and development. In terms of international trade, the World Trade Organization (WTO) exercises strong control over access to essential medicines by member states through the application of a powerful legal treaty known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). With regard to international development, three major development-related agencies (i.e. the World Bank, UNAIDS, and the Global Fund) have entered the global health space in an attempt to address HIV/AIDS due to its extreme devastation upon developing countries as well as the initial lack of funding and attention. The problem in both scenarios (i.e. access to medicines under international trade or development) is that the governance of AEM (including international assistance and cooperation efforts) has become convoluted by the overlapping, and often competing, interests imposed by other institutions. This chapter also identifies the areas of dominance by the international institutions for trade and development over access to medicines and analyzes their interactions with the international health institution.

For the second sub-question on state international assistance and cooperation, my thesis analyzes state norm implementation under the current international order. Theoretically, a state may engage in norm implementation through a progressive series of phases whereby it is influenced by internal and external pressures to create

or alter its policies, laws, and activities in recognition of an international norm.¹³⁰ My research analyzes the implementation of IAC standards for AEM by developed countries through a study of the United Kingdom in Chapter 5. While state actors may commit to support and implement certain international health norms, this process is not always straightforward. State actors, in the case of AEM, can implement norms in an interpretive fashion and in a manner that best suits their interests. Yet, there are ways that states could be influenced in their implementation by international institutions and non-state actors (i.e. nongovernmental organizations and businesses) through the processes of socialization, monitoring and reporting, investigations, arbitration, activism, lobbying, joint programme collaboration, and other mechanisms. The chapter looks at the approaches towards implementation taken and how the state has progressed in meeting IAC standards under the current international order.

To address the third sub-question, my thesis identifies alternative approaches of governance, which could enable greater international assistance and cooperation in access to essential medicines. Given that the issue of AEM does not exist in a static world, a few recent efforts within the international order have emerged in an attempt to rectify the problem. In Chapter 6 (Emerging Changes in Governance), I conduct an evaluation of these recent efforts and note the shortcomings of and challenges for each. An initiative addressing the international health institution's interactions with the trade and development institutions is discussed as well as the potential for greater international human rights institutional involvement. The first trade-related initiative is the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, which allowed the WHO to serve as a forum for discussion on

¹³⁰ This will be explained in Chapter 2 on the theoretical framework for analysis.

trade and intellectual property matters pertaining to medicines and has resulted in a new WHO resolution (titled the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property). The second initiative discussed is the UNAIDS' Global Task Team, which sought to improve AIDS coordination among multilateral and international donors. This initiative was sponsored by UNAIDS and involved an array of actors (such as the WHO, the World Bank, U.S., U.K., and several NGOs). Both initiatives are being implemented, but there are initial indications (based on reports and interviews) regarding implementation stalemates and various remaining unaddressed concerns. In terms of international human rights, the UN's Committee on Economic, Social and Cultural Rights holds the potential to address IAC for AEM implementation given its concern with the right to health. The chapter explores its powers and the role that it can play.

Finally, in Chapter 7 (Conclusion), I provide a summary of my thesis and concluding reflections. In the sections leading up to this chapter, I provide a description and discussion of the current state of governance over AEM, the problems within the current system (in terms of the institutions, interactions, and state implementation), and the emerging alternatives to address these issues. This chapter reflects upon issues highlighted and the potential improvements to be made in IAC for AEM.

The empirical research for this thesis entailed a combination of observation, interviews and personal communications, and primary source information collection. As AEM is an issue that has evolved over time (especially in the last decade and a half), it was necessary to engage in some historical research on the subject in order to

understand how the international order has become what it is today. (This is apparent in parts of Chapters 3 on the WHO, Chapter 4 on Institutional Interactions, and Chapter 5 on the national case studies.) Fieldwork was conducted at the World Health Organization in order to observe its operations and its interactions with external groups (i.e. member states and other institutions). A series of semi-structure interviews and personal communications were conducted over the course of my research. To supplement my observations, interviews and communications, I attended a series of invitation-only presentations and public talks to gather more information. A number of primary sources were also used in my research and typically provided by those who I communicated with (due to their close involvement with or leadership over different committees, programmes, etc.). These sources include: reports, memos, meeting minutes, working papers, and other organizational documents.

Chapter 2: THEORETICAL FRAMEWORK FOR ANALYSIS

Introduction

This chapter establishes a theoretical framework that will be used for the analysis of IAC for AEM governance and implementation. As described in the last chapter, this thesis seeks to understand how developed countries can be influenced to implement IAC norms for AEM with a view to the improvement of international governance over this matter. Three sub-questions were identified for the analysis of this issue: (1) what is the current international order governing access to essential medicines; (2) what are the processes and mechanisms that the international order has used to influence developed countries and how have the countries responded; and (3) what is an alternative approach to the current governance structure.

To address these three questions, the theoretical framework developed in this chapter draws upon concepts from a range of areas in the social sciences research literature including international relations, organizational theory, international law, human rights, and sociology. The first part of this chapter provides a general background discussion on how ‘norm implementation’ can be approached, which explains the structure of my analysis around the key components of standards, institutions, and processes. An understanding of norm implementation relies upon a study of the international dimension as well as domestic level activities. Hence, in the second half of this chapter, a framework is established to analyze the governance of

AEM by the international order as well as its interactions and potential influence upon states in trying to influence them towards the implementation of IAC norms.

For the purposes of this thesis, it is important to clarify my use of the term ‘implementation’. The human rights literature tends to discuss a state’s implementation of norms for the benefit of its own citizens rather than those located outside the country. This thesis, however, is concerned with a state’s implementation of IAC standards for the realization of AEM in other countries. This approach challenges the narrow view held by some scholars,¹³¹ who believe that nation states only possess obligations towards their own citizens. Yet, as discussed in Chapter 1 (Introduction), AEM actually entails significant international responsibilities and such extraterritorial obligations are increasingly being ‘rediscovered’ to support the realization of rights.¹³²

An Approach to Norm Implementation

A key question with regard to IAC for AEM¹³³ is how it can be implemented or, in other words, put into effect by developed countries. In socio-legal scholarship, implementation has been defined as ‘the process by which standards are made effective in the actions and decisions of those to whom they apply’.¹³⁴ Henry Steiner

¹³¹ J Donnelly, *Universal Human Rights In Theory & Practice* (2nd edn, Cornell University Press, Ithaca 2003).

¹³² Skogly, p. 13 and p. 30.

¹³³ As noted in Chapter 1, I will be using abbreviated forms for ‘access to essential medicines’ (AEM) and ‘international assistance and cooperation’ (IAC) in the thesis.

and Philip Alston more specifically define it as ‘the means by which ... [norms] can be given effect and governments can be held accountable to fulfil their obligations’.¹³⁵

Yet, these definitions lead one to ask what are the ‘processes’ and ‘means’ exactly?

Also, what holds national governments accountable? In approaching such questions,

Denis Galligan and Deborah Sandler have identified that norm implementation

depends upon ‘a system of standards, institutions, and processes ... designed to control

the actions of those involved in certain activities in order to achieve certain goals’.¹³⁶

These key components of (1) standards, (2) institutions, and (3) processes deserve attention and explanation.

With regard to the first component, normative standards set out ‘shared expectations about [the] appropriate behaviour held by a community of actors’.¹³⁷

They also serve to ‘both constra[n] and enabl[e] action by defining the boundaries of acceptable behaviour’.¹³⁸ Hence, standards not only provide the basis from which

states can be evaluated, criticized, and persuaded¹³⁹ but also ‘the power to mobilize, ...

justify, and ... legitimize action’.¹⁴⁰ Standards can be declared at the international

¹³⁴ D Galligan and D Sandler, ‘Socio-Legal Perspectives on Human Rights in the National Context’ in S Halliday and P Schmidt (eds) *Human Rights Brought Home: Socio-legal Perspectives on Human Rights in the National Context* (Hart Publishing, Oxford 2004), p. 29.

¹³⁵ Steiner and Alston, p.248.

¹³⁶ Galligan and Sandler, p. 26. Michael Freeman also makes the analogy between the human rights system and regulatory regimes. See also M Freeman, *Human Rights: An Interdisciplinary Approach* (Polity Press, 2003), p. 95.

¹³⁷ M Finnemore, *National Interests in International Society*. (Cornell University Press, Ithica, NY 1996), p. 22.

¹³⁸ Youde, p. 417.

¹³⁹ Galligan and Sandler, p. 27.

¹⁴⁰ A Hurrell, *On Global Order: Power, Values, and the Constitution of International Society* (Oxford University Press, Oxford, UK 2007), p. 18

level through laws, commitments, or guidance, but they need not always be formally codified - 'though they may eventually be [formalised]'.¹⁴¹ In order to translate principles and norms (such as those described in Chapter 1) to a lower level of abstraction, rules are typically generated. Rules, as defined by Laurence Helfer, 'encompass the specific prescriptions and proscriptions by which ... principles and norms are given effect'.¹⁴²

The second component, institutions, plays a central role in facilitating the implementation of international standards. According to Douglas North, institutions are the 'framework' for generating rules and keeping society in alignment with them.¹⁴³ Institutions can take various forms, ranging from formal organizations to informal networks, and their attributes ('such as membership and voting rules, scope of issues covered, resources allocated, centralization of tasks, flexibility of applicable rules, control mechanisms, and permeability to non-state actors') will differ.¹⁴⁴ In addition, standards sometimes give rise to the creation or involvement of multiple institutions in supervision. This is a critical issue that needs to be addressed in implementation for it could lead to highly detrimental problems in coordination and overlap over authority, administration, finances, etc.¹⁴⁵ (The various forms and characteristics of institutions are explored in greater detail later in this chapter.)

¹⁴¹ Youde, p. 417

¹⁴² L Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 (1) *Yale Journal of International Law* 2, p. 11.

¹⁴³ D North, *Institutions, Institutional Change, and Economic Performance* (Cambridge University Press, Cambridge, UK 1990), p. 3-4; Similarly, Laurence Helfer calls institutions 'cooperative arrangements' for the creation of rules. See Helfer, p. 11.

¹⁴⁴ Helfer, p. 11.

¹⁴⁵ Galligan and Sandler, p. 40.

The third component of implementation, processes (or mechanisms),¹⁴⁶ serves to achieve compliance with standards. The mechanisms can take a variety of forms, ranging from strict formal measures (such as enforcement¹⁴⁷) to more informal, and sometimes compromising, measures (such as persuasion and exchange). Enforcement, a process where compliance is secured through the threat of punishment, has been noted as ‘probably the least used mechanism’.¹⁴⁸ This is attributed to a few factors. First, the approach of enforcement is often a mechanism of ‘last resort’ in that other intermediate mechanisms may occur before enforcement is actually invoked.¹⁴⁹ Another reason is the institutional reluctance to apply enforcement. Enforcement is an expensive and lengthy procedure, and cooperation is often favoured over enforcement as a preferred means of achieving compliance with often better results.¹⁵⁰ Finally, enforcement mechanisms are sometimes too weak, or simply unavailable, to certain institutions. This is a critical problem for international institutions, which often lack powers of enforcement in securing the compliance of states with international standards.¹⁵¹ As a result, these institutions must turn to other available mechanisms, such as shaming and communications exchange (e.g. negotiations), which will be detailed later in this chapter. It is noteworthy that the uses of the various

¹⁴⁶ I will interchangeably use the term ‘processes’ and ‘mechanisms’ throughout the thesis. For the purposes of implementation, they carry the same objective.

¹⁴⁷ While some scholars may consider ‘enforcement’ apart from ‘implementation’, I chose to adopt the approach of Denis Galligan and Deborah Sandler by including enforcement as a mechanism under implementation.

¹⁴⁸ D Galligan, *Law in Modern Society* (Clarendon Law Series, Oxford University Press, Oxford 2007), p. 303.

¹⁴⁹ *ibid.*

¹⁵⁰ G Richardson, AI Ogus and P Burrows, *Policing pollution: a study of regulation and enforcement* (Oxford University Press, Oxford 1982).

¹⁵¹ Galligan and Sandler, ‘Socio-Legal Perspectives on Human Rights in the National Context’, p. 39-40. See also Galligan, *Law in Modern Society*, p. 303.

aforementioned mechanisms are ‘not as distinct as they appear to be in principle, with elements of each present [in practice]’.¹⁵² Instead, implementation will often involve a ‘mixture’ of the various forms, ‘although one or the other is likely to dominate’.¹⁵³

The achievement of norm implementation involves both the international and national dimensions; despite the fact that actual implementation is performed at the state-level.¹⁵⁴ In the case of international cooperation and assistance, the international order plays a critical role in governing state interactions as well as individual state behaviour. Hence, these three components of standards, institutions, and processes need to be considered in the context of states as well as the international order. In the next section of this chapter, the international and national dimensions are discussed to detail their respective roles and interactions in norm implementation. This discussion helps form the theoretical framework that is applied in the thesis.

The International Order and its Role

The international order, as defined by Anne-Marie Slaughter, is ‘a system of global governance that institutionalizes cooperation and sufficiently contains conflict such that all nations and their peoples may ... reach minimal standards of human dignity’.¹⁵⁵ Such conceptualizations of order at the international level have arisen in

¹⁵² Galligan, *Law in Modern Society*, p. 304.

¹⁵³ *ibid.*, p. 309.

¹⁵⁴ Galligan and Sandler, ‘Socio-Legal Perspectives on Human Rights in the National Context’, p. 41.

¹⁵⁵ AM Slaughter, *A New World Order* (Princeton University Press Princeton, NJ 2004), p. 15.

response to various ‘global challenges’ (e.g. climate change or infectious disease spread), which span beyond national borders and depend heavily upon international cooperation.¹⁵⁶ As a result, under the international order, states assume the role of ‘agents or interpreters of some notion of an international public good and some set of core norms against which state behaviour should be judged and evaluated’.¹⁵⁷

‘A System of Global Governance’

To parse Slaughter’s definition of the international order down further, there is a need to consider what is meant by a ‘system of global governance’. The concept of global governance has been described as ‘the establishment and operation of social institutions ... capable of resolving conflicts, facilitating cooperation, or more generally, alleviating collective action problems in a world of interdependent actors’.¹⁵⁸ It has also been defined in a more narrow sense as ‘encompass[ing] the collection of authority relationships designated to monitor, enforce, and amend any transnational set of rules and regulations’.¹⁵⁹

Institutions

Yet, what are these ‘institutions’? An institution is a broadly defined concept that encompasses ‘persistent and connected sets of rules that prescribe behavioural roles,

¹⁵⁶ Hurrell, p. 1. See also D Drezner, *All Politics is Global: Explaining International Regulatory Regimes* (Princeton University Press, Princeton, NJ 2007), p. 57.

¹⁵⁷ Drezner, p. 62-63.

¹⁵⁸ Hurrell, p. 14-15. See also T Risse, ‘Global Governance and Communicative Action’ (2004) 39 (2) *Government and Opposition* 2004 Volume 39 Issue 2 288, p. 289.

¹⁵⁹ Drezner, p. 11-12.

constrain activity, and shape expectations'.¹⁶⁰ According to W.R. Scott, institutions possess normative, regulative, and cultural-cognitive elements.¹⁶¹ The normative element captures the 'prescriptive, evaluative, and obligatory dimension,' which helps to define the objectives and goals for a society through rules.¹⁶² In other words, this element provides an understanding of what is ideal and how it should be performed. The regulative element presents the institutional dimension of 'constrain[ing] and regulariz[ing] behavior'.¹⁶³ Namely, institutions engage in activities such as 'rule-setting, monitoring, and sanctioning [i.e. issuing rewards and penalties]'.¹⁶⁴ The cultural-cognitive element 'stresses the shared conceptions that constitute the nature of social reality and the frames through which meaning is made'.¹⁶⁵ Hence, this dimension helps to establish a common understanding which shapes the way a society 'perceives and understands'.¹⁶⁶ W.R. Scott cautions that the regulative dimension should not be 'conflate[d]' and that the normative and cultural-cognitive elements should also be recognized.¹⁶⁷ This is because of the ambiguity of many rules, which 'do not provide clear prescriptions for conduct' and are 'better conceived as an occasion for sense making and collective interpretation'.¹⁶⁸

¹⁶⁰ R Keohane, 'International Institutions: Two Approaches' (1988) 32 *International Studies Quarterly* 379, p. 386

¹⁶¹ WR Scott, *Institutions and Organizations* (3rd edn, Sage Publications, London, UK 2008), p. 48.

¹⁶² *ibid*, p. 54-56.

¹⁶³ *ibid*, p. 51.

¹⁶⁴ *ibid*, p. 52.

¹⁶⁵ *ibid*, p. 57.

¹⁶⁶ Galligan, *Law in Modern Society*, p. 106.

¹⁶⁷ Scott, p. 54.

¹⁶⁸ *ibid*, p. 54.

In the context of global governance, the rules ‘stipulate the ways in which states should cooperate and compete with each other’ by providing ‘statements that forbid, require or permit particular kinds of actions’.¹⁶⁹ International institutions, as a category, have been used to capture an array of structures (i.e. ‘authority relationships’) – ranging from complex regimes to well-defined organizations.¹⁷⁰ At the international level, institutions involve activities that occur outside the jurisdictional boundaries of states, cut across international jurisdictional boundaries of states, or involve actions having a direct impact on the interests of two or more states.¹⁷¹ This allows an institution to act as a ‘focal point’ for competing actors to agree and work in mutually beneficial ways.¹⁷² For example, institutions can ‘assist [with] collective decision-making, ... provide more efficient dispute resolution, and ... enhance domestic policy credibility’.¹⁷³

¹⁶⁹ B Simmons and L Martin, 'International Organizations and Institutions' in W Carlsnaes, T Risse and B Simmons (eds) *Handbook of International Relations* (Sage Publications, Thousand Oaks (CA) 2002), p. 194.

¹⁷⁰ Keohane, p. 384. Regimes are sometimes considered an institutional sub-category; however, like institutions, its definitions have varied widely from ‘patterns of behaviour or practice’ and ‘social arrangements’ to ‘multilateral agreements’. For the purposes of this thesis, I consider regimes to be institutions. (See OR Young, 'International Regimes: Problems of Concept Formation' (1980) 32 (3) *World Politics* 331; O Young, *Resource Regimes: Natural Resources and Social Institutions* (University of California Press, Berkeley 1982), p. 20; O Young, *Compliance and Public Authority: A Theory with International Applications* (Resources for the Future, Washington, D.C. 1979); V Agganval, *Liberal Protectionism: The International Politics of Organized Textile Trade* (University of California Press, Berkeley 1985); S Haggard and BA Simmons, 'Theories of International Regimes' (1987) 41 (3) *International Organization* 491; GK Rosendal, 'Impacts of overlapping international regimes : the case of biodiversity' (2001) 7 (1) *Global Governance* 95; S Krasner, 'Structural Causes and Regime Consequences: Regimes as Intervening Variables' (1982) 36 (2) *International Organization* 185.)

¹⁷¹ Young, 'International Regimes: Problems of Concept Formation', p. 333.

¹⁷² R Keohane, 'International Institutions: Can Interdependence Work?' (1998) Spring (110) *Foreign Policy* 82.

¹⁷³ Drezner, p. 65.

Organizations

The coordination of states, however, is not an easy task. For this reason, there often exists an international organization ‘to monitor, manage, and modify [an international institution’s] operation’¹⁷⁴ Oran Young elaborates that organizations are the ‘material entities ... generally possess[ing] legal personality’,¹⁷⁵ while Thomas Risse calls them ‘inter-state institutions “with a street address”’.¹⁷⁶ Though not all international institutions possess organizational arrangements, a benefit to having an organization is ‘to resolve problems of interpretation and dispute settlement’ as well as deal with ‘problems of social choice and compliance.’¹⁷⁷ Organizations have also been described as ‘purposive institutions’, which possess ‘explicit rules, specific assignments of roles to individuals and groups [i.e. a hierarchy], and the capacity for action’.¹⁷⁸ Robert Keohane adds that international organizations also have the ability to ‘engage in goal-directed activities such as raising and spending money, promulgating policies, and making discretionary choices’ on behalf of states for the purposes of international coordination.¹⁷⁹ Kenneth Abbott and Duncan Snidal also note that organizations possess the unique characteristic of being able to provide centralization in the form of a ‘concrete and stable organizational structure and an administrative apparatus [to manage] collective activities’, and that such benefits are realized in the form of balanced ‘support for direct state interactions’ (e.g. provide

¹⁷⁴ R Breckinridge, 'Reassessing Regimes: The International Regime Aspects of the European Unions' (1997) 35 (2) *J of Common Market Studies* 173, p. 179; R Keohane, *International Institutions and State Power: Essays in International Relations Theory* (Westview, Boulder, CO 1989).

¹⁷⁵ Breckinridge; Young, 'International Regimes: Problems of Concept Formation'.

¹⁷⁶ Risse, p. 290

¹⁷⁷ Young, 'International Regimes: Problems of Concept Formation', p. 345.

¹⁷⁸ Keohane, 'International Institutions: Two Approaches', p. 384.

¹⁷⁹ *ibid.*, p. 384.

constitutionalized representation and voting rules, assist with background research, and sponsor negotiations) and ‘operational activities’ (e.g. manage budgets and provide technical assistance).¹⁸⁰

It is important to recognize that organizations are not necessarily ‘neutral arenas for the solution of common problems’.¹⁸¹ On the surface, it can be easily understood why an organization would be formed or selected by an international community of states. An international organization would give legitimacy to the coordination of an issue area in terms of technocratic expertise (i.e. specialized knowledge on technical issues), democratic representation, transparency, and accountability. Also, from a functional perspective, organizations ‘simply make it easier’ for states to negotiate treaties as they do not require a ‘revisit[ation] [of] basic rules of procedure and voting’; ‘permit reliance on “independent” secretariats for compromise formulations and final clauses’; and ‘provide a neutral central registry for ratifications and reservations’.¹⁸²

Yet, in practice, organizations tend to also serve as sites for political struggle between strong and weak states. Depending on how the organization operates, states could use the organization as: a ‘platfor[m] for the promotion of favoured values and for locking other states into particular policy choices’; ‘a means of levelling power [between states]’; a way of ‘constraining the freedom of the most powerful [states] through established rules and procedures’; a forum to ‘“voice opportunities” that

¹⁸⁰ K Abbott and D Snidal, 'Why States Act through Formal International Organizations' (1998) 42 (1) *The Journal of Conflict Resolution* 3, p. 9-10.

¹⁸¹ Hurrell, p. 11.

¹⁸² J Alvarez, 'International Organizations: Then and Now' (2006) 100 *American Journal of International Law* 325, p. 330.

allow relatively weak states to make known their interests and to bid for political support in the broader marketplace of ideas'; and a chance for 'insider-activism' by working within an organization to 'catalyze' action (e.g. initiate diplomatic efforts, meetings, and expert groups from 'behind the scenes' in order to 'push [an] agenda forward' or 'manoeuvre and shape how problems are understood').¹⁸³ In addition, organizational settings provide a 'political space' whereby weaker states could form coalitions that would allow them to 'counterbalance or at least deflect' the initiatives of stronger states.¹⁸⁴ The feasibility of these activities depends upon the membership and structure of the organization. As Daniel Drezner points out, organizations are 'not all the same type of actor'.¹⁸⁵ For example, 'club' organizations possess more limited and selective membership than 'universal' organizations.¹⁸⁶ Sometimes club organizations, which are initially comprised of like-minded states, can expand into a more broadly inclusive, 'near-universal' organization through material inducements to encourage other states to join.¹⁸⁷

Organizations also possess the ability to empower or disempower non-state actors by either granting or prohibiting access to rule-making venues; a relationship that Jose Alvarez describes as 'symbiotic'.¹⁸⁸ In situations where non-state actors are permitted to participate, organizations can provide 'legitimizing' avenues (such as

¹⁸³ Hurrell, p. 69-74.

¹⁸⁴ *ibid.*, p. 74.

¹⁸⁵ Drezner, p. 86.

¹⁸⁶ *ibid.*, p. 88.

¹⁸⁷ *ibid.*, p. 75-76.

¹⁸⁸ Alvarez, p. 333.

observer status or amicus briefs) to these actors.¹⁸⁹ There are other situations, however, where non-state actors might be barred from participation in an organization. This could thus cause these actors to protest against the organization and form networks or coalitions with those states who hold a weaker position within the organization or are excluded.¹⁹⁰

Despite the state politics, organizations possess a certain level of autonomy and develop an internal culture that affects its governing behaviour as an institution. In addition, organizational competition can be a factor in how organizations govern. Autonomy, as Laurence Helfer explains, ‘creates opportunities for [international organizations] ... to develop preferences and goals that diverge from those of their founders’.¹⁹¹ In particular, autonomy allows for opportunities to change its ‘structures, mandates, and norms’.¹⁹² Not all organizations, however, possess the same level of autonomy. It has been observed by international organizational scholars that those organizations with greater levels of autonomy have more opportunities to change or affect the direction of institutional governance.¹⁹³ Another factor that affects

¹⁸⁹ *ibid.*, p. 333. (Also, according to Jose Alvarez, these avenues have allowed nongovernmental organizations to gain prominence in international lawmaking by acting as ‘behind-the-scenes treaty drafters and promoters’. See also S Charnovitz, ‘Nongovernmental Organizations and International Law’ (2006) 100 *American Journal of International Law* 348.)

¹⁹⁰ Drezner, p. 76-79.

¹⁹¹ L Helfer, ‘Understanding Change in International Organizations: Globalization and Innovation in the ILO’ (2006) 59 *Vanderbilt Law Review* 649, p. 659. See also Abbott and Snidal, pp. 3-32., p. 9.

¹⁹² Helfer, ‘Understanding Change in International Organizations: Globalization and Innovation in the ILO’, p. 659

¹⁹³ *ibid.*, p. 659; D Kapur, ‘Processes of Change in International Organizations’ in D Nayyar (ed) *Governing Globalization: Issues and Institutions* (Oxford University Press, Oxford, UK 2002), p. 345

international organizational governance is the organization's internal culture.¹⁹⁴ This includes the consideration of the organization's historical and current leadership, the technocratic nature of the organization's staff and capabilities, and the internal politics of the organization. Both the factors of autonomy and internal culture indicate that the 'relationship between the conventions of an [institution] and those participating in it is dynamic', which means that organizations could engage in changing or creating new rules.¹⁹⁵ Though officials who staff organizations have purposes defined by legal rules,¹⁹⁶ these officials could possess 'other purposes besides those expressed'.¹⁹⁷ In situations where there are informal processes within an organization, the instigation and definition of rules may be closely tied to the 'attitudes and experiences of the [organization]'.¹⁹⁸ Likewise, the interpretation of rules could also be influenced by the organization and may lead to rule 'modif[ication] and marginaliz[ation]'.¹⁹⁹ A final growing factor affecting governance is the issue of organizational competition and survival. The competition for financing at the international level among organizations can be a critical factor that might drive an organization to expand its institutional mandate (e.g. 'mission creep') in order to secure funds for its survival.²⁰⁰ In other cases, some states might promote a preferred organization to expand its mandate for

¹⁹⁴ M Tierney and C Weaver, 'Principles and Principals? The Possibilities for Theoretical Synthesis and Scientific Progress in the Study of International Organizations' (2005) Working Paper (Under Review at Cornell University Press)
<<http://mjtier.people.wm.edu/recent%20papers/principals%20and%20principals.pdf>> .

¹⁹⁵ Galligan, *Law in Modern Society* , p. 108.

¹⁹⁶ See generally D Sarooshi, *International Organizations and their Exercise of Sovereign Powers* (OUP, Oxford 2005).

¹⁹⁷ Galligan, *Law in Modern Society* , p. 108.

¹⁹⁸ *ibid*, p. 108.

¹⁹⁹ *ibid*, p. 108.

²⁰⁰ Alkire and Chen, p. 1072.

political reasons.²⁰¹ The resulting overlap in organizational mandates, in either situation, can affect how organizations select to govern states in order to enhance or protect its survival in the international arena. Hence, it is important to recognize that organizations can be more than just ‘creatures of their member states’ in order to explain their behaviour.²⁰² (Chapter 3 will analyze the World Health Organization, which is the core international institution for health, in relation to the aforementioned factors.)

Institutional Interactions

When thinking about an international order, it has been noted by Andrew Hurrell that the word ‘order’ may give the ‘exaggerated’ impression of a ‘neat, tidy’ system.²⁰³ In reality, neatness is rarely the case. The demand for governance to deal with the issues that arise with increasing globalization and the need for international cooperation is creating a ‘remarkably thick institutional environment’.²⁰⁴ The growing ‘institutional density’ of ‘both formal organizations ... as well as more informal cooperative structures’ has raised concerns among scholars about the resulting ‘regime complexes’ that can arise when multiple institutions operate in the same issue area.²⁰⁵ According

²⁰¹ This type of occurrence is discussed in greater detail in the next section on ‘institutional interactions’.

²⁰² Tierney and Weaver, p. 11; Helfer, ‘Understanding Change in International Organizations: Globalization and Innovation in the ILO’, p. 667-668.

²⁰³ Hurrell, p. 20.

²⁰⁴ Drezner, p. 40.

²⁰⁵ K Raustiala, ‘Density and Conflict in International Intellectual Property Law’ (2007) 40 University of California Davis Law Review 1021. The issue has also been more narrowly termed ‘treaty congestion’ and ‘regime density’ in the political science and legal research literature. T Gehring and S Oberthur, ‘Introduction’ in S Oberthur and T Gehring (eds) *Institutional Interaction in Global Environmental Governance* (MIT Press, Cambridge, MA 2006), p. 4; D Fidler, ‘The Challenges of Global Health Governance. International Institutions and Global Governance Program Report’ (2010) Council on Foreign Relations Press

to Kal Raustiala and David Victor, regime complexity can be defined as ‘a collective of partially overlapping and even inconsistent regimes that are not hierarchically ordered, and which lack a central decisionmaker or adjudicator’.²⁰⁶ (The term ‘regime’, as noted earlier, is applied loosely in my thesis and used interchangeably with ‘institution’.²⁰⁷) In other words, there may be multiple institutions with authority or jurisdiction regarding an issue area; thus creating ‘boundary problems’ in terms of the ‘political responsibilities and social spheres of influence’ between different institutions.²⁰⁸

As Oran Young and his colleagues point out, it is critical to recognize that institutions are not purely ‘self-contained entities’ when studying situations of regime complexity.²⁰⁹ This means that institutions operating in the same issue area may ‘interact’ whereby ‘one institution intentionally or unintentionally affects another’.²¹⁰ Institutional interactions can arise when new institutions are established or when

<http://www.cfr.org/content/publications/attachments/IIGG_WorkingPaper4_GlobalHealth.pdf> (June 20, 2010), p. 9.; K Alter and S Meunier, 'The Politics of International Regime Complexity' (2009) 7 (1) *Perspectives on Politics* 13, p. 13.; W Chambers, J Kim and C ten Have, 'Institutional Interplay and the Governance of Biosafety' in O Young and others (eds) *Institutional Interplay: Biosafety and Trade* (United Nations University Press, New York, NY 2008), p. 5.

²⁰⁶ Raustiala; K Raustiala and D Victor, 'The Regime Complex for Plant Genetic Resources' (2004) 58 *International Organization* 277; Raustiala and Victor, 'The Regime Complex for Plant Genetic Resources', p. 279. (Alter and Meunier refine this definition to incorporate not only ‘partially overlapping’ regimes but also ‘nested, ... and parallel international regimes that are not hierarchically ordered’. Nested, overlapping, and parallel regimes are defined a bit later in this chapter. See Alter and Meunier, p. 13.)

²⁰⁷ See n166.

²⁰⁸ Chambers, Kim and ten Have, p. 5. Alter and Meunier acknowledge that while there are ‘[international] “conflict of law” rules of thumb’ to address unintended conflicts between regimes, the lack of a ‘supreme international authority’ does not solve the problem when states ‘fundamentally disagree about which rule or institution they prefer’. Alter and Meunier, p. 13. See also K Alter and S Meunier, 'Banana Splits: Nested and Competing Regimes in the Transatlantic Banana Dispute' (2006) 13 (3) *Journal of European Public Policy* 362, p. 365 and 377.

²⁰⁹ Chambers, Kim and ten Have, p. 5.

²¹⁰ *ibid*, p. 3. These inter-institutional interactions are also referred to as ‘interplay’, ‘interlinkage’, or ‘interconnection’. See also Gehring and Oberthur, p. 4.

‘existing institutions co-evolve through international and national implementation’.²¹¹

Such interactions could be synergistic or disruptive, depending on whether the institutions support or undermine each other, and thus play a critical part in the effectiveness of global governance.²¹²

To establish an approach to analyzing situations of institutional interactions, as in the case of AEM (discussed in detail in Chapter 4), it is helpful to turn to recent research on this matter in other issue areas.²¹³ An emerging body of research on institution interaction provides guidance on how to disaggregate institutional complexity for analysis and consider its role in global governance. According to Sebastian Oberthur and Thomas Gehring, in cases of regime complexity, institutions should be considered ‘interacting units’, each with two key components.²¹⁴ The first component includes the rules and obligations determined by the institution because of their role as ‘principal instruments of governance’ with a direct impact on the behaviour of those addressed.²¹⁵ The second component is the decision-making processes from which rules emerge within the institution. This component is critical because of its impact on the formation and interpretation of rules. It is also beneficial to consider a third component in this analysis, which is compliance. Compliance mechanisms and processes (such as reporting systems, dispute systems, etc.) can

²¹¹ Chambers, Kim and ten Have, p. 3.

²¹² Gehring and Oberthur, p. 1.

²¹³ Recent research on this emerging issue has been performed in the areas of biosafety, environmental governance, plant genetics, intellectual property, and trade. See *ibid*, p. 3.

²¹⁴ S Oberthur and T Gehring, ‘Conceptual Foundations of Institutional Interaction’ in S Oberthur and T Gehring (eds) *Institutional Interaction in Global Environmental Governance* (MIT Press, Cambridge, MA 2006), p. 22.

²¹⁵ *ibid*, p. 23.

interact between two institutions in the sense that one might overpower or legally override the other.

In framing the analysis of these interacting institutions, W. Bradnee Chambers, Joy Kim, and Claudia ten Have believe that three analytical questions should be asked: (1) ‘what are the links of inter-institutional influence and interaction’; (2) ‘what implications does this [interaction] hold for the interests of stakeholders, for the formation, operation and implementation of the specific institution, for its performance and effectiveness, and for the overall governance context’; and (3) ‘in what ways can issues and processes across institutions be strategically linked and arranged to reinforce each other’.²¹⁶ On the first question, regarding the links of interaction, this helps to identify the process of interaction occurring between institutions. The second question, which pertains to the implications of interactions, seeks to understand the politics and other factors that might motivate and influence institutional actors and what this means for the governance of an issue area (e.g. access to essential medicines). The final question seeks to address the management of interaction that is occurring with the objective of improving governance by determining ways to reduce institutional conflict in terms of the ‘legal, normative, operational and functional’ dimensions.²¹⁷

To address the first analytical question, it is important to consider the different forms of interactions (or ‘linkages’) between institutions. These interactions can assume several different forms, which include: (1) overlap, (2) parallelism, (3)

²¹⁶ Chambers, Kim and ten Have, p. 3-4.

²¹⁷ *ibid*, p. 4.

nesting,²¹⁸ and (4) clustering.²¹⁹ Overlapping institutions are typically formed for different purposes without reference to one another, and the overlap that occurs is often ‘unforeseen and unintended’ by their creators.²²⁰ This earlier definition of overlapping institutions, however, was later modified by other scholars to include situations where ‘intentional’ overlap occurs between institutions.²²¹ (For example, a new regime could form an overlap with another existing regime on purpose for strategic reasons.) G. Kristen Rosendal redefines overlapping regimes as situations where ‘their policy goals and regulations prescribed for problem solving intersect within the same issue area’.²²² Parallel regimes refer to the sometimes supportive or competitive relations that can occur between regimes in an issue area. According to Abbott and Snidal, parallel regimes possess a non-hierarchical relationship and are usually ‘trying to achieve roughly the same purpose.’²²³ Nested regimes can be

²¹⁸ The term ‘embedding’ is sometimes used in the academic literature as a form of linkage and attributed to Oran Young; however, I consider this form of interaction to be in the same general category as ‘nesting’. The difference between the two terms is that embedding is used expansively to refer to institutions that ‘depen[d] on the existence of a broader set of constitutive principles and norms [in international society]’ whereas nesting refers to specific governance arrangements brought within another institution in an issue area. See M Koenig-Archibugi, ‘Mapping Global Governance’ in D Held and A McGrew (eds) *Governing Globalization: Power, Authority and Global Governance* (Blackwell Publishers Inc., Malden, MA 2002), p. 60. In contrast, other scholars such as Karen Alter and Sophie Meunier, use the term ‘nesting’ and incorporate ‘embedding’ within it. See Alter and Meunier, ‘The Politics of International Regime Complexity’, p. 15.

²¹⁹ O Young, ‘Institutional Linkages in International Society: Polar Perspectives’ (1996) 2 *Global Governance* 1; K Abbott and D Snidal, ‘Nesting, Overlap and Parallelism: Governance Schemes for International Production Standards’ (Conference on Nested and Overlapping Regimes 2006); GK Rosendal, ‘Impacts of overlapping international regimes : the case of biodiversity’ (2001) 7 (1) *Global Governance* 95.

²²⁰ O Young, ‘Institutional Linkages in International Society: Polar Perspectives’ (1996) 2 *Global Governance* 1, p. 6; Young, *Resource Regimes: Natural Resources and Social Institutions* .

²²¹ GK Rosendal, ‘Overlapping International Regimes: The Case of the Intergovernmental Forum on Forests (IFF) between Climate Change and Biodiversity’ (2001) *International Environmental Agreements: Politics, Law and Economics* 447; A Sydnes, ‘Overlapping Regimes: The SPS Agreement and the Cartagena Biosafety Protocol’ in O Young and others (eds) *Institutional Interplay: Biosafety and Trade* (United Nations University Press, New York, NY 2008), p. 73.

²²² Rosendal, ‘Overlapping International Regimes: The Case of the Intergovernmental Forum on Forests (IFF) between Climate Change and Biodiversity’, p. 458.

understood as the relationship where a more specific institution is found within a broader institution. Such a governance arrangement could be either ‘created within, or subsequently brought under, [a] more comprehensiv[e] arrangement that deal with the same set of issues at a more general level’.²²⁴ The interaction between nested regimes is seen as a ‘hierarchical’ relationship whereby ‘hierarchical rules resolve any conflict among layers of a regime.’²²⁵ Finally, clustered regimes can occur when ‘different functional arrangements are combined into comprehensive package deals.’²²⁶ This type of linkage typically involves a non-hierarchical arrangement intended to increase the institutions’ ‘problem-solving capacity’ through tactical collaboration.²²⁷ Institutional competition is a fifth form of interaction that has suggested by Mathias Koenig-Archibugi.²²⁸ While competition can certainly occur between institutions, I do not consider this a distinct category of interaction but rather an implication of interaction (as discussed in the next question).

After characterizing the institutional interaction that is occurring, an analysis of the second analytical question on its implications helps to identify the interactional problems that are affecting the governance of the issue area. This can be performed by studying the normative, political, and operational implications that result from

²²³ K Abbott and D Snidal, 'Nesting, Overlap and Parallelism: Governance Schemes for International Production Standards' (Conference on Nested and Overlapping Regimes 2006).

²²⁴ Koenig-Archibugi, p. 60.

²²⁵ Abbott and Snidal, 'Nesting, Overlap and Parallelism: Governance Schemes for International Production Standards' .

²²⁶ *ibid.*

²²⁷ Koenig-Archibugi, p. 61.

²²⁸ *ibid.*, p. 62.

institutional interactions.²²⁹ For example, in terms of the normative implications, what are the norms or rules that overlap between the institutions and which set prevails in situations of conflict? Does one institution carry more rigorous reporting procedures than the other? Does one institution possess stronger enforcement mechanisms? What are the behavioural effects of the interactions upon states? With regard to the political implications, researchers have observed that institutional complexity can lead to empowering particular states (i.e. sometimes the developed countries and other times developing countries and NGOs).²³⁰ As states ‘increasingly recognize the constraints [of a particular institution]’, they can ‘employ the opportunities arising from growing institutional density and interdependence [by working through other related institutions]’.²³¹ More specifically, institutional interaction can be used by states to pursue forum shopping for ‘purposive policy development’ in a more favourable organization or regime shifting to ‘overcome obstacles ... hinder[ing] policy development within [an] institution’.²³² Institutional interactions may also lead to the enhancement of cooperation in some cases or detrimental competition in others.²³³

The final analytical question on managing institutional interactions seeks to deal with the present state of institutional complexity in global governance for the purposes of resolving conflict and inefficiencies (e.g. duplications and gaps). Addressing this question will depend upon the findings gathered from the first two

²²⁹ Sydnes, p. 71.

²³⁰ Alter and Meunier, 'The Politics of International Regime Complexity', p. 13.

²³¹ Gehring and Oberthur, p. 3; Raustiala and Victor, 'The Regime Complex for Plant Genetic Resources'; Oberthur and Gehring, p. 20.

²³² Gehring and Oberthur, p. 3; Drezner, p. 86.

²³³ Alter and Meunier, 'The Politics of International Regime Complexity', p. 13.

questions (i.e. on the form of interaction and on the motivations and implications of interactions on the issue area). For example, is the overlap between two institutions impeding the governance of the issue area and how is it affecting the individual institutions?²³⁴ In terms of ways to deal with interactions, Jose Alvarez observes that international organizations may turn to the establishment of normative hierarchies in situations of institutional complexity where rules cannot easily be resolved.²³⁵ He observes, in the case of the International Labour Organization (ILO), that with the proliferation of organizations engaging in ‘mission creep’ and the inability of states to meet their reporting obligations, organizations may turn to the ‘enunciat[ion] [of] “core” obligations expected of all members, even though no such setting of priorities is explicitly authorized by its constitutive instruments or the underlying ... conventions’.²³⁶ Alternatively, in cases of parallel institutions that experience significant fragmentation in an issue area, it might make sense to ‘cluster’²³⁷ these institutions to achieve greater coordination and cooperation.²³⁸ Another idea to address problematic institutional interactions is to create a new ‘overarching’ legal framework or institution that provides structure and general oversight to an issue area experiencing institutional complexity.²³⁹ In other words, nest (or embed) the institution within another.

²³⁴ Sydnes, p. 71; Chambers, Kim and ten Have, p. 3.

²³⁵ Alvarez, p. 327-328.

²³⁶ *ibid*, p. 327.

²³⁷ As Gehring and Oberthur observe in the area of environmental governance, there have been suggestions to ‘cluster’ multilateral environmental agreements – ‘that is, to integrate groups of such agreements or certain of their parts’. See Gehring and Oberthur, p. 2.

²³⁸ *ibid*, p. 1-2.

²³⁹ *ibid*, p. 2.

Hence, when considering the role of the international order in norm implementation, it is critical to understand the individual institutions and complexes operating in the governance of a global cooperative issue area – such as access to essential medicines. In addition, it is necessary to understand the internal and external forces affecting an institutional organization’s approach to state governance. Norm implementation is intricately tied to how states are governed by the international order, and the relative success or failure in state implementation could be attributed to crippling problems within the international order itself.

Influencing States

The international order serves an important purpose in the implementation of IAC for AEM. It establishes IAC rules and influences states to comply with them. Yet, the question remains as to how the international order influences the national regimes (i.e. industrialized states) to carry out these standards. According to Denis Galligan and Deborah Sandler, there are three overarching international approaches that can be applied for implementation: (1) the process of international law (i.e. international court procedures), (2) direct intervention, or (3) indirect influence on member states.²⁴⁰ In the case of IAC for AEM, the first two procedures are not directly applicable. This is because an established international law procedure (via an international court system such as the International Court of Justice) does not readily exist for cases pertaining to IAC for AEM.²⁴¹ Also, direct intervention by the international order in the domestic

²⁴⁰ Galligan and Sandler, 'Socio-Legal Perspectives on Human Rights in the National Context', p. 44.

²⁴¹ While the International Court of Justice (ICJ) will entertain contentious cases for states that have accepted their jurisdiction, the ICJ has never dealt with a case pertaining to the right to health. According to John Crook, the majority of ICJ cases have dealt with land disputes and maritime boundaries. He notes that decisions pertaining to human rights law have '[historically] been a small part of the docket'. See J Crook, 'The International Court of Justice and Human Rights' (2004) 1 *Northwestern University Journal of International Human Rights* 2. (The ICJ was requested to give an

affairs of developed countries is not applicable in this situation. The use of direct intervention is typically reserved for humanitarian cases against massive and grave human rights violations (e.g. genocide) in a state. Instead, my international implementation analysis will focus on the approach of indirect influence on member states.

The indirect approach, which will be analyzed throughout this thesis, essentially ‘devises ways of influencing states at the international level with the object of getting them to give effect to standards within their national systems’.²⁴² It aims to encourage compliance by states and is argued to be the approach that is ‘more likely to produce positive and lasting results’.²⁴³ This approach is based off of the ‘transnational legal process’ for international human rights enforcement and involves three interrelated phases – interaction, norm interpretation, and norm internalization within the domestic system.²⁴⁴ The phase of interaction occurs when action is incited in a national or supranational law-declaring forum, which ‘forces an interpretation or enunciation of the global norm applicable to the situation’.²⁴⁵ This then leads to a

advisory opinion on the legality of the use of nuclear weapons in armed conflict by WHO; however, it ruled that the WHO did not have legal standing to make the request.) The World Trade Organization, as discussed in Chapter 4, has a Dispute Settlement Body that can adjudicate state disputes pertaining to international trade matters (e.g. the trade-related aspects of intellectual property) which encompasses patent disputes over AEM. AEM patent-related issues, however, are only one aspect of current problems and there are troubling biases that the WTO DSB would bring to their decisions due to its trade-focus in disputes. A potential tribunal has arisen in the form of the UN Committee on Economic, Social and Cultural Rights (CESCR), which was recently approved to serve as a ‘quasi-judicial’ body based on the Optional Protocol to the ICESCR. It has not entered into force yet and it is largely uncertain whether it will receive cases pertaining to IAC for AEM. (The CESCR is discussed in Chapter 6.)

²⁴² Galligan and Sandler, 'Socio-Legal Perspectives on Human Rights in the National Context', p. 45.

²⁴³ *ibid.*

²⁴⁴ H Koh, 'How is International Human Rights Law Enforced?' (1999) 74 *Indiana Law Journal* 1397, p. 1399.

²⁴⁵ *ibid.*, p. 1414; JK Levit, 'A Bottom-up Approach to International Lawmaking: The Tale of Three Trade Finance Instruments' (2005) 30 *The Yale Journal of International Law* 125, p. 181.

phase of internalizing the interpretation of the norm into the domestic legal system with the ‘aim to “bind” [the state] to obey the interpretation as part of its internal value set’ and eventually lead the state to perceive the norm-interpretation as ‘an internal obligation’.²⁴⁶

The phase of internalization, however, can be complex. Generally, there are two things that the international order strives to achieve in norm implementation by states. The first (i.e. the formal component) involves obtaining state ratification of the relevant treaty and promoting the incorporation of treaty standards into domestic law. The second (i.e. the informal component) involves the inducement of states to ‘give substantive effect to the law’.²⁴⁷ Yet, there are certain hurdles that international order may encounter in this process.

Sometimes, as in the case of AEM, the standards are not yet crystallized in the form of hard law. Rather, the norm is recognized in terms of international resolutions, declarations, official guidance, codes of conduct, and other forms (as noted in chapter 1) which are often categorized as ‘soft law’. According to Kenneth Abbott and Duncan Snidal, ‘the realm of “soft law” begins once legal arrangements are weakened along one or more dimensions of obligation, precision, and delegation’ with ‘varying

²⁴⁶ Koh, p. 1414; Levit, p. 181.

²⁴⁷ Galligan and Sandler, 'Socio-Legal Perspectives on Human Rights in the National Context', p. 45. Harold Koh describes three forms of norm internalization (i.e. social, political, and legal). Social internalization, according to Koh, ‘occurs when a norm acquires so much public legitimacy that there is widespread general adherence to it’. Political internalization describes a state when ‘political elites accept an international norm, and advocate its adoption as a matter of government policy’. Finally, legal internalization refers to ‘when an international norm is incorporated into the domestic legal system ...’. Koh states that these forms of internalization can occur in any order and the occurrence of one form could help to trigger another form. See Koh, p. 1413-1414. (I do not follow the precise categorization provided by Koh, but my framework recognizes the importance of the social, political, and legal dimensions and their reinforcing nature in norm implementation.)

degrees along each dimension and in different combinations across dimensions'.²⁴⁸

This is not to say, however, that soft law is any less important or useful compared to hard law. In fact, some argue that soft law is often deliberately selected as a 'superior' legal arrangement and 'offers many of the advantages of hard law, avoids some of the costs of hard law, and has certain independent advantages of its own'.²⁴⁹ For example, soft law is typically 'easier to achieve' and can better 'deal with uncertainty' in comparison to the rigid process involved in the establishment of hard law.²⁵⁰

Even if the standards were captured in 'hard law' form (e.g. a treaty or regulation), there are issues that would need to be considered. For example, states may decide to refuse to sign or ratify a treaty. States may also decide to submit an array of reservations that would weaken the power of a treaty. However, even if a state decides to proceed with ratification of a treaty, the process will falter if a state does little to give effect to the treaty afterwards. This may occur due to the dominance of existing domestic norms over newly introduced international standards that are imposed by an external source and 'may not have the cultural support and political legitimacy to secure their internalization'.²⁵¹

Nevertheless, there are certain strategies that the international order can apply to influence the norm internalization process. One strategy is to build up the role of

²⁴⁸ K Abbott and D Snidal, 'Hard and Soft Law in International Governance' (2000) 54 (3) *International Organization* 421, p. 422. Hard law, on the other hand, 'has a very high value on each of [these] three dimensions.' See J Kirton and M Trebilcock, 'Introduction: Hard Choices and Soft Law in Sustainable Global Governance' in J Kirton and M Trebilcock (eds) *Hard Choices, Soft Law: Voluntary Standards in Global Trade, Environment and Social Governance* (Ashgate, Aldershot, UK 2004), p. 8.

²⁴⁹ Abbott and Snidal, 'Hard and Soft Law in International Governance', p. 423.

²⁵⁰ *ibid.*, p. 423.

²⁵¹ Galligan and Sandler, 'Socio-Legal Perspectives on Human Rights in the National Context', p. 46.

international institutions in facilitating state implementation of standards.

International institutions are the ‘international equivalent’ of national government institutions (i.e. departments and agencies).²⁵² Though they may lack the powers of national institutions, international institutions actually ‘have a range of significant powers which are greater and more effective than imagined ... [but] [o]ften they are simply not used.’²⁵³ International institutions, as Galligan and Sandler explain, have the ‘quiet capacity’ to apply informal authority and discretions and to work with states (i.e. via national agencies and officials) in ways that would ‘foster conditions within society for the positive adoption of international norms and standards’.²⁵⁴ In particular, the use of informal mechanisms such as persuasion, negotiation and accommodation play a critical part of this process. Furthermore, an international institution can establish links to other institutions to build up its own powers.

It has also been emphasized that the impact of international institutions in the supervision of reporting and complaint systems should not be overlooked.²⁵⁵

Reporting and complaint systems serve important functions in influencing state practices because they allow international institutions to bring public pressure upon states for norm violations or inadequacies. This mechanism can be quite effective because states are highly concerned with their international reputation. Reporting can also support state implementation of rights by fostering a culture of periodic self-reviews of practice, uncovering inadequacies or violations in practice, and prompting

²⁵² *ibid.*, p. 46-47.

²⁵³ *ibid.*

²⁵⁴ *ibid.*

²⁵⁵ Donnelley, p. 173-176.

remedial action.²⁵⁶ At the international level, reporting can also promote an opportunity for international information exchange and allow states to learn from each other's experiences.²⁵⁷ There are serious shortcomings, however, in most international reporting and complaint systems because neither system is usually effectively enforced.²⁵⁸ In the case of reporting, there is heavy reliance on voluntary self-reporting by states which often result in lax submissions in terms of timeliness and completeness. Complaint systems, which are usually loosely enforced by international institutions, fall victim to unenforceable sanctions and ineffective follow-up procedures.²⁵⁹ Yet, despite these issues, it is ultimately agreed that these systems carry significant influential powers and that the absence of such systems would make it easier for states to elude compliance.

Another strategy for the internalization of norms by the international order is the process of socialization. Under this process, state governments are influenced by both international and domestic pressures into accepting international norms as collective expectations about proper behaviour which leads to eventual implementation.²⁶⁰ There are three major forms of socialization: material inducement, moral consciousness-raising, and acculturation.²⁶¹

²⁵⁶ *ibid*, p. 174.

²⁵⁷ *ibid*, p. 175.

²⁵⁸ Also, sometimes reporting is an end in itself and nothing follows from it.

²⁵⁹ *ibid*, p. 176.

²⁶⁰ Galligan and Sandler, 'Socio-Legal Perspectives on Human Rights in the National Context', p. 47. See also T Risse, S Ropp and K Sikkink (eds), *The Power of Human Rights* (Cambridge University Press Cambridge 1999), p. 11.

²⁶¹ Risse, Ropp and Sikkink (eds), *The Power of Human Rights*, p. 11; R Goodman and D Jinks, *Socializing States: Promoting Human Rights through International Law* (Oxford University Press,

One approach to socialization is material inducement, which is where the international order uses coercion or enticement, through material rewards and punishments, to influence state behaviour by ‘escalating the benefits of conformity or the costs of nonconformity’.²⁶² It has been asserted that while a state may alter its behaviour due to a material cost-benefit analysis that favours conformity, this approach does not require ‘a change in the [state’s] underlying preferences’.²⁶³ In other words, material inducement could simply involve the superficial appearance of conformance by a state. Thomas Risse and his colleagues label this phenomenon ‘adaptation and strategic bargaining’ whereby a state may respond to external and internal pressures by making tactical concessions (i.e. instrumental or material adaptations) for the purposes of advancing its own interests.²⁶⁴ It is noted, however, that norm internalization cannot be achieved under this approach alone for norm violations would occur once ‘material incentives and/or the threat of sanctions are removed’.²⁶⁵

A second approach to socialization is ‘moral consciousness-raising’, whereby international institutions and advocacy groups engage the state government in moral discourse about a state’s practices through the use of argumentation, persuasion,

Oxford, UK Forthcoming); R Goodman and D Jinks, 'How to Influence States: Socialization and International Human Rights Law' (2004) 54 (3) *Duke Law Journal* 621.

²⁶² Goodman and Jinks, *Socializing States: Promoting Human Rights through International Law*, p. 4; Goodman and Jinks, 'How to Influence States: Socialization and International Human Rights Law', p. 633-634.

²⁶³ Goodman and Jinks, 'How to Influence States: Socialization and International Human Rights Law', p. 633.

²⁶⁴ Risse, Ropp and Sikink (eds), *The Power of Human Rights*, p. 12.

²⁶⁵ Risse, 'Global Governance and Communicative Action', p. 307.

shaming, and other forms of dialogue.²⁶⁶ Specifically, this approach involves a process of moral and social learning in which the international order communicates with states to ‘actively assess the content of a particular message [i.e. the norm] ... and “change their minds”’.²⁶⁷ It operates on the assumption that ‘the more [states] are convinced of the legitimacy of the rule, the more [they] will comply voluntarily with norms and rules’.²⁶⁸ Thomas Risse explains that the rule’s legitimacy can be derived from either the norm itself or the ‘validity of the procedure’ (e.g. negotiations or expert guidance) by which the norm was formed.²⁶⁹ In some cases, this communicative process can occur before an audience (e.g. the public) which would decide upon the arguments presented.²⁷⁰ States that are sensitive to public perceptions of its behaviour will likely adapt as part of the ‘learning’ process. In addition, the use of ‘framing and cuing’²⁷¹ could be applied in moral discourse with states in an attempt to change their views of norms. The intended outcome of this influence is to have states ‘redefine their interests and identities’ in accordance with their new understanding of the norm for state behaviour.²⁷² In other words, this approach does not seek to make a state behave a particular way (e.g. comply with a norm), rather, the goal is to have the state reach a

²⁶⁶ Risse, Ropp and Sikkink (eds), *The Power of Human Rights*, p. 13.

²⁶⁷ Goodman and Jinks, *Socializing States: Promoting Human Rights through International Law*, p. 6

²⁶⁸ Risse, 'Global Governance and Communicative Action', p. 293.

²⁶⁹ *ibid.*, p. 293.

²⁷⁰ *ibid.*, p. 298.

²⁷¹ According to Goodman and Jinks, ‘framing’ structures an issue ‘to resonate with already accepted norms’ and ‘cuing’ introduces new information to ‘prompt [states] “to engage in a high intensity process of cognition, reflection, and argument”’. Goodman and Jinks, *Socializing States: Promoting Human Rights through International Law*, p. 6.

²⁷² *ibid.*, p. 4

‘reasoned consensus’ about state behaviour and ‘[voluntarily] change [its] views ... or interests in light of the better argument’.²⁷³

The third approach to socialization is acculturation, which is derived from behavioural and sociological ideas of how states might react to influence. According to Ryan Goodman and Derek Jinks, this approach induces states to conform to the appropriate attitudes and behaviour due to self-imposed or social pressures.²⁷⁴ The internal, or cognitive, pressures that can drive a state’s behaviour and beliefs are based on the social role (or identity) that the state has internalized.²⁷⁵ (In other words, what the state wants to be.) Social pressure, on the other hand, is based on states’ motivation to ‘hoard social legitimacy and status’ (e.g. ‘keeping up with the Joneses’) whereby they seek to minimize the social-psychological costs (e.g. shaming and shunning) and maximize social-psychological benefits (e.g. displays of public approval).²⁷⁶ Conformity based on social pressure, however, is likely to depend on several factors relating to the social group – such as the group’s importance to the state, the size of the group, and the state’s exposure to the group.²⁷⁷ Goodman notes that acculturation has a tendency to lead states towards the ‘incomplete internalization’ of norms because the process only requires ‘public [i.e. outward] compliance with, but not private acceptance of, social norms’.²⁷⁸

²⁷³ Risse, 'Global Governance and Communicative Action', p. 294.

²⁷⁴ Goodman and Jinks, *Socializing States: Promoting Human Rights through International Law*, p. 2

²⁷⁵ *ibid.*, p. 9

²⁷⁶ *ibid.*, p. 7

²⁷⁷ *ibid.*, p. 9

²⁷⁸ *ibid.*, p. 8

Ultimately, the aim of these various approaches is to help the state reach the goal of norm internalization. As they reach this stage, states will tend to ‘institutionalize’ and ‘habitualize’ norms. The institutionalization process involves the formal acceptance of standards into domestic practice (e.g. through the incorporation of standards into domestic laws), while the habitualization process refers to when standards are ‘taken for granted’ and followed without external pressure.²⁷⁹ These two processes, which occur in the later phases of socialization, are possible when state governments find themselves ‘entangled’ by their moral rhetoric and growing, incremental concessions towards international norms.²⁸⁰ The research literature notes that the various socialization approaches described in this section tend not to operate exclusively but rather in combination with each other.²⁸¹ The use of the socialization process in the context of IAC for AEM will be considered in Chapter 5.

The Role of States

While international institutions possess significant influence on the implementation of norms, states are ultimately the principal actors in IAC implementation because this is the level at which norms are executed. Before turning to the topic of state implementation, however, it is important to consider the role of states in the global governance process and the influence that powerful states (such as developed countries) can have upon the international order. Such interactions between the international order and states indicate that norm implementation is sometimes a

²⁷⁹ Risse, Ropp and Sikkink (eds), *The Power of Human Rights*, p. 16-17.

²⁸⁰ *ibid*, p. 16-17.

²⁸¹ Risse, 'Global Governance and Communicative Action', p. 307.

dynamic process whereby the move towards IAC does not necessarily follow a linear path of adoption and compliance.

States and the Governance Process

States, especially powerful ones, are not passive actors in the system of global governance. They can actively seek to affect the process through which governance occurs and the powerful states, in particular, can ‘substitute [between] different governance structures’.²⁸² Governance structure substitution, also known as ‘forum shopping’,²⁸³ is a tactic that is commonly used by states in their pursuit of a forum (e.g. international organization) that provides the most favourable conditions for national interests. According to Daniel Drezner, the most powerful states (typically the developed countries) ‘will have the greatest success employing this tactic’.²⁸⁴ Powerful states can strategically use this tactic to empower preferred institutions (or organizations) with operational or enforcement powers while emasculating those which are seen as unfavourable. In addition, these states could create new, and more accommodating, institutions to rival existing ones. Alternatively, states could consciously ‘tolerate the absence of effective cooperation’ by neglecting an existing institution or the formation of one.²⁸⁵

Drezner has also developed a governance typology theory, which

‘demonstrates the extent to which [powerful states] will engage in forum-shopping to

²⁸² Drezner, p. 63

²⁸³ K Abbott and D Snidal, ‘Pathways to International Cooperation’ in E Benvenisti and M Hirsch (eds) *The Impact of International Law on International Cooperation* (Cambridge, UK 2004); Helfer, ‘Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking’.

²⁸⁴ Drezner, p. 64.

²⁸⁵ *ibid.*, p. 64.

match the proper [intergovernmental organization] to the proper political environment'.²⁸⁶ According to his theory, there are four possible processes of international coordination - depending on the form of the standards (i.e. harmonized standards, club standards, rival standards, and sham standards). Harmonized standards, which represent one end of the extreme for coordination, can occur when there is a 'similarity' in state preferences and is likely lead to 'the harmonization of domestic regulations'.²⁸⁷ On the other end of the coordination spectrum, sham standards can occur when 'governments agree to a notional set of global standards with weak or nonexistent monitoring or enforcement schemes' and are least likely to lead to actual coordination.²⁸⁸

In addition, states can also form their own governance structures – either with or without an international organization binding them together. Transgovernmental networks, according to Anne-Marie Slaughter and Kal Raustiala, have emerged as a new form of governance whereby state bureaucrats (such as regulators, lawmakers, judicial officials, etc.) bond together informally to develop international coordination on an issue.²⁸⁹ Examples of transgovernmental networks have occurred in the areas financial banking and environmental regulation. While these structures do not necessarily require more formal measures (such as an international organization or international agreement), they can incorporate one into their governance structure at a later point. Anne-Marie Slaughter observes that transgovernmental networks do not

²⁸⁶ *ibid*, p. 88.

²⁸⁷ *ibid*. p. 73.

²⁸⁸ *ibid*, p. 81.

²⁸⁹ Slaughter; K Raustiala, 'The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law' (2002) 43 *Virginia Journal of International Law* 1

replace international organizations; rather, they may exist in parallel to each other.²⁹⁰

This thesis will explore the emerging trend of networked governance in access to essential medicines (including networks between intergovernmental organizations and networks between states in Chapter 6).

State Implementation of Norms

States have a variety of powerful options in determining whether and how to implement norms. Notably, states possess the power of: (1) selecting whether or not to apply international standards domestically, (2) deciding how to interpret and apply international standards in the national context, and (3) determining what mechanism is available, or which needs to be developed, to attain compliance with standards (e.g. the formation of administrative offices or programmes, special ministerial appointments, executive declarations or orders, and adoption of domestic laws).²⁹¹

It is also interesting to note that ‘international rules and norms can affect national policy choices by operating through the domestic political process’.²⁹²

According to this argument, domestic actors (i.e. state or societal) may chose to leverage an international norm to serve their political interests at the state level.

Hence, the international norm ‘can enter [domestic] policy debate ... [and potentially] influenc[e] the type of policy a country pursues’.²⁹³ Factors influencing this process

²⁹⁰ Slaughter, p. 153.

²⁹¹ Galligan and Sandler, 'Socio-Legal Perspectives on Human Rights in the National Context', p. 311.

²⁹² A Cortell and J Davis, 'How do international institutions matter? The domestic impact of international rules and norms.' (1996) 40 *International Studies Quarterly* 451, p. 457.

²⁹³ *ibid*, p. 471.

include the domestic structure where the policy debate occurs as well as the 'political salience or legitimacy' of the international norm.²⁹⁴

Yet, even if state powers were exercised in relation to a norm, a state's commitment to norm implementation also needs to be considered.²⁹⁵ First, the legal status of the norm under domestic laws is an important factor. While signing a treaty or making a commitment is a symbolic first step in state acceptance of standards, what actually sets implementation into action is how the standards are incorporated into domestic laws or reflected constitutionally.²⁹⁶ A second consideration is the existence of national institutions (i.e. agencies, committees, etc.) that play a role in the oversight of domestic recognition and support of the IAC for AEM. If such institutions do not exist at the national level, new special bodies may need to be established to assume domestic oversight tasks. A final consideration is whether there are adequate remedies and procedures available to bring about compliance, as well as to address non-compliance.²⁹⁷

While it is hoped that a nation would be receptive enough to execute the process of domestic implementation detailed above, there are situations where a state government may be resistant to international standards. This can significantly complicate the implementation process and require a drawn out process of external and internal pressures upon a state to conform. In such situations, it is helpful to adapt

²⁹⁴ *ibid*, p. 471.

²⁹⁵ Galligan and Sandler, 'Socio-Legal Perspectives on Human Rights in the National Context', p. 49.

²⁹⁶ *ibid*, p. 50-51.

²⁹⁷ Galligan, *Law in Modern Society*, p. 305.

Thomas Risse's socialization 'spiral model'²⁹⁸ as a framework for the analysis of norm implementation under resistant governments. The spiral model allows for the operationalisation of the three forms of socialization processes (i.e. material inducements, moral consciousness-raising, and acculturation), which were described earlier, to understand how a state can progress towards the implementation of international norms.²⁹⁹ The adapted form of the spiral model includes four key phases for evolution towards national implementation; these phases are: (1) denial, (2) tactical concessions, (3) prescriptive status, and (4) rule-consistent behaviour.³⁰⁰

In starting with the first phase, denial, the norm-violating state rejects the validity of international norms and its application to state practices.³⁰¹ During this phase, the practices of state are brought to international attention and instigate the mobilization of the international community. The international community engages in the socialization processes of state blaming and shaming. In the case of the AEM, other actors (e.g. developing countries) may decide to apply pressure upon norm-violating industrialized nations by engaging in symbolic or indirect actions. Symbolic actions might entail 'recalling ambassadors, ... endorsing international investigations, and voting for condemnatory resolutions in international organizations', whereas indirect actions could involve the support of human rights activists and NGOs.³⁰²

²⁹⁸ Risse, Ropp and Sikkink (eds), *The Power of Human Rights*, p. 22-33.

²⁹⁹ *ibid*, p. 17-19.

³⁰⁰ Risse and his colleagues provide five phases in the original 'spiral model'; the first phase being 'repression'. For the purposes of my thesis, I do not include the first phase due to the nature of issue being studied (i.e. international assistance and cooperation for access to essential medicines) and the fact that it does not involve the initial phase of repression. Rather, it starts with the next phase of 'denial'. (The reasoning behind this is discussed further in Chapter 5.)

³⁰¹ Risse, Ropp and Sikkink (eds), *The Power of Human Rights*, p. 23.

In the second phase of ‘tactical concessions’, the state no longer denies the validity of international standards and attempts to pacify international criticism with ‘cosmetic changes’ and by ‘talking the talk’.³⁰³ These actions are taken in an attempt to save the state’s reputation, and they may temporarily improve the outlook of national implementation. In the case of industrialized nations, tactical concessions are also often used in bilateral foreign relations for the purposes of gaining a particular material advantage. During this phase, however, the state government begins to find itself entrapped in moral dialogue and targeted in shaming for inconsistent practices from its tactical concessions. As a result, this allows domestic opposition groups to gather confidence in launching their own campaign against the state government in support of implementation.

In the third and fourth phases of the spiral model, states begin to show greater commitment towards the implementation of the international standards. During the third phase, known as ‘prescriptive status,’ the state starts to show that it accepts standards as legitimate through the ratification of treaties, the incorporation of standards into domestic law, and the use of other state institutionalization practices.³⁰⁴ At this point, though the validity of standards is no longer debated, implementation remains imperfect. Finally, in the fourth phase of ‘rule-consistent behaviour’, state compliance with international standards has become habitual.³⁰⁵

³⁰² Donnelley, p. 166.

³⁰³ Risse, Ropp and Sikink (eds), *The Power of Human Rights*, p. 25-27.

³⁰⁴ *ibid.*, p. 29.

³⁰⁵ *ibid.*, p. 30. See also Freeman, p. 135-136. (The final phase might be considered a rather idealistic phase for all but the most uncontroversial issues.)

In the course of this socialization process, however, a number of state challenges will need to be overcome to achieve implementation. One challenge is the national preoccupation with maintaining state sovereignty.³⁰⁶ Another challenge is the issue of national competing interests, such as issues related to economics or trade, which can conflict with or demote an issue on the national agenda.³⁰⁷ A third challenge is the cost of implementing international standards. As Michael Freeman notes, the ‘principle of limited sacrifice’ indicates that states are ‘willing to pay only a limited price in implementing [standards]’ which can be detrimental to domestic norm recognition.³⁰⁸ Finally, bureaucratic politics can serve as a serious impediment to effective national implementation of standards.³⁰⁹ This is because the existence of uncoordinated bureaucratic organizations in state governments can lead to inconsistency, inefficiency, and other administrative problems in norm implementation and practice.

The spiral model, though helpful in providing a structured analysis of state socialization, has been criticized on various fronts. A frequent criticism of the spiral model pertains to its overly deterministic and linear character.³¹⁰ As Todd Landman

³⁰⁶ Freeman, p. 132. See also Donnelley, p. 35.

³⁰⁷ Freeman, p. 134. See also Donnelley, p. 162.

³⁰⁸ Freeman, p. 134.

³⁰⁹ Donnelley, p. 171.

³¹⁰ According to Christopher Marsh and Daniel Payne, the ‘model is very linear, even tautological: it has an ultimate destination and there are no points along the way marking possible detours or obstacles to derail movement in the planned direction’. See C Marsh and DP Payne, ‘The globalization of human rights and the socialization of human rights norms’ (2007) [2007] Brigham Young University Law Review 665; A Jetschke and A Liese, ‘The Spiral Model: How Does It Score After Ten Years?’ (2009) <http://faculty.maxwell.syr.edu/hpschmitz/Human_Rights_2009/JetschkeLiese_Spiral%20Model_Review.pdf> (June 1, 2010), p. 14.

argues, '[the spiral model] is perhaps too ambitious in its attempt to provide universal generalizations and to displace realism'.³¹¹ A related criticism points to the model's lack of specification on the 'lasting effects' or permanence of the results achieved at each phase in the model.³¹² While these are valid concerns, Risse and his colleagues have stated that the spiral model phases may not always progress forward smoothly. For example, Risse and his colleagues note the possible reversibility in progress as well as the likelihood of stalemates during the phases of the spiral model.³¹³

Another criticism of the model is that it does not take into account the possibility that a state might only accept particular aspects of a right and, thus, 'may not fully implement the [right] in practice'.³¹⁴ A similar criticism points out that the model treats the state as a 'homogenous conglomerate' whereby the entire country either 'move[s] forward towards norm compliance, or alternatively remain stagnant'.³¹⁵ Anthony Chase argues that the model also does not account for the potential 'struggle between internal politics and domestic forces' occurring within a state, while Laura Landolt criticizes the model's overemphasis of elite views.³¹⁶ Essentially, the model mischaracterizes domestic actors (e.g. civil society

³¹¹ T Landman, 'Review Article: The Political Science of Human Rights' (2005) 35 *The British Journal of Political Science* 549, p. 565.

³¹² R Schwarz, 'The Paradox of Sovereignty, Regime Type, and Human Rights Compliance' (2004) 8 (2) *Journal of Human Rights* 199, p. 202-203; T Solomon, 'Norms and Human Rights in International Relations' (2006) 4 *Political Studies Review* 36; LK Landolt, '(Mis)constructing the Third World? Constructivist analysis of norm diffusion' (2004) 25 (3) *Third World Quarterly* 579, p. 588.

³¹³ Risse, Ropp and Sikkink (eds), *The Power of Human Rights*, p. 23.

³¹⁴ AB Çelik, 'Transnationalization of Human Rights Norms and its Impact on Internally Displaced Kurds' (2005) 27 (3) *Human Rights Quarterly* 969-997, p. 970.

³¹⁵ Jetschke and Liese, p. 17.

³¹⁶ AT Chase, 'The State and Human Rights: Governance and Sustainable Development in Yemen' (2003) 17 (2) *International Journal of Politics* 213, p. 217; Landolt, p. 586.

organizations and other non-state actors) as always having a unified position and does not account for the possible divergence between them. A final criticism of the model is that it does not consider the role of competing norms.³¹⁷ For example, as in the case of access to medicines, a government is likely to be faced with the competing norm of intellectual property rights. It may also be faced with potentially reinforcing norms, such as national security and development. In my research, as presented in Chapter 5, I recognize these various factors as critical to state influence and account for them in the analysis. I do not feel that these factors need to be simplified (as suggested by the critics) nor ignored in the analysis, but it does add a layer of complexity to the analysis.

In the end, though the spiral model possesses some limitations, it remains the best approach in the attempt to demystify how socialization (through a combination of ‘instrumental interest, material pressures, argumentation, persuasion, institutionalization, and habitualization’) influences states.³¹⁸ In other words, the ‘spiral model allows us to ask the right questions about crucial periods and actors of human rights change’ though it may ‘not necessarily answer those questions’.³¹⁹ To apply the model in my research, I adapt it to four stages (as mentioned earlier) and use it as a general guide to study the complex question of norm implementation. The model provides a basic analytical structure to interpret historical and recent events as well as postulate what the state might do next.

³¹⁷ Jetschke and Liese, p. 20.

³¹⁸ Risse, Ropp and Sikkink (eds), *The Power of Human Rights*, p. 37.

³¹⁹ Simmons and Martin, p. 532.

Conclusion

This chapter detailed the theoretical framework that will guide the analysis of IAC for AEM governance and implementation in this thesis. Norm implementation involves three components (i.e. standards, institutions, and processes). In the introductory chapter (Chapter 1), a set of IAC standards was presented based on current international agreements and guidance pertaining to access to essential medicines. These standards are mainly derived from the international human right to health, but also supported by a strong normative foundation. Due to the shortcomings in international assistance and cooperation for the issue of AEM, this thesis turns to the problems of governance and implementation involved.

Governance and implementation hold an interrelated and cyclic relationship. Poor governance could lead to poor implementation, but poor implementation can help inform how governance should be improved (i.e. a feedback loop). Governance structures and arrangements are not necessarily impervious to change and can evolve over time. Analyzing the governance and implementation dimensions of IAC for AEM can help indicate how states could be induced to implement IAC norms for AEM through improved governance. To address the three research sub-questions presented earlier in this chapter,³²⁰ a theoretical framework was established to guide the analysis. Building on the ideas presented by Denis Galligan and Deborah Sandler on norm implementation, I determined that it would be essential to understand the international and national dimensions of IAC for AEM implementation as well as their interrelationship.

³²⁰ Three research sub-questions were identified: (1) what is the current international order governing access to essential medicines; (2) what are the processes and mechanisms that the international order has used to influence developed countries and how have the countries responded; and (3) what is an alternative approaches to the current governance structure.

My first research sub-question sets out to map the current international order governing access to essential medicines. Based on scholarship from the social sciences (i.e. international relations, organizational theory, sociology, and international law), I set out to define the key components to be identified (i.e. institutions and its subparts) as well as broadly review what their characteristics are and how they interrelate (i.e. institution-to-institution and institution-to-state). For the study of IAC for AEM, the analysis of the international order is divided into two chapters. Chapter 3 (on the international institution for health) studies the World Health Organization (WHO), which is the central institution specified by the UN for the governance of international health matters and guided by the principle of the right to health. This chapter applies Oran Young's characterization of institutions (as being comprised of substantive rules and policies, procedures for collective action, and compliance mechanisms) for the study of the organization.³²¹ It considers the WHO's policies and activities pertaining to AEM, its powers as an international organization, and its internal culture and operations. Chapter 4 (on Interacting Institutions) addresses the institutional interactions that are occurring over the issue of AEM. Two primary interactions are observed in this research; one is the interaction between the institutions for international health and trade (i.e. WHO and World Trade Organization) and the other interaction occurs between international health and development (i.e. WHO and the World Bank as well as UNAIDS and the Global Fund). The chapter applies the ideas set out earlier on international interactions, particularly the tripartite analytical framework (i.e. 3 major questions) that W. Bradnee

³²¹ Young, 'International Regimes: Problems of Concept Formation', p. 333-338.

Chambers, Joy Kim, and Claudia ten Have ask about interactions – (1) what are the links; (2) what are the implications; and (3) what are the management possibilities.

To address the second research sub-question pertaining to the processes and mechanisms of the international order, I conducted a national case study of the United Kingdom to understand how states have been influenced to implement IAC for AEM norms and how they responded to such influence. This analysis can be found in Chapter 5. The chapter applies the ‘spiral model’, as described earlier, to guide my analysis of the state’s pathway towards gradual norm acceptance and implementation.

After having analyzed the national and international dimensions, attention is given to the third research sub-question addressing an alternative approach for the governance of AEM in Chapter 6. In the course of this research, it was discovered that the governance of AEM has not remained static and that two governance changes were emerging based on the various institutional and state interactions. First, the institutional interactions between international health and trade over AEM have triggered a potential regime shift to the WHO (through the Intergovernmental Working Group in Public Health, Innovation and Intellectual Property). Second, the institutional interactions between international health and development have triggered concerns about international coordination between institutions. This leads UNAIDS to reattempt to coordinate and harmonize the various institutions through the Global Task Team. In addition, there could be a role for the UN Committee on Economic, Social and Cultural Rights (CESCR) to play on the matter of IAC for AEM based on its particular powers of state monitoring and a new quasi-judicial mechanism (i.e. the

Optional Protocol). The conclusion (Chapter 7) reflects upon these findings and considers the potential improvements to be made in IAC for AEM.

Chapter 3: THE INTERNATIONAL INSTITUTION FOR HEALTH – THE WORLD HEALTH ORGANIZATION (WHO)

Introduction

As discussed in the last chapter, an ‘institution’ is a broadly defined concept that represents ‘persistent and connected sets of rules that prescribe behavioural roles, constrain activity, and shape expectations’.³²² In an effort to define institutions with greater clarity, Oran Young has laid out the three major components that are common to every international institution.³²³ The first component is the ‘substantive component,’ which is a collection of rights and rules. The second component in an institution is the ‘procedural component,’ which includes arrangements for resolving situations requiring social or collective actions.³²⁴ Young notes that this component can vary in terms of its level of formality. Some examples of such mechanisms are voting systems and administrative decision making. Finally, the third institutional component is the compliance mechanism. This mechanism is a necessary part of institutions, which supports the effective implementation of its substantive and procedural components by regime actors.³²⁵ It is noted, however, that compliance mechanisms can vary in their level of formality and tend to be quite weak due to underinvestment by regime members.³²⁶ In the following sections, the three major institutional components of the WHO are identified and analysed.

³²² Keohane, 'International Institutions: Two Approaches', p. 386

³²³ Young, 'International Regimes: Problems of Concept Formation', p. 333-338.

³²⁴ *ibid*, p. 336.

³²⁵ *ibid*, p. 340.

³²⁶ *ibid*, p. 340.

This chapter focuses on the characterization and analysis of the World Health Organization (WHO) as the core institution for international health. The WHO, as this section will reveal, has historically played a weak role in the governance of access to essential medicines (and other health issues in general). This has allowed other institutions, namely those for development and trade, to dominate key health issues as the WHO fell into the background.³²⁷ In the first section of this chapter, the three key institutional components of the World Health Organization are identified and described. This is followed by an analysis of the WHO's struggles as an institution for health due to various endogenous and exogenous factors. (As explained in Chapter 2, internal and external factors could prompt an organization to change in order to remain viable in international society. Otherwise, it faces the risk of being marginalized or replaced). This chapter will mainly address the endogenous factors influencing the WHO while the subsequent chapters, namely chapters 4 and 5, will address exogenous factors based on the WHO's interactions with other powerful international institutions (i.e. the World Trade Organization, the World Bank, UNAIDS, and the Global Fund) and nation states.

The Substantive Component: WHO's Mission and Functions

The WHO was established in 1948 and includes 193 member states. As the UN specialised agency for health, it is 'the primary multilateral organization charged with implementing the right to health'.³²⁸ The WHO Constitution envisioned an agency that would act as the 'directing and coordinating authority on public health' (Art. 2) and

³²⁷ The interactions between the WHO and the development and trade institutions will be discussed and analyzed in Chapter 4.

³²⁸ A Taylor, 'Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions of Health' (1992) 18 American Journal of Law and Medicine 301, p. 312.

endowed it with extensive normative powers to proactively promote the attainment of ‘the highest possible level of health’.³²⁹ According to the WHO’s ‘General Programme of Work’,³³⁰ a core function of the WHO is to establish standards and to promote and monitor their implementation.³³¹ In terms of access to medicines, the WHO’s activities have ‘varied throughout its history, with an emphasis on elaborating international standards’.³³² (For an illustration of this, see Appendix table 1 of WHA resolutions pertaining to access to medicines.)

A prominent example of the WHO’s normative function is the publication of a biennial ‘model list’ of essential medicines for countries. This rather technical focus on essential medicines, however, was later significantly broadened through the ‘Revised Drug Strategy’³³³ resolution due to growing international concern over the inequity in access faced by developing countries and the WTO’s TRIPS Agreement. The ‘Revised Drug Strategy’ extended the WHO’s mandate to ensure greater access to essential medicines, which includes addressing ‘the interface between health, trade and intellectual property issues’.³³⁴ A number of developed countries reportedly opposed earlier versions

³²⁹ WHO Constitution, Article 2.

³³⁰ The General Programme of Work is the WHO’s main planning instrument.

³³¹ WHO, ‘Engaging for Health Eleventh General Programme of Work, 2006-2015 A Global Health Agenda’ <http://whqlibdoc.who.int/publications/2006/GPW_eng.pdf>.

³³² GL Burci and CH Vignes, *World Health Organization* (Kluwer Law International, The Hague 2004), p. 187.

³³³ WHA Resolution 52.19 (1999).

³³⁴ C Raghavan, ‘Health: Assembly adopts new revised drug strategy’ (1999) <<http://www.twinside.org.sg/title/assembly-cn.htm>> See also D Banta, ‘Increase in Global Access to Essential Drugs Sought’ (2000) 283 *Journal of the American Medical Association* 321, p. 323.

of the strategy, but it was finally passed with ‘toned-down’ wording.³³⁵ The resolution, rather vaguely, asks member states:³³⁶

[T]o make every effort to promote equitable access to medicines,
 [T]o take effective measures in accordance with international law and international agreements ... in order to ensure improved access to medicines,
 [T]o provide financial support and technical cooperation to enable Member States in need to expand access of their populations to essential drugs.

Following the expansion of the WHO’s mandate, another resolution (WHO Medicines Strategy³³⁷) was passed to define the WHO’s work on access to medicines. The Strategy draws the WHO’s attention to: (1) the rational selection and use of medicines, (2) medicine prices and impact of trade agreements, (3) medicine financing, and (4) reliable health and supply systems for medicines.³³⁸

WHO’s ‘3 by 5’ Initiative

Under WHO’s mandate, it also has the ability to announce global health emergencies.³³⁹ In September 2003, Director-General Lee Jong-wook announced that the lack of access to ARVs was a global health emergency.³⁴⁰ Shortly afterwards, the WHO and UNAIDS launched the ‘3 by 5’ initiative as an effort to treat three million people by 2005.³⁴¹ The

³³⁵ Raghavan.

³³⁶ WHA Resolution 52.19 (1999).

³³⁷ WHA Resolution 54.11 (2001).

³³⁸ Burci and Vignes, p. 188.

³³⁹ MI Nemes and others, *Evaluation of WHO's Contribution to "3 by 5" (Main Report)* (2006), p. 24. (The evaluation states that ‘WHO ... was the only institution with the mandate and credibility to declare the lack of access to ART a global health emergency’.)

³⁴⁰ *ibid.*, p. 4.

³⁴¹ L Jong-wook, ‘Global health improvement and WHO: shaping the future’ (2003) 362 (9401) *The Lancet* 2083, p. 2085.

WHO decided that, due to its ‘emergency’ nature, the initiative would not be managed as a ‘conventional programme of work’ (including things such as milestones or other details).³⁴² As described later this chapter (in the section on ‘AIDS as a catastrophic event’) and in Chapter 4 (on Institutional Interactions), WHO sought to position itself on HIV/AIDS work through a leadership role in the health sector and to establish the initiative as a ‘core priority’ within the organization.³⁴³ The ‘3 by 5’ initiative did not succeed in treating three million by 2005 (due to a host of factors discussed in Chapter 4), but there are ‘retrospective’ perceptions that the initiative had ‘played a major role in making access to ART a widely accepted essential public health intervention, by demonstrating that this is possible even under resource constraints’.³⁴⁴

In particular, through the ‘3 by 5’ initiative, the WHO developed a ‘prequalification’ programme (PQP) that aims to ensure the quality, safety, and efficacy of innovative and generic medicines for procurement (i.e. bulk purchase) purposes by international agencies. The PQP involves a 5 step process: invitation (by WHO or another UN agency addressed to manufacturers to apply for prequalification); dossier submission (i.e. providing comprehensive data); assessment; inspection of manufacturing sites; and decision before a drug is added to the WHO Prequalification list.³⁴⁵ The PQP originally started as an approval process for HIV/AIDS, tuberculosis and malaria medicines, but was later expanded to address medicines for reproductive health and the management of acute diarrhoea in children. To date, the PQP has ‘prequalified over 240

³⁴² Nemes and others, p. 23.

³⁴³ *ibid*, p. 24.

³⁴⁴ *ibid*, p. 23.

³⁴⁵ The WHO reports that it ‘bases its activities on international pharmaceutical standards for medicines quality, safety and efficacy’.

medicines for priority diseases’ and it has been noted by the other international agencies working on HIV/AIDS that the PQP was ‘one of the most important contributions that WHO has made to “3 by 5”’.³⁴⁶ It not only helped to promote the generic medicines industry by ‘increas[ing] confidence in the use [of their products]’, but it also had the effect of increasing competition and lowering prices on medicines.³⁴⁷ The WHO PQP has even been observed to have influenced the U.S. regulatory body on medicines (i.e. the Food and Drug Administration) into ‘establishing a “tentative approval” mechanism that now has many characteristics of the WHO prequalification process’.³⁴⁸ Today, the WHO Prequalification list is relied upon by the World Bank, the Global Fund to Fight AIDS, tuberculosis and malaria, and other agencies.³⁴⁹

The Procedural Component: WHO’s Structure and Operations

The organizational structure of the WHO has a major influence on how its functions are carried out. The organization is comprised of the World Health Assembly (WHA), the Executive Board, and the Secretariat. The WHA, the supreme decision-making body of the WHO, consists of representatives³⁵⁰ from all WHO member states and meets once a year. The functions of the WHA include: determining WHO policies,³⁵¹ appointing the WHO Director-General (DG), supervising the financial policies of the WHO, and

³⁴⁶ Nemes and others, p. 49.

³⁴⁷ *ibid*, p. 51; Schwartlander, Grubb and Perriens, p. 542.

³⁴⁸ Nemes and others, p. 50.

³⁴⁹ Leach, Paluzzi and Munderri, p. 44.

³⁵⁰ It is observed that WHA representatives typically come from member states’ ministries of health based on a review of annual attendance lists of representatives from recent years (2006-2009).

³⁵¹ This includes the approval of WHA laws, such as treaties, regulations and recommendations.

approving the proposed programme budget. WHA voting is based on a ‘one state – one vote’ principle,³⁵² and decisions are usually passed based on unanimity.

The Executive Board, which plays a central role in setting the direction of the organization, consists of 32 individuals who are appointed by a rotating selection of WHO member states.³⁵³ It is charged with the following functions: preparing the provisional agenda of the WHA, considering proposals for WHA resolutions on technical matters,³⁵⁴ nominating the WHO DG to the WHA, and implementing the WHA’s decisions and policies. While the WHO’s founders intended for the Executive Board to be a non-political group comprised of technical experts who act in a ‘personal capacity’,³⁵⁵ this is considered ‘fiction’³⁵⁶ because of the increasingly political nature of Board’s work and the fact that the appointed individuals represent the interests of their respective member states or regions. As Gian Luca Burci (WHO Legal Counsel) and Claude Vignes (former WHO Legal Counsel) explain, it can be difficult for the Board ‘to disregard [its] political responsibility ... when preparing the agenda of the [WHA] given that the inclusion or non-inclusion of an item and the title given to it may be of the essence, particularly when “sensitive” questions are at issue’.³⁵⁷

³⁵² M Koivusalo and E Ollila, *Making a Health World: Agencies, Actors and Policies in International Health* (Stakes, Finland 1997), p. 8

³⁵³ The selection of Member States is determined by the WHA and is based on the criteria proportionate regional distribution (i.e. the number states represented on the Executive Board is ‘more or less proportional to the total numbers of members included in the region’. Currently, the distribution of states on the Executive Board (by region) is: Africa 7; Americas 6, South-East Asia 3; Europe 7; Eastern Mediterranean 5; and Western Pacific 4. See Burci and Vignes, p. 45-46.

³⁵⁴ The Executive Board may also submit unsolicited proposals or advice to the WHA.

³⁵⁵ Koivusalo and Ollila, p. 8.

³⁵⁶ Interview DC (20 Feb 2008).

³⁵⁷ Burci and Vignes, p. 48.

The Secretariat is the final major component, or organ, of the WHO. Under the leadership of the Director-General (DG), the Secretariat is charged with management of the WHO and its programmes. This includes the preparation, logistics, and documentation of the WHA and Executive Board meetings, as well as other WHO conferences. Furthermore, the Secretariat is expected to execute the decisions of these constitutional bodies. Though the Secretariat's role is predominantly administrative in nature, there is significant influence that this organ can wield in its various functions. For example, the Secretariat has the ability to select officers for the preparation of draft resolutions.³⁵⁸ In addition, the Secretariat has the ability to choose the external agencies (as well as their respective officers) for collaboration or consultation on WHO reports and other initiatives. Yet, the Secretariat's performance is highly dependent on the leadership of the WHO DG. The WHO DG undertakes 'all the administrative decisions' of the organization and is 'the person to whom all business concerning [the WHO] should be addressed'.³⁵⁹ This role is highly political, as the WHO DG is expected to liaise with Member State representatives and serve as a 'go-between' to resolve disputes.³⁶⁰

The WHO Secretariat operates with its headquarters in Geneva and six regional offices³⁶¹ around the world. The regional offices are each led by a Regional Director-General (DG), who is appointed by the member states in each region and not the WHO DG. Interestingly, this creates a complex political dynamic where the Regional DG believes its duty is to the region and not the WHO DG. Though the WHO's founders

³⁵⁸ *ibid*, p. 52. In the case of access to medicines, I observed that such efforts often involve multiple individuals and may even be interdepartmental.

³⁵⁹ *ibid*, p. 50.

³⁶⁰ *ibid*, p. 50.

³⁶¹ These include the: African (AFRO), Pan American (PAHO), Eastern Mediterranean (EMRO), European (EURO), South-East Asian (SEARO), and Western Pacific (WPRO) regional offices.

intended for the WHO headquarters to handle norm setting and the regional offices to address technical assistance, the division of labour is not quite as distinct in practice given the high level of autonomy granted to regional offices by the headquarters. Critics of the WHO's current approach to regional management call for 'reform' in order to make the regional offices 'more accountable both financially and politically'.³⁶²

The Compliance Component: WHO's Legal Mechanisms

WHO has an international legal personality that is considered by many scholars to be innovative and powerful. According to its Constitution, WHO has the express authority to apply several different legal mechanisms to achieve its objectives. These mechanisms can be viewed as a 'hierarchy of powers', which includes treaties, regulations and recommendations.³⁶³

Treaty powers, as granted by Article 19 of the WHO Constitution, empower the WHA 'to adopt conventions or agreements with respect to any matter within the competence of the Organization'.³⁶⁴ Yet, like other international laws, the treaty will come into force only when it has been ratified by a Member State.³⁶⁵ Hence, the WHO treaty approach faces the 'inherent risk of delay, non-uniformity of take-up and outright rejection by states.'³⁶⁶

³⁶² Koivusalo and Ollila, p. 8

³⁶³ A Lakin, 'The Legal Powers of the World Health Organization' (1997) 3 (1) *Medical Law International* 23, p. 29.

³⁶⁴ D Fidler, 'The Future of the World Health Organization: What Role for International Law?' (1998) 31 (5) *Vanderbilt Journal of Transnational Law* 1079, p. 1087; WHO Constitution, Art. 19.

³⁶⁵ Lakin, p. 29.

³⁶⁶ *ibid*, p. 25.

Another mechanism available to the WHO is the use of regulatory powers. Under Article 21 of the WHO Constitution, the WHA has the ability to adopt regulations concerning:³⁶⁷

- [a] sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease
- [b] nomenclatures with respect to diseases, causes of death and public health practices
- [c] standards with respect to diagnostic procedures for international use
- [d] standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce
- [e] advertising and labelling of biological, pharmaceutical and similar products moving in international commerce

The WHO constitution, under Article 22, further specifies that WHA adopted regulations are ‘binding on all WHO member states except those that notify the Director-General of rejection or reservations within a specified time.’³⁶⁸ David Fidler notes that this approach ‘makes it harder for states to reject regulations if they have to contract out of them.’³⁶⁹

The third WHO mechanism is the use of recommendations.³⁷⁰ Recommendations can take various forms, but two primary types include resolutions and codes of conduct. Resolutions are recommendations of the WHA that help ‘draw international attention to important issues faster than multilateral treaty approaches’ and allow member states great flexibility with its implementation.³⁷¹ Codes of conduct are recommendations that often ‘call upon governments to pass national legislation and urge industry to adhere

³⁶⁷ Fidler, ‘The Future of the World Health Organization: What Role for International Law?’, p. 1087.; WHO Constitution, Art. 21.

³⁶⁸ Lakin, p. 29.; WHO Constitution, Art. 22.

³⁶⁹ Fidler, ‘The Future of the World Health Organization: What Role for International Law?’, p. 1087-1088.

³⁷⁰ Lakin, p. 34.; WHO Constitution, Art. 23.

³⁷¹ *ibid*, p. 33.

voluntarily to [its] provisions.’³⁷² Both recommendation approaches are considered to be ‘persuasive with no binding legal power’³⁷³ or, in other words, soft law.

Burci and Vignes note that WHO ‘soft law’ standards can also be produced without the endorsement or approval of the WHO governing bodies (i.e. WHA or Executive Board). These standards fall into the following two categories: (1) standards and recommendations developed by the Secretariat on the basis of a grant or authority by a governing body and (2) standards developed by expert bodies convened by the Secretariat and published by WHO.³⁷⁴

Institutional Analysis of WHO

The following sections consider some of the key problems and weaknesses in WHO’s role as an international institution for health, and how these factors can impede its assertion of a leadership role in global health.

WHO’s Use of Legal Mechanisms

From a historical perspective, the adoption of legal mechanisms under the WHO has been highly skewed towards recommendations over treaties and regulations. In fact, it was not until 2003 when the first and only WHO treaty known as the Framework Convention on Tobacco Control (FCTC) was created.³⁷⁵ Yet, the background account of Ruth Roemer

³⁷² *ibid.*

³⁷³ *ibid.*

³⁷⁴ Burci and Vignes, p. 142.

and Allyn Taylor regarding the creation of the FCTC details a long and trying process that took almost ten years.³⁷⁶ A proposal for a legal approach to tobacco control was introduced by Roemer and Taylor to the WHO secretariat in 1993; however, it did not gain traction at the WHO until it was later espoused by a Canadian delegate (Jean Lariviere) to the WHA. The secretariat initially recommended that they either pursue another forum (i.e. UN) for their treaty or transform their proposal into a non-binding 'WHO code of conduct on tobacco control'.³⁷⁷ In 1996, however, Lariviere was able to convince the Finnish and Irish representatives on the Executive Board³⁷⁸ to sponsor a resolution for the development of the FCTC. This resolution³⁷⁹ was subsequently passed by the WHA later that year. Still, WHO efforts in the implementation of the FCTC's development languished for two years due to the lack of 'political support and policy direction'.³⁸⁰ It was not until the appointment of the DG Brundtland³⁸¹ in 1998 that FCTC negotiations actually began and a WHO Tobacco Free Initiative with dedicated funding was established. On the final negotiated text of the FCTC, Roemer and Taylor comment that it 'neglects to incorporate many mechanisms used in other global framework conventions to encourage state parties to comply with their legal

³⁷⁵ WHO, 'The WHO FCTC: a global health treaty' <<http://www.who.int/tobacco/framework/background/en/index.html>> (19 Feb 2007).

³⁷⁶ R Roemer and A Taylor, 'The Origins of the WHO Framework Convention on Tobacco Control' (2005) 95 (6) *American Journal of Public Health* 936.

³⁷⁷ Roemer and Taylor., p. 937

³⁷⁸ Lariviere could not sponsor the FCTC before the Executive Board because Canada did not hold a seat on the board that year.

³⁷⁹ WHA 49.16

³⁸⁰ Roemer and Taylor, p. 938.

³⁸¹ DG Brundtland was a key political force behind the creation of the FCTC. Upon entering office, she had announced tobacco control as one of her priorities.

commitments', which means that it will have to depend on the factors of 'expanded global awareness and national political commitment' for success.³⁸²

While a number of industrialized nations (such as the U.K. and Canada) readily signed and ratified this treaty,³⁸³ the U.S. was opposed to doing so because of a clause which prohibited member states from attaching reservations to the treaty.³⁸⁴ Frederic Kirgis remarks that the U.S. government tends to show 'reluct[ance] to enter into multilateral treaties that impose obligations directly on the national government, unless it can attach significant reservations to those treaties.'³⁸⁵ The U.S. had also argued that the FCTC posed U.S. constitutional First Amendment concerns, as well as 'potential encroachments on states' rights within the U.S.'³⁸⁶ Yet, the U.S. decided to sign the treaty on 10 May 2004 but made 'no immediate commitment' regarding its ratification.³⁸⁷

Regulations are another rarely applied mechanism that the WHO has historically used in only 'very limited and traditional contexts.'³⁸⁸ Alison Lakin speculates that this could be due to the political sensitivity of the WHO towards state perceptions of

³⁸² Roemer and Taylor, p. 938.

³⁸³ The UK signed the treaty on 16 June 2003 and ratified it on 16 December 2004. Canada signed the treaty on 15 July 2003 and ratified it on 26 November 2004. See A Langley, 'World Health Meeting Approves Treaty to Discourage Smoking' *New York Times* (May 22, 2003).

³⁸⁴ F Kirgis, 'Reservations to Treaties and United States Practice' (2003) <<http://www.asil.org/insights/insigh105.htm> > (12 Dec 2006).

³⁸⁵ He also identifies that the U.S. is 'less inclined to attach significant reservations when the treaties regulate private conduct' (e.g. conventions on international sales of goods or on the civil aspects of international child abduction). See *ibid.*

³⁸⁶ *ibid.*

³⁸⁷ Langley.

³⁸⁸ Taylor, 'Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions of Health', p. 343.

regulations as ‘a system merely designed to circumvent state consent’,³⁸⁹ since regulations are considered automatically binding on states unless they select to submit a reservation. It could also be due to the WHO’s reluctance to encroach on state sovereignty. To date, only two sets of regulations have been created since the WHO’s inception. One set is known as the Nomenclature Regulations, which relates to the nomenclature of diseases or causes of death. The second set of regulations, initially called the International Sanitary Regulations (ISR) in 1951 but later renamed the International Health Regulations (IHR) in 1969, serves ‘to ensure the maximum security against the international spread of diseases with a minimum interference with world traffic.’³⁹⁰ These regulations were recently revised again in 2005, which is the fourth time since its creation.

The latest version of the IHR (known as the IHR 2005) was passed in response to the aftermath of the SARS epidemic and in anticipation of an avian flu outbreak, and as ‘the international health community [came to] recogniz[e] that pandemic planning and response is an inherently multigovernmental concern.’³⁹¹ This revision to the IHR has been considered to be a major turning point³⁹² for the WHO’s role in international law because it grants greater authority to the WHO and places increased responsibility upon

³⁸⁹ Lakin, p. 29.

³⁹⁰ WHO International Health Regulations 1969.

³⁹¹ K Wilson, C McDougall and R Upshur, ‘The New International Health Regulations and the Federalism Dilemma’ (2006) 3 (1) PLoS Med See also WHO, ‘WHO International Health Regulations’ <<http://www.who.int/csr/ihr/en/>> (19 Feb 2007). According to the WHO, Member States are ‘required to develop, strengthen and maintain core surveillance and response capacities to detect, assess, notify and report public health events to WHO and respond to public health risks and public health emergencies.’ In addition, the WHO is required to collaborate with States Parties to evaluate their public health capacities, facilitate technical cooperation, logistical support and the mobilization of financial resources for building capacity in surveillance and response.

³⁹² D Fidler and L Gostin, ‘The New International Health Regulations: An Historic Development for International Law and Public Health’ (2006) 34 (1) Journal of Law, Medicine & Ethics 85.

member states.³⁹³ While it appears that most member states are supportive of the IHR revisions, the U.S. has raised concerns about the conflict that the IHR presents to federal systems of government.³⁹⁴ In the case of the U.S., public health functions fall primarily within the jurisdiction of the local states. Compliance with IHR 2005, however, requires the increased involvement of federal government in public health. As a result, this ‘could be viewed as expanding federal authority (beyond discretionary use of the commerce and spending powers).’³⁹⁵

Beyond the potential issue of Member State reservations to IHR 2005, some public health proponents also express concern about the ‘level of political commitment countries will demonstrate in implementing IHR 2005’.³⁹⁶ Past experience with IHR 1969 illustrated that it had ‘suffered because it failed to generate compliance by WHO member states ... [which] frequently failed to report notifiable diseases and routinely applied excessive trade and travel restrictions.’³⁹⁷ Hence, while regulations offer the benefit of binding legal obligations upon states, WHO’s limited use of enforcement through reporting or monitoring mechanisms can still lead to inconsistent compliance.³⁹⁸

³⁹³ Wilson, McDougall and Upshur. See also D Fidler, 'The Exercise of Public Health Sovereignty: Trends and Trajectories.' (The State of National Governance Relative to the New International Health Regulations 2006).

³⁹⁴ G Schatz, 'International Health Regulations: New Mandate for Scientific Cooperation' (2005) ASIL Insight .

³⁹⁵ *ibid.*

³⁹⁶ M Baker and D Fidler, 'Global Public Health Surveillance under New International Health Regulations' (2006) 12 (7) Emerging Infectious Diseases .

³⁹⁷ D Fidler, *International law and Infectious Diseases* (Clarendon Press, Oxford 1999).

³⁹⁸ B Plotkin and A Kimball, 'Designing an International Policy and Legal Framework for the Control of Emerging Infectious Diseases: First Steps' (2007) 3 Emerging Infectious Diseases 1; D Leive, *International regulatory regimes: case studies in health, meteorology and food* (Lexington Books, Lexington (MA) 1976); K Tomasevski, 'Health' in O Schachter and C Joyner (eds) *United Nations Legal Order* (Cambridge University Press, Cambridge, United Kingdom 1995).

A feature of the IHR 2005 that could counteract this weakness is its dispute settlement mechanism. According to Article 56 of the IHR 2005, state parties that cannot settle their dispute (by means of negotiations, mediation or conciliation) can either refer it (1) to the WHO DG for settlement or (2) to arbitration.³⁹⁹ The IHR also mentions that states may seek ‘to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement’. Currently, the effectiveness of the IHR dispute settlement mechanism is still uncertain.⁴⁰⁰

Finally, recommendations have been the most popular mechanism under the WHO.⁴⁰¹ One of the best known recommendations is the WHO’s International Code of Marketing of Breast-milk substitutes.⁴⁰² This code arose from concerns over the processed food industry’s controversial marketing practices for breast-milk substitutes. These concerns led to a 1979 joint meeting on infant and young child feeding by WHO and UNICEF, and a draft code was submitted to the WHO Executive Board for consideration in 1981. A key topic of discussion at this meeting was whether to adopt the code as a regulation or a recommendation. Interestingly, the WHO Legal Counsel at the time argued that breast-milk substitutions should be considered ‘nutritional medicine’ which meant that this topic could be regulated under Article 21. The Executive Board, however, ultimately decided upon the application of a recommendation in order to ‘avoid

³⁹⁹ Arbitration is conducted according to the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States. IHR 2005, Article 56(3). According to Plotkin and Kimball, ‘a member state is authorized to bring the dispute to the International Court of Justice in the Hague for decision (1, art. 93[3]). ... WHO’s right to request advisory opinions from the International Court of Justice has yielded court rulings in only two cases. Thus, disputes appear to be usually handled informally through the WHO bureaucracy.’ Plotkin and Kimball.

⁴⁰⁰ It has been noted, however, that the former IHR dispute settlement mechanism was ‘largely underutilized’. See Burci and Vignes, p. 138.

⁴⁰¹ Lakin, p. 34. See also Fidler and Gostin, ‘The New International Health Regulations: An Historic Development for International Law and Public Health’, p. 93.

⁴⁰² Resolution WHA 34.22 (1981). See also Burci and Vignes, p. 142.

rejection of a binding code by a number of developed countries trying to safeguard their commercial interests'.⁴⁰³ This recommendation⁴⁰⁴ was approved by the WHA later that year but without unanimity due a dissenting vote from a developed country.

Generally, recommendations do not require reporting obligations unless it was 'explicitly' drawn under Article 23 of the WHO Constitution.⁴⁰⁵ Burci and Vignes observe that the WHA has rarely invoked Article 23, except for the 'four or five such instances' he found in WHA records. (One of these instances includes the International Code of Marketing of Breast-milk substitutes.) They believe that, from a legal point of view, use of Article 23 'does not change the recommendatory nature of the decisions'.⁴⁰⁶ They also comment that the WHO has never enforced strict reporting requirements, which renders the significance of recommendations under Article 23 to be 'insubstantial'.⁴⁰⁷ The WHO's weak enforcement of reporting practices for recommendations may partially explain Lawrence Gostin and David Fidler's observation of the 'mixed record of state compliance with WHO [recommendations]' in past decades.⁴⁰⁸

Given the apparent preference for soft law mechanisms over the WHO's available hard law options, one might ask why this has been the case. Some WHO officials

⁴⁰³ *ibid.*, p. 144.

⁴⁰⁴ Resolution WHA 33.23

⁴⁰⁵ Burci and Vignes, p. 142. (If a recommendation is drawn under Article 23, then Member States are obligated to report annually to the WHO under Article 62 of the Constitution; WHO Constitution, Art. 62.)

⁴⁰⁶ *ibid.*, p. 142.

⁴⁰⁷ *ibid.*, p. 142.

⁴⁰⁸ Fidler and Gostin, 'The New International Health Regulations: An Historic Development for International Law and Public Health', p. 93.

attribute this strictly to member state preferences.⁴⁰⁹ Essentially, the WHO acts on member state demands determined at the WHA and there has been a lack of ‘political will’ to utilize the harder law mechanisms (i.e. treaties and regulations) over recommendations at the WHO.⁴¹⁰ It has been argued, however, that soft law mechanisms are ‘useful’, that a lack of treaties or regulations does not mean that WHO has ‘failed’, that hard law mechanisms (such as treaties) are simply a ‘means to an end’, and that international lawyers are often biased towards these mechanisms as the solution.⁴¹¹ Burci and Vignes have also noted that the decisive factor for the negotiations of hard law under the WHO is ‘the attitude of WHO’s member states, in particular their confidence in the organization as an instrument for establishing, monitoring and administering international binding instruments’.⁴¹² The lack of ‘normative tradition’ in WHO’s governing bodies makes many delegations and ministries of health ‘unfamiliar or even uncomfortable with negotiating and debating international legal instruments’.⁴¹³ Hence, the success of the FCTC ‘will probably be instrumental in overcoming or confirming this reluctance’.⁴¹⁴

Burci and Vignes provide several reasons for the preference of soft law over hard law mechanisms. One reason is found in ‘the difficulties inherent in formalizing technical requirements in a rapidly evolving domain’ and the ‘reluctance of the

⁴⁰⁹ Interviews WHO (17 Sept 2007).

⁴¹⁰ Interview DC (23 April 2008).

⁴¹¹ *ibid.*

⁴¹² Burci and Vignes, p. 155.

⁴¹³ *ibid.*, p. 155.

⁴¹⁴ *ibid.*, p. 155.

Organization to indulge in ... the “making of official science””.⁴¹⁵ Another reason is the ‘need for adaptability to local circumstances’ given the ‘uneven development of states in science and technology’.⁴¹⁶ Burci and Vignes also claim that ‘the cost of maintaining centralized facilities for the administration of legally binding instruments’ can be burdensome to an organization like WHO.⁴¹⁷ Hence, the WHO’s present utilization of non-binding recommendations has been viewed as a ‘more rational approach to norm creation’ and that WHO ‘have more impact than we think and are actually harder through their credibility – even without the courts and enforcement mechanisms’.⁴¹⁸

Other Organizational Issues

The WHO’s problems in influencing member states to act in ways that promote international health extend beyond their application of legal mechanisms. The explanations for its weaknesses are often economic, cultural, and political. In addition, these issues are derived from a mix of factors that are endogenous and exogenous to the organization. (As noted earlier in this chapter, this section will primarily consider the endogenous factors as the next two chapters will assess some of the exogenous factors that have affected the organization.)

⁴¹⁵ *ibid.*, p. 153.

⁴¹⁶ *ibid.*, p. 141.

⁴¹⁷ *ibid.*, p. 141.

⁴¹⁸ Interview DC (20 Feb 2008).

Economic Limitations of the WHO

Many of WHO's organizational problems are linked to its severe budgetary constraints, which in effect limit its financial autonomy as an institution and creates resource shortages for its core functions. The WHO's budget is financed as two distinct parts. One part is the General Budget, which receives assessed contributions from governments. The second part is known as the Extrabudgetary Funds, which receives voluntary (but earmarked) contributions from governments,⁴¹⁹ other UN agencies, and other sources (e.g. nongovernmental organizations and the private sector). The ongoing practice by member states of primarily funding outside the WHO General Budget, which receives only 28% of non-earmarked funds while 72% goes into specified programs (under the Extrabudgetary Funds),⁴²⁰ has transformed WHO into a very 'donor-driven' organization and restricted its ability to direct and coordinate the agenda.⁴²¹ A consequence is that WHO's operations have become increasingly fragmented, compartmentalized programs so that donors can claim credit and assert control. It is believed that this has also led to the associated problem of 'unhealthy competition among departments within the

⁴¹⁹ The major donors to the extrabudgetary funds have been the USA, Sweden, the UK, the Netherlands, Norway, Denmark, Japan, Canada, Italy, and Switzerland. The largest donors, US and Sweden, have together provided approximately 27% of the total extrabudgetary funds.

⁴²⁰ A recent study by Stuckler et al. revealed that WHO's general budget "was much more closely aligned with the actual global burden of disease than were the extra-budgetary funds." WHO's general budget (2006-2007) allocates 61% to infectious diseases, 38% to noncommunicable diseases and about 1% to injuries. On the other hand, WHO's extra-budgetary funds (for 2006-2007) allocate 91% to infectious diseases, 8% to non-communicable diseases, and about 1% to injuries. D Stuckler and others, 'World Health Organization Budget and burden of disease: a comparative analysis' (2008) 372 *The Lancet* 1563.

⁴²¹ WHO, 'Working for health: An introduction to the World Health Organization' (2007) Geneva <www.who.int/about/brochure_en.pdf (accessed Oct. 10, 2008)> ; Burci and Vignes. (According to Laurie Garrett, another consequence of this financial imbalance is that 'countries with the greatest health needs have to listen to the countries with the most money'. See T Johnson, 'The World Health Organization' (2009) Council on Foreign Relations <http://www.cfr.org/publication/20003/world_health_organization.html> (10 Aug 2009).)

WHO'.⁴²² This trend has also caused WHO competition with other international agencies for the financial support of member states and the private sector.

It has also been observed that the topic of budgets 'often dominate meetings' at the WHO, due to the volume of voluntary contributions to the Extrabudgetary Fund and state concerns over financial transparency, and results in more time and energy expended on 'financial discipline and budgets than on definition and formulation of policy'.⁴²³

Another concern regarding WHO's Extrabudgetary Fund pertains to the lack of coherence between donor objectives and the WHO's health objectives. This is because the allocation of state donor funds to the WHO tends to be conducted by state development agencies and their objectives are not always aligned with WHO policies and objectives for health.⁴²⁴ Furthermore, the imbalance in funding between the General Budget and Extrabudgetary Fund has caused the WHO to rely increasingly on temporary staffing, through short-term contracts in order to better control its resource costs, and the use of external consultants for contracted work. This has a significant impact on the WHO's internal knowledge base because of the high turnover in experts.

WHO's Agency Culture

Criticism has been directed at the WHO for its reluctance to apply stronger international health governance mechanisms, despite the bold mission and sweeping powers granted in

⁴²² People's Health Movement, Medact and Global Equity Gauge Alliance, *Global Health Watch 2 (2007—08)* (Zed Books, London 2008).

⁴²³ Koivusalo and Ollila, p. 9-10

⁴²⁴ *ibid.*, p. 10.

its constitution.⁴²⁵ As indicated in the legal mechanism analysis, WHO has shown a ‘reluctance to utilize its legal powers or adopt legal principles as a means of facilitating its health strategies’.⁴²⁶ Scholars observe that the organization ‘appears to envision its legislative role as neither active nor even reactive, but merely observational’.⁴²⁷ This has resulted in beliefs that WHO’s weak policy controls are ‘slavishly in thrall to its Member States’, whereby ‘[a]ppropriate respect for national sovereignty ‘ has been ‘overtaken by [WHO’s] blind obeisance to narrow national wishes’.⁴²⁸ These critics argue that the meaning of ‘sovereign state’ has changed in the context of today’s global health environment,⁴²⁹ and WHO must ‘reorient its attitude towards Member State[s]’.⁴³⁰ Such an effort would require WHO to revamp its current reputation for observational data collection and technical medical standardization to one of ‘dynamic’ international governance, as originally intended by its Constitution.⁴³¹

While scholars have attributed WHO’s reluctance to apply its legal powers to the organization’s ‘traditional conservatism’, it is observed that WHO’s organizational behaviour has actually been changing since the term of Director-General Gro Brundtland

⁴²⁵ Lakin; Fidler, 'The Future of the World Health Organization: What Role for International Law?'; A Taylor, 'Governing the Globalization of Public Health' (2004) 32 (3) J L Medicine and Ethics 500.; Taylor, 'Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions of Health'; Gostin.

⁴²⁶ Lakin, p. 24. See also D Fidler, 'Developments involving SARS, International Law, and Infectious Disease Control at the Fifty-Sixth Meeting of the World Health Assembly' (2003) ASIL Insight .

⁴²⁷ Taylor, 'Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions of Health', p. 343.

⁴²⁸ Fidler, 'The Future of the World Health Organization: What Role for International Law?', p. 1121.

⁴²⁹ *ibid.*, p. 1106.

⁴³⁰ *ibid.*, p. 1121

⁴³¹ Lakin, p. 24. See also Taylor, 'Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions of Health', p. 317.

(which ran between 1998-2003).⁴³² Examples, such as the WHO's changing attitude towards its engagement with other institutions (e.g. WTO), approach to health issues (e.g. human rights) and use of legal powers (e.g. the 2005 IHR revision and the FCTC negotiations),⁴³³ indicate a significant move from being a strictly technical organization. Yet, given the frequent turnover in WHO leadership that has occurred since 2003 (with the sudden death of Lee Jong-wook in 2006, the interim direction of Anders Nordstrom, and the recent instalment of Margaret Chan), it remains unclear whether Brundtland's legacy of organizational change will be carried on to achieve a 'genuine adaptation or evolution of WHO's conservative culture'.⁴³⁴ It was observed that a sense of heightened political sensitivity to powerful member state interests remains within the organization, although there are unofficial actions that the Director-General and officials can exercise to influence organization's direction. These actions, as described in the case study on the WHO's Intergovernmental Working Group (in Chapter 6), include the appointment of committee 'experts', the approval of certain nongovernmental organizations to 'official relations', and other influential activities.

⁴³² Taylor, 'Governing the Globalization of Public Health', p. 505.

⁴³³ Another example of a WHO effort to apply a stronger legal mechanism, though not successful, is illustrated by the case of the International Code of Marketing of Breast-milk substitutes. This code arose from concerns over the processed food industry's controversial marketing practices for breast-milk substitutes. These concerns led to a 1979 joint meeting on infant and young child feeding by WHO and UNICEF, and the subsequent draft code that was submitted to the WHO Executive Board for consideration in 1981. A key topic of discussion at this meeting was whether to adopt the code as a regulation or a recommendation. Interestingly, the WHO Legal Counsel at the time argued that breast-milk substitutions should be considered 'nutritional medicine' which meant that this topic could be regulated under Article 21. The Executive Board, however, ultimately decided upon the application of a recommendation in order to 'avoid rejection of a binding code by a number of developed countries trying to safeguard their commercial interests'. Burci and Vignes.

⁴³⁴ Taylor, 'Governing the Globalization of Public Health'.

The Impact of AIDS as a 'Catastrophic Event' on WHO & the Problem of Internal Politics

Disasters and crises can be a major factor leading to change in an international organization.⁴³⁵ The HIV/AIDS epidemic in developing countries has had a profound impact on the WHO as an institution. This crisis not only highlighted the WHO's weakness as an institution for global health, but it also brought the issue of access to essential medicines to centre stage in the international arena. In 1986, the emerging global HIV/AIDS crisis was brought to the attention of then-Director General (DG) Halfdan Mahler who was initially sceptical of its severity but later convinced by a prominent AIDS expert, Jonathan Mann.⁴³⁶ DG Mahler decided to appoint Mann as the head of a 'special program[me] on AIDS that bypassed WHO's [usual] chain of command' and the programme quickly 'grew headlong ... [into] one of the organization's biggest program[me]s'.⁴³⁷ This programme, known as the Global Programme on AIDS (GPA), did not enjoy its special status for very long due to internal organizational politics.

In 1988, when DG Mahler retired, Hiroshi Nakajima was appointed as the new WHO DG. DG Nakajima, like some others within the Secretariat, held a 'general displeasure at Mann's privileged status and unorthodox style'.⁴³⁸ Nakajima also did not share DG Mahler's belief that HIV/AIDS would lead to a global health crisis and set about limiting Mann's (and hence the GPA's) powers within the WHO.⁴³⁹ In response to

⁴³⁵ Kapur.

⁴³⁶ B Gellman, 'An Epidemic of Inaction' *Seattle Times* (Seattle, Washington (USA) 14 July 2000).

⁴³⁷ *ibid.*

⁴³⁸ *ibid.*

the new DG's political tactics, Mann decided to resign from the WHO but a more constrained GPA programme continued under another internal appointee. As the AIDS crisis grew, the WHO's weak response and lack of leadership led to the entry of other powerful international organizations (such as the World Bank) which established a growing number of AIDS-related projects in developing countries.⁴⁴⁰ An international organizational 'turf battle' over HIV/AIDS programmes ensued and the UN was called upon by donor governments to find a solution to this problem.⁴⁴¹ The UN responded by forming a Joint UN Programme on HIV/AIDS (known as UNAIDS) in 1996. (UNAIDS is discussed in further detail in Chapter 4 on Institutional Interactions). This new international organization was created to help coordinate and harmonize UN agency activities on HIV/AIDS, which resulted in the disbanding of GPA at WHO and the transfer of 'its competencies, personnel and resources to [UNAIDS]'.⁴⁴²

WHO's normative involvement in HIV/AIDS, however, was reinstated in 2000 under the term of DG Gro Brundtland. During DG Brundtland's term, WHO 'started to develop its own HIV/AIDS policy' and build up its HIV/AIDS department - resulting in direct competition between WHO and UNAIDS for the lead role in the governance of this issue area.⁴⁴³ This led to criticism over the 'duplication of structures' and the growing

⁴³⁹ *ibid.* It has been reported that DG Nakajima cut the GPA's resources, refused to grant GPA the 'legal authority to send [its] budget', excluded Mann from meetings, and rejected Mann's travel requests.

⁴⁴⁰ W Hein, S Burris and C Shearing, 'Conceptual Models for Global Health Governance' in K Buse, W Hein and N Drager (eds) *Making Sense of Global Health Governance* (Palgrave MacMillan, Basingstoke, UK 2009).

⁴⁴¹ Gellman.

⁴⁴² L Kohlmorgen, 'International Governmental Organizations and Global Health Governance: the Role of the World Health Organization, World Bank and UNAIDS' in W Hein, S Bartsch and L Kohlmorgen (eds) *Global Health Governance and the Fight Against HIV and AIDS* (Palgrave Macmillan, Basingstoke, UK 2007), p. 130.

⁴⁴³ *ibid.* p. 130.

lack of distinction in organizational mandates.⁴⁴⁴ WHO attempted to re-establish its leadership role on HIV/AIDS, under the subsequent term of DG Lee Jong-wook, through the creation of the ‘3 by 5’ initiative in 2003. (The ‘3 by 5’ initiative was discussed earlier in this chapter in the ‘substantive component’ discussion.) Though the initiative fell short of its total goal in 2005, the DG Lee has commented that ‘3 by 5’ was an attempt by WHO to go beyond ‘business as usual’ and ‘chang[e] its way of working, alongside member states and financial and technical partners, to reach key national health goals and strengthen equity’.⁴⁴⁵ WHO has also commented that the actual ‘goal’ was to take a step towards ‘making universal access of HIV/AIDS prevention and treatment accessible for all who need them as a human right’ and that the three million was simply a ‘target’ in working towards that goal.⁴⁴⁶ Critics of ‘3 by 5’ felt that the WHO’s ‘lack of programme structure’, ambitious targets, and lack of initially secured funding commitments, was a major weakness of the initiative in that it ‘reflect[ed] the uncertainty with which WHO was working’ and ‘mirror[ed] the reactive way in which [the] “emergency” initiative was managed’.⁴⁴⁷

Some major internal challenges can be attributed to the shortfall in achieving ‘3 by 5’. For example, an evaluation of the ‘3 by 5’ initiative found that interdepartmental collaboration between different technical departments was weak and led to problems of conflict and duplication.⁴⁴⁸ In addition, the ‘3 by 5’ relied heavily on extrabudgetary

⁴⁴⁴ *ibid.* p. 130.

⁴⁴⁵ Jong-wook., p. 2083.

⁴⁴⁶ WHO, ‘The 3 by 5 Initiative’ <http://www.who.int/3by5/en/>.

⁴⁴⁷ Nemes and others, p. xxvii.

⁴⁴⁸ *ibid.* p. 92; P Nunn, A Reid and KM DeCock, ‘Tuberculosis and HIV Infection: The Global Setting’ (2007) 196 *Journal of Infectious Diseases* S5–14, p. S10.

funds, which left the initiative ‘vulnerable to the perception of donors and their willingness to fund the organization’.⁴⁴⁹ There was a lack of commitment (and legal hurdles) in financing the ‘3 by 5’ initiative by the U.S. and the Global Fund; however, Canada ‘rescued’ the initiative with a significant donation of US \$ 81.7 M (which was over half of the government contributions to the initiative).⁴⁵⁰ This led to problematic delays in the implementation of the initiative and the staffing of key personnel (e.g. ‘3 by 5’ country officers), which did not occur until near the end of the initiative’s allotted time period.⁴⁵¹ Furthermore, the autonomy of the WHO regional offices and their impact on the performance of WHO programmes at the country level proved to be problematic due to the WHO regional leadership’s lack of ‘proactive [and willing] participation’ in an initiative that was being ‘championed from a headquarters level’.⁴⁵²

There are academics who argue that the ‘3 by 5’ initiative was a strategic move by WHO to ‘play a more prominent role in this central field of global health governance in order to defend its claim to be a legitimately responsible institution for global health’.⁴⁵³ This could very well have been the case as the HIV/AIDS field has no single organization leader,⁴⁵⁴ the general perception that ‘WHO is the multilateral agency mandated to lead the global health sector response to HIV’.⁴⁵⁵ Such an effort, however, would be heavily

⁴⁴⁹ Nemes and others, p. xxix.

⁴⁵⁰ *ibid.*, p. 26. (It is reported that other significant donations to the initiative were made by the U.K. [US \$23.4M], Sweden [US \$14.8M], and Norway [US \$8.6 M]. See Nemes and others, p. 66)

⁴⁵¹ Nemes and others, p. 61.

⁴⁵² *ibid.*, p. 61.

⁴⁵³ Kohlmorgen, p. 134.

⁴⁵⁴ Nemes and others, p. 60.

⁴⁵⁵ *ibid.*, p. 83. (According to an external evaluation conducted on the ‘3 by 5’ evaluation, it found that there existed a ‘consensus’ on this WHO mandate ‘among stakeholders, development partners, other United Nations institutions and national governments’.)

reliant on partnership with and support of the other UN agencies and the Global Fund operating in the HIV/AIDS environment. (Chapter 4 on Institutional Interactions will continue a discussion on this point regarding the ‘3 by 5’ initiative.)

WHO’s Non-State Actor Relations and Credibility Concerns

Over the years, non-state actors (e.g. private businesses, special interest and activist groups, and philanthropic organizations) have come to play an increasingly important role in global health – especially in the area of access to essential medicines. WHO is encouraged by its constitution to ‘interact, consult, and cooperate’ with nongovernmental organizations (NGOs) and it possesses the capacity to work with them formally or informally.⁴⁵⁶ In a formal capacity, WHO can establish relations with non-state actors that have entered into ‘official relations’ with the organization.⁴⁵⁷ This status confers several rights to NGOs, which include: designation of a non-voting representative to WHO meetings (as well as committees and conferences); access to non-confidential documents and Director-General approved information; and submission of memorandums to the Director-General.⁴⁵⁸ NGO entry into WHO official relations starts with ‘mutually benefiting acts’ that builds through an informal, long-term relationship.⁴⁵⁹ The Executive Board ultimately gets to decide whether or not to grant official relations status to the NGO. In the past, the process of obtaining ‘official relations’ has been criticized as long, bureaucratic, demanding, and formal.⁴⁶⁰ WHO is addressing these concerns through the

⁴⁵⁶ R Loewenson, 'Civil society influence on global health policy' (2003) WHO Civil Society Initiative

⁴⁵⁷ WHO, Principles governing relations with nongovernmental organizations. <http://www.who.int/civilsociety/relations/principles/en/index.html>

⁴⁵⁸ CONGO, 'NGO participation arrangements at the UN and in other agencies of the UN System' (2006) The Conference of NGOs in Consultative Relationship with the United Nations

⁴⁵⁹ *ibid.*

application of a special ‘fast-track’ process to permit greater NGO participation at its meetings. The fast-track procedure has been used in recent major WHO meetings, such as the sessions for the Framework Convention on Tobacco Control and the Intergovernmental Working Group (IGWG) for Public Health, Innovation and Intellectual Property (to be discussed in Chapter 6).⁴⁶¹

Informal relations with WHO can take the form of public-private partnerships (PPPs),⁴⁶² and this is an approach that the WHO has utilized to leverage industry strengths (i.e. funding, manufacturing of medical-related goods, research and development). In fact, it has been suggested that WHO’s engagement with or creation of PPPs could serve as a way to ‘strengthen it[s] [role] as a central actor in [global health governance]’ within an increasingly crowded and competitive landscape of international actors.⁴⁶³ For example, the WHO has formed partnerships in the past where ‘drugs were donated by [a pharmaceutical company]’ and ‘private sector support for the funding of new financial arrangements for health within TDR^[464] and inter-agency health research initiatives’ were actively sought.⁴⁶⁵ Critics fear that the WHO’s relations with private industry (e.g. pharmaceutical companies) will create problems in terms of ‘equity,

⁴⁶⁰ WHO, 'A study of WHO’s Official Relations system with Nongovernmental Organizations' (2002) WHO Civil Society Initiative <<http://www.who.int/civilsociety/documents/en/study.pdf>> ; WHO, 'WHO’s interactions with Civil Society and Nongovernmental Organizations' (2002) <<http://www.who.int/civilsociety/documents/en/study.pdf>> .

⁴⁶¹ WHO, 'A study of WHO’s Official Relations system with Nongovernmental Organizations' ;WHO, 'WHO’s interactions with Civil Society and Nongovernmental Organizations' ; WHO, '120th Session of the Executive Board Decision and List of Resolutions - EB120/DIV/3' (2007) World Health Organization <http://www.who.int/gb/ebwha/pdf_files/EB120/B120_DIV3-en.pdf> (22 January 2007)

⁴⁶² PPPs are joint ventures between the WHO and a private actor (e.g. business).

⁴⁶³ Kohlmorgen, p. 128.

⁴⁶⁴ TDR is a Special Programme for Research and Training in Tropical Diseases that is co-sponsored by four international organizations (including WHO).

⁴⁶⁵ Koivusalo and Ollila, p. 19.

normative functions and the orientation of global health policies' in WHO's 'role as a public interest organization'.⁴⁶⁶ There have also been concerns raised about the need for more balanced representation in WHO's interactions with non-state actors as more engagement is needed with NGOs from developing countries (rather than only developed states). Hence, these criticisms highlight the importance of transparency, balanced representation, and accountability for the WHO to preserve its legitimacy as a central international health institution.

Conclusion

This chapter sought to characterize and analyze the WHO as the core international institution for health. The application of Young's three component analysis reveals the strengths and weaknesses of the WHO's laws, policies, and programmes; structure and operations; and compliance mechanisms in relation to international health issues, such as AEM. The WHO has established an expansive array of AEM-related resolutions and even launched two bold projects related to AEM (i.e. the '3 by 5' initiative and the inclusion of ARV generics on the prequalification list), despite the highly political nature of these efforts. While the WHO does not rely on material inducement and coercion to influence states (due to its limited resources and general preference for soft law),⁴⁶⁷ there are other ways through which the secretariat can influence member states (as illustrated by the WHO's AEM programmes and technical policies). As described in Chapter 6, the WHO's recent efforts with the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property may signal a potential change in the WHO's

⁴⁶⁶ *ibid.*, p. 16

⁴⁶⁷ The reasons for this were discussed in the 'Institutional Analysis of WHO' on the WHO's use of legal mechanisms and other organizational issues.

past submissiveness to powerful member state preferences and its traditional tendency towards handling apolitical technical issues. As this chapter indicates, the WHO's ability to assert its leadership on AEM will also highly depend on the director-general's willingness to champion the issue.

While the WHO has various legal mechanisms available to address AEM (e.g. treaties, regulations and recommendations), the official procedures and member state politics can make it challenging to frame AEM using hard law. Also, even if a treaty could be established on AEM, the process of ratification and enforcement could prove problematic for WHO. At present, the WHO has developed a substantial body of 'soft law' pertaining to AEM (which either directly addresses the issue or mandates WHO to address the related matters of trade or intellectual property).⁴⁶⁸ These resolutions, though not binding upon states, could prove useful. In relation to IAC for AEM, these resolutions can provide a basis from which developed countries can be evaluated and judged by fellow countries and non-state actors. The processes of socialization (particularly moral consciousness-raising through shaming and persuasion) could provide a useful means of inducing developed countries towards IAC for AEM implementation. Another key means of achieving compliance with resolutions would require WHO to exercise its monitoring and reporting powers (under Article 62). This would provide a means for state self-evaluation and comparison against other states, which could perhaps help trigger the process of acculturation. States may be motivated to act differently, if reports are publicized or if they receive damaging criticism, in order to avoid looking bad. WHO's ability to exercise its monitoring and reporting powers, however, are hindered by its limited general budgetary resources.

⁴⁶⁸ The WHA resolutions expanding the WHO's mandate into international trade-related matters will be explored further in Chapter 4 on Institution Interactions.

WHO's role in the governance of AEM is critical because of its health (and right to health) mission, expertise, and universal convening power, but the institution faces a number of daunting challenges operationally and structurally. While these challenges can be attributed to endogenous factors (e.g. agency culture, bureaucracy, and internal politics), much of this can also be attributed to the exogenous factors of state politics, competing issues (e.g. intellectual property rights), and the struggle for financial power in the international arena. The next two chapters will describe and examine these external factors in relation to IAC for AEM.

Chapter 4: INSTITUTIONAL INTERACTIONS ON ACCESS TO ESSENTIAL MEDICINES

Introduction

The problem of access to medicines has brought forth numerous calls for greater direction by the World Health Organization (WHO), but the existing international institutions for trade and development which interact on this issue present significant complications for coherent and coordinated governance. While the institutions for trade and development may not have intended to preside over this issue area, their influence and activities have serious implications for how states can implement AEM as a matter of public health. As a result, global misaligned priorities, duplicate projects and conflicting agendas are some of the daunting challenges that face the governance of access to medicines today.

To make sense of the chaos surrounding the issue of access to medicines, there is a need to understand how current international institutions interact over the issue of AEM. The previous chapter (Chapter 3) discussed the institutional role that the WHO plays in global health and how it has dealt with the issue of AEM, but this chapter will show that there are significant complications over its mandate and functions with other major international institutions (i.e. institutions for trade and development). These interactions lead to the question of whether institutional synergies and conflicts between health and other regimes can be addressed and how. This chapter uses theories from the social sciences⁴⁶⁹ (as discussed in Chapter 2 on the Theoretical Framework) to characterize the interactions between these institutions on the governance of access to essential medicines.

⁴⁶⁹ For example, these include theories from international relations and organizational behaviour.

The chapter is organized into four parts. The first part of the chapter will provide a brief recapitulation of the theoretical concepts applied in the current study of institutional interactions between international health and other regimes (i.e. trade, development, and human rights) over the issue area of AEM. The second part of the chapter provides a brief summary of the international trade regime's involvement in AEM and how it interacts with the World Health Organization. The third part of the chapter includes a brief summary of the major organizations for international development in health and how they interact on the matter of AEM (in terms of HIV/AIDS assistance). The final part of this chapter concludes with a discussion of the implications of these institutional complexes for IAC for AEM.

The Analysis of Institutional Interactions: A Brief Recapitulation

The chapter applies the tripartite analytical framework developed by W. Bradnee Chambers, Joy Kim, and Claudia ten Have for the study of institutional interactions. This framework, as discussed in Chapter 2, specifies three questions for analysis:

- (1) 'What are the links of inter-institutional influence and interaction?';
- (2) 'What implications does this [interaction] hold for the interests of stakeholders, for the formation, operation and implementation of the specific institution, for its performance and effectiveness, and for the overall governance context?';
- (3) '[I]n what ways can issues and processes across institutions be strategically linked and arranged to reinforce each other?',⁴⁷⁰

The first question sets out to characterize the type of institutional linkage occurring between the international health institution and the other institutions (i.e. trade and development). The form of linkage can assume one of four common forms: (1) overlap;

⁴⁷⁰ Chambers, Kim and ten Have, p. 3-4.

(2) parallelism; (3) nesting or embedding; and (4) clustering.⁴⁷¹ Institutional interactions can arise in a variety of ways (such as organizational mandates or operational functions, rule formation and implementation, etc.), but they do not all lead to the same outcome.⁴⁷² By identifying the form of linkage that is occurring between the institutions, this can help determine whether the different institutions might be in conflict due to institutional overlap or competition due to institutional parallelism.

The second question sets out to determine the normative, political, and operational implications of these institutional interactions and to identify the interactional problems (e.g. conflict or competition) that are affecting the governance of AEM. In terms of the normative and operational implications, I consider the effect of different rules and objectives, organizational functions, reporting procedures, and enforcement mechanisms on IAC for AEM. With regard to the political implications, my analysis considers the potential empowerment of different states (e.g. developed or developing countries) and the strategic manoeuvres that can be taken by these states.

The third question takes the information gathered from the first two analytical questions to consider how institutional interaction is and could be managed to improve the governance of AEM and to attain greater IAC for this issue. A discussion of this will be covered in this chapter as well as Chapter 6 (Emerging Trends in the Governance of AEM). Due to the lengthy and involved nature of this analysis, I have set the discussion

⁴⁷¹ Please refer to Chapter 2 (theoretical framework) for details about each form.

⁴⁷² I uncovered these linkages of interaction through an analysis of organizational documents pertaining to AEM (in terms of the institution's mandate and operations), interviews with and/or public statements by former and current organization officials and staff, and a review of the emerging academic literature and NGO policy briefs on the interactions between the WHO and other institutions.

of two case studies of recent efforts to manage institutional interactions (i.e. one occurring in health and trade and the other in health and development) for Chapter 6.

The Institutional Interactions between International Health and Trade

A key reason for the interaction between the international institutions for health and trade is the issue of access to medicines.⁴⁷³ As discussed in the introductory chapter (Chapter 1), the international intellectual property rules established via the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) creates the need for all World Trade Organization (WTO) members to grant patent protection for medicines. This includes numerous developing countries where patent protection previously did not exist and had to be adopted into national law in order to conform with WTO rules. Many developing countries are concerned, however, that establishing patent protection for critical medicines will limit their access (e.g. due to high prices and the lack of affordability).

This section briefly introduces the international institution for trade (i.e. the World Trade Organization) and its rules related to medicines. It also describes the WTO's functions and mechanisms in relation to AEM governance (namely the work of its rule-setting and dispute settlement bodies). The section then proceeds with an analysis of the institutional interactions between the WTO and WHO through the tripartite analysis (i.e.

⁴⁷³ There are other reasons for interactions between international health and trade, such as the issues of the trade in health services or products. These other issues are associated with the WTO's other body of laws – i.e. the General Agreement on Tariffs and Trade (GATT), General Agreement on Trade in Services (GATS), the Agreement on Technical Barriers to Trade (TBT), and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). These other issues and agreements, however, are not directly applicable to my discussion on access to essential medicines and outside the scope of my research.

characterizing the interaction, identifying implications of the interaction, and considering the management of the interaction).

The World Trade Organization

The World Trade Organization (WTO) is the international institution for trade that has become involved in the governance of access to essential medicines, albeit unintentionally. In its functional capacity as an international organization, it serves as a forum for the establishment of trade agreements and as an adjudicator of disputes brought between its member states.⁴⁷⁴ The WTO, by its legislative function, became faced with the issue of access to essential medicines after a powerful group of developed countries pushed for the passage of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).⁴⁷⁵ TRIPS was an agreement, reached during the Uruguay Round (1986-1994) of WTO discussions, which sought to 'establish minimum levels of protection that each government has to give to the intellectual property of fellow WTO members'.⁴⁷⁶ One such protection is that patents are granted a minimum of 20 years in exclusivity, which means that low cost generic versions of a patented medicine would have to wait at least two decades before they could be brought to market.

⁴⁷⁴ K Iida, 'Is WTO Dispute Settlement Effective?' (2004) 10 *Global Governance* 207, p. 207.

⁴⁷⁵ WTO was selected as the forum for TRIPS negotiations by developed countries, rather than the World Intellectual Property Organization (WIPO), because they would be able to influence developing countries to accept the agreement in light of other trade deals. In an interview, a former government official involved in the Uruguay Round negotiations, revealed that the agreement was initially conceptualized as an anticounterfeiting agreement that was considered for establishment within the World Intellectual Property Organization (WIPO). WIPO was eventually discounted as a negotiating forum and the WTO was selected instead due to the greater political leverage the developed countries held within the WTO and WIPO's lack of enforcement powers and strong developing country influence. See S Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press, Cambridge, UK 2003); S Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 (3) *Wisconsin International Law Journal* 481, p. 486.

⁴⁷⁶ WTO, 'Understanding the WTO: The Agreements (Intellectual Property: Protection and Enforcement).' <http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm> (10 Dec 2006).

The TRIPS agreement, however, grants governments certain patent protection ‘flexibilities’ in its provisions. One such flexibility is the application of compulsory licensing, which is when a government allows a third-party or government agency to produce a patented product or process without the patent owner’s consent.⁴⁷⁷ According to TRIPS, the first required step in obtaining a licence is to seek a voluntary licence from the patent holder on ‘reasonable commercial terms’. This step does not apply to situations of national emergency or other circumstances of extreme urgency, as well as cases of non-commercial use (i.e. government use). TRIPS also specifies that compulsory licences are not exclusive to new licensees (i.e. the patent-holder still holds the right to produce), and that the use of such licences is primarily for the supply of the domestic market.⁴⁷⁸ Furthermore, if a compulsory licence is granted, adequate remuneration must be paid to the patent holder.⁴⁷⁹ Unfortunately, despite the existence of these flexibilities to address public health crises (such as HIV/AIDS), ‘some governments were unsure of how these [rules] would be interpreted, and how far their right to use them would be respected.’⁴⁸⁰ In recognition of this problem, the African Group of WTO members pushed an initiative that eventually led the WTO’s Ministerial Council (the highest governing body of the WTO) to issue the ‘Doha Declaration on TRIPS and Public Health’ in November of 2001.

⁴⁷⁷ WTO, ‘Compulsory Licensing of Pharmaceuticals and TRIPS’ (2005) <http://www.wto.org/English/tratop_e/trips_e/public_health_faq_e.htm> (10 Dec 2006). See also Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2.

⁴⁷⁸ WTO, *WTO OMC Fact Sheet* (2006).

⁴⁷⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C/IP/1, Article 31h.

⁴⁸⁰ WTO, ‘Understanding the WTO: The Agreements (Intellectual Property: Protection and Enforcement).’

The Doha Declaration was lauded as a critical move in pushing for governmental support of access to essential medicines – with its proclamations of the ‘need for the WTO Agreement on [TRIPS] to be part of the wider national and international action to address [public health] problems’ and ‘affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all’.⁴⁸¹ To substantiate these proclamations, the Doha Declaration clarified the rights that member states possess to address the public health challenges in their countries. These include:⁴⁸²

- (1) ‘[T]he right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.’
- (2) ‘[T]he right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.’
- (3) ‘[T]he free[dom] to establish its own regime for [the exhaustion of intellectual property rights] without challenge.’

The Doha Declaration’s statement of Member State freedom ‘to establish its own regime for [the exhaustion of intellectual property rights] without challenge’ serves to reaffirm Article 6 of the TRIPS Agreement on parallel importation.⁴⁸³ Under Article 6, ‘practices relating to parallel importation cannot be challenged under the WTO dispute settlement system.’ The rationale for parallel importation, in terms of access to essential medicines, is to allow member states to obtain patented medicines from another country’s market for a lower price.⁴⁸⁴

⁴⁸¹ Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2.

⁴⁸² *ibid.*, Para. 5(b).

⁴⁸³ Parallel importation is the importation of a patented product from another country’s market.

⁴⁸⁴ Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2.

An issue that was initially unresolved in the 2001 Doha Declaration pertained to how member states with insufficient or non-existent manufacturing capacity could make effective use of compulsory licensing. It was suggested that other capable member states could help produce the medicines (under compulsory licence on an incapable state's behalf) and export them. This solution, however, violated the TRIPS provision on compulsory licensing which requires that generic production be 'predominantly for the supply of the domestic market [of a country conferring a compulsory licence].'⁴⁸⁵ The issue was later addressed in August of 2003 under a WTO General Council 'implementation agreement',⁴⁸⁶ which permits member states to apply compulsory licensing to medicines for export by means of a temporary waiver. (This is also referred to as the 'paragraph 6' system.) The decision waives the following:⁴⁸⁷

- (1) 'Exporting countries' obligations under Article 31(f) are waived – any member country can export generic pharmaceutical products made under compulsory licences to meet the needs of importing countries.'
- (2) 'Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.'
- (3) 'Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.'

The U.S. was initially opposed to the agreement because it wanted to restrict the health conditions under this approach to only HIV/AIDS, malaria, tuberculosis and other severe infectious illnesses.⁴⁸⁸ Yet, after strong public criticism, the U.S. relented and signed the waiver agreement in August of 2003. Any WTO Member State is eligible to import

⁴⁸⁵ M Bloche and E Jungman, 'Health Policy and the WTO' (2003) 31 (4) J L Medicine and Ethics 529, p. 535.

⁴⁸⁶ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003) WT/L/540.

⁴⁸⁷ WTO, *TRIPS and Pharmaceutical Patents (Fact Sheet)* (2006), p. 14.

⁴⁸⁸ Bloche and Jungman, p. 535.

under the agreement; however, a number of countries have selected to opt-out or to only use the waiver measures to import in times of national emergency or extreme urgency.⁴⁸⁹ To date, Canada, Norway, India, and the European Union have amended their national laws to allow for production of medicines that would be exclusively used for export under compulsory licence.⁴⁹⁰ The waiver agreement further specifies that any government that uses the system must inform all other WTO member states, in order to prevent the diversion of medicines to the wrong markets, but only to the extent of ‘reasonable measures within their means’ and ‘proportionate to their administrative capacities’.⁴⁹¹ An agreement to convert the temporary waiver into a permanent measure through the amendment of TRIPS Article 31(f) was reached in December of 2005.⁴⁹² In order for the amendment to be formally incorporated into the TRIPS Agreement, two-thirds of WTO member states must adopt it by December of 2011.⁴⁹³

Beyond the technical issues of compulsory licensing and parallel importation, the Doha Declaration also ‘reaffirm[ed] the commitment of developed-country Members to

⁴⁸⁹ WTO, *TRIPS and Pharmaceutical Patents (Fact Sheet)* .

⁴⁹⁰ *ibid.*

⁴⁹¹ *ibid.*

⁴⁹² D Matthews, 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries' (2006) 2 *Intellectual Property Quarterly* 91, p. 2.

⁴⁹³ WTO, 'Members accepting amendment of the TRIPS Agreement' (2010) World Trade Organization <http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> (15 July 2010). (The original deadline for ratifications was December of 2007 and then December of 2009, but it was extended yet again when the required number of ratifications had not been reached in 2009. It is also worth noting that the procedure approved by the 2005 Amendment to TRIPS has only been used once ‘since its inception in 2003 – by a company that has vowed never to use the system again’ due to ‘the time and difficulty involved’. K Mara, 'Medicines Access Again Captures Attention at WTO as Progress Urged in Round' *Intellectual Property Watch* (Geneva 30 October 2009); K Mara, 'Efficacy Of TRIPS Public Health Amendment In Question At WTO' (2010) *Intellectual Property Watch* <<http://www.ip-watch.org/weblog/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/>> (1 March 2010); C Saez, 'Drug Access Waiver Debate Looms For June TRIPS Council Meeting' (2010) *Intellectual Property Watch* <<http://www.ip-watch.org/weblog/2010/05/31/drug-access-waiver-debate-looms-for-june-trips-council-meeting/>> (31 May 2010).)

provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2.⁴⁹⁴ At the Doha Ministerial Conference in 2001, the member states agreed that the TRIPS Council should create ‘a mechanism for ensuring the monitoring and full implementation of the obligations’.⁴⁹⁵ This mechanism, which is currently being implemented, involves the submission of periodic reports by developed country members on progress and the review of the TRIPS Council on the ‘effectiveness of the incentives provided in promoting and encouraging technology transfer to least-developed country members’.⁴⁹⁶ The success of the developed country technology transfer initiative will be critical to helping least developed countries attain a sustainable, long-term solution for access to essential medicines.

Furthermore, Article 67 of TRIPS specifies that ‘developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members’.⁴⁹⁷ However, as Duncan Matthews notes, this provision is geared towards the protection and enforcement of intellectual property rights which benefit the interests of developed countries.⁴⁹⁸ Matthews also observes that the language of the provision tends to favour the position of the provider of cooperation (i.e. developed country). This is because the

⁴⁹⁴ Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2.

⁴⁹⁵ WTO, 'TRIPS Issues: Technology Transfer' <http://www.wto.org/english/tratop_e/trips_e/techtransfer_e.htm > (10 Dec 2006).

⁴⁹⁶ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003) WT/L/540.

⁴⁹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C/IP/1, Article 67.

⁴⁹⁸ D Matthews, 'Bilateral Technical Assistance' (Oxford Intellectual Property Seminar Series 2007).

act of ‘requesting’ cooperation would create a sense of dependency for the developing country upon the developed country. Also, the need to reach ‘mutually agreed terms and conditions’ on the request would require the developing country to bargain with the developed country. Unsurprisingly, the uptake of such cooperation by developing countries has not been very successful.⁴⁹⁹

WTO Functions and Mechanisms

In order for the WTO to bring effect to the implementation of the Doha Declaration, it relies heavily upon the powers of the TRIPS Council and the WTO Dispute Settlement Body (DSB). The TRIPS Council, which opens its membership to all member states of the WTO, holds the ‘responsibil[ity] for administering the TRIPS Agreement, in particular monitoring the operation of the Agreement’.⁵⁰⁰ Other functions of the TRIPS Council include assistance to the DSB, if requested, and consultation to member states on TRIPS matters.⁵⁰¹

The DSB, on the other hand, serves to arbitrate disputes between member states. The DSB is comprised of all WTO members and has the authority to establish expert panels that will consider the case. After a panel hears the case and reports on its findings, the DSB decides whether to accept the panel’s report and turn it into a ruling or recommendation. The DSB then also has the responsibility of monitoring the implementation of the ruling. Countries that have caused offence are expected to comply

⁴⁹⁹ *ibid.*

⁵⁰⁰ WTO, ‘WTO Uruguay Round Agreements: TRIPS. (Part VII - Institutional Arrangements; Final Provisions.)’ <http://www.wto.org/english/docs_e/legal_e/27-trips_09_e.htm> (10 Dec 2006)

⁵⁰¹ *ibid.*

by ‘bringing its policy into line with the rulings or recommendations’.⁵⁰² If a country does not comply with the ruling, the DSB has the power to authorize trade sanctions against the offending country.⁵⁰³ The WTO Dispute Settlement mechanism is considered ‘revolutionary’ in the sense that it gives ‘treaties [such as TRIPS] impact that is very unusual in international law’.⁵⁰⁴ As David Fidler highlights, ‘[o]ne of the historical problems with treaties ... has been the unwillingness of states to create dispute settlement bodies that have compulsory jurisdiction and the power to authorize enforcement against violators.’⁵⁰⁵ Consequently, the WTO’s DSB is an institutional characteristic that sets it apart from other intergovernmental organizations.⁵⁰⁶

TRIPS Cases under the DSB

There have been two major cases brought before the WTO DSB on the TRIPS ‘flexibility’ of compulsory licensing use. The first case involved a dispute that was brought by the European Union against Canada over whether the TRIPS Agreement ‘allowed governments to permit generic drug manufacturers to undertake and complete the task of obtaining regulatory approval from the public health authorities for the generic

⁵⁰² WTO, ‘Understanding the WTO: Settling Disputes’
<http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm> (10 Dec 2006).

⁵⁰³ *ibid.* See also J Rein, ‘International Governance Through Trade Agreements: Patent Protection for Essential Medicines’ (2001) 21 *Northwestern Journal of International Law & Business* 379, p. 394. (More specifically, ‘[c]laims for breach of intellectual property obligations can be remedied by injunctions, monetary damages, or forfeiture of infringing goods or some form of mutually acceptable compensation.’)

⁵⁰⁴ D Fidler, *Global Health Governance: Overview of the Role of International Law in Protecting and Promoting Global Public Health* (World Health Organization Discussion Paper No 3 on Global Health Governance 2002), p. 26.

⁵⁰⁵ *ibid.*, p. 26.

⁵⁰⁶ The importance of the Dispute Settlement mechanism with the WTO is well explained by Gregory Shaffer. He notes that ‘[t]he difficulty of amending or interpreting WTO law through the WTO political process enhances the impact of WTO jurisprudence.’ G Shaffer, ‘Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection’ (2004) 7 (2) *Journal of International Economic Law* 459, p. 470.

version before the expiry of the patent term'.⁵⁰⁷ Canada sought to apply this approach, known as the 'Bolar Exception',⁵⁰⁸ because it would allow them to bring the generic version of a medicine to the market faster. The Dispute Panel 'validated the Canadian law allowing generic drug makers to test patented drugs or undertake other actions necessary for the purposes of seeking marketing approval for their generic versions or file for licences prior to the patent's expiration'.⁵⁰⁹ They also ruled, however, that TRIPS does not permit any stockpiling or large-scale commercial production of generic medicines before patent expiration.⁵¹⁰

The second case was a dispute brought by the U.S. against Brazil over a provision in the Brazilian industry property law. The U.S. claimed that the Brazilian law's 'framework for the grant of compulsory licence' was inconsistent with the TRIPS Agreement.⁵¹¹ This case, however, was eventually settled between the two countries in June of 2001 when Brazil agreed to engage 'in bilateral talks with the U.S. prior to the issue of compulsory licences on patents held by U.S. companies'.⁵¹² Though this approach prevents Brazil from directly granting a compulsory licence, the 'threat of compulsory licensing' has actually proven useful in allowing Brazil to achieve 'more

⁵⁰⁷ WHO and WTO, 'WTO Agreements & Public Health: A joint study by the WHO and the WTO Secretariat' (2002) <http://www.wto.org/English/res_e/booksp_e/who_wto_e.pdf> (10 Dec 2006), p. 98-99.

⁵⁰⁸ The name 'Bolar Exception' refers to the name of a similar provision in U.S. law

⁵⁰⁹ WHO and WTO, 'WTO Agreements & Public Health: A joint study by the WHO and the WTO Secretariat', p. 98-99.

⁵¹⁰ *ibid.*

⁵¹¹ *ibid.*, p. 104-105.

⁵¹² *ibid.*

favourable terms in its negotiations for the supply of HIV/AIDS drugs with major pharmaceutical companies' on at least two occasions.⁵¹³

There has also been another recent case regarding medicines to enter the WTO dispute settlement process in May 2010, which involves a complaint by India and Brazil against the European Union and the Netherlands.⁵¹⁴ The dispute arose in response to the Dutch customs authorities' seizure of generic medicines that were passing through the country in transit to Brazil.⁵¹⁵ The European Union claimed that its actions were justified under an EU regulation (i.e. EC 1383/2003) as it suspected that there was patent infringement. India and Brazil, however, felt that Dutch (and, hence, EU) actions violated the principles set under TRIPS and the Doha Declaration, among other WTO laws. Under WTO dispute settlement procedures, the two parties are required to first enter into a period of consultation without the WTO involvement. After the consultation period is over, and if parties have not reached a resolution, a dispute settlement panel is formed and the case goes before this body for a decision.⁵¹⁶ (The consultations between the two parties are still in process at the time of this writing.) It is interesting to note

⁵¹³ *ibid.*

⁵¹⁴ World Trade Organization *Complaint by Brazil: European Union and a Member State - Seizure of Generic Drugs in Transit* Geneva (12 May 2010) Dispute Settlement - DS409; World Trade Organization *Complaint by India: European Union and a Member State - Seizure of Generic Drugs in Transit* Geneva (11 May 2010) Dispute Settlement - DS408.

⁵¹⁵ The case is related to a shipment of losartan potassium, which is a treatment used for hypertension, from India to Brazil. The medicines were passing through the Netherlands, where they were seized by Dutch customs authorities. This was not the only incidence of a medicines seizure by the Netherlands. From 2008 through early 2009, there have been at least 18 seizures of generic medicines by customs officials. Mara, 'Medicines Access Again Captures Attention at WTO as Progress Urged in Round'; K Mara, 'Concerns Continue Over Generic Drug Seizures as Legality Debates Begin' *Intellectual Property Watch* (Geneva 5 March 2009); D Cronin, 'Risk of Wrongful Medicines Seizures Seen in EU-Central America Trade Deal' *Intellectual Property Watch* (Geneva 6 April 2010).

⁵¹⁶ WTO, 'Understanding the WTO: Settling Disputes' (2007) <http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm> (10 July 2009).

some of the different positions taken by the different parties as well as the WHO's reaction. Indian officials have commented before the TRIPS Council that the 'underlying drug seizures [are] ... a deliberate mixing up of the issues of spurious [or] sub-standard drugs ... with [intellectual property rights]' and that 'such actions fit into a larger trend [of promoting an intellectual property maximalist agenda] that risks upsetting the "delicate balance" between [intellectual property] rights holders and public policy goals'.⁵¹⁷ Brazil has supported India with statements that the EU was acting at the 'request of a [medicines'] rights holder' and that it was pursuing an 'excessive and inappropriate interpretation of [intellectual property] rights'.⁵¹⁸ Brazil also commented that Dutch officials 'had no authority to decide if drugs meet Brazil's regulatory standards, since they were only passing through the Netherlands and not destined there'.⁵¹⁹ A WHO official, Hans Hogerzeil, has supported India and Brazil with comments that 'WHO deplores that this happened. We had asked both the Netherlands and the EU at that time what was happening, and we ask them to make sure that this does not happen again. It was an improper, unfortunate use of counterfeit legislation'.⁵²⁰ There appears to be an overall sense on one side that the EU was 'using the cover of a fight against counterfeit medicines to protect pharmaceutical [companies] and suppress legitimate generic drugs'.⁵²¹ The EU, on the other hand, stated before the TRIPS Council that it is critical to 'allow the customs authorities to control goods in transit suspected to infringe IP rights so

⁵¹⁷ Mara, 'Concerns Continue Over Generic Drug Seizures as Legality Debates Begin'

⁵¹⁸ *ibid.*

⁵¹⁹ *ibid.*

⁵²⁰ S Mehdudia, 'EU Seizure of Drugs Improper: WHO' *The Hindu* (New Delhi 23 May 2010).

⁵²¹ *ibid.*

that they can stop the traffic of potentially dangerous products, such as fake medicines, even when the shipments are destined for any country'.⁵²²

Analyzing the Institutional Interactions between International Health and Trade

The Overlap between WHO and WTO Norms

Based on the previous discussion of the World Trade Organization, there is a clear normative overlap between the international institutions for health and trade. TRIPS was established without regard for the public health concern of AEM. In fact, it has been observed that the WHO was 'largely absent from the TRIPS negotiations, although it was obvious that placing newly-developed pharmaceuticals under universal patent protection would have an impact on public health systems throughout the world'.⁵²³ Rather, TRIPS was created under the WTO organizational umbrella at the behest of a strong international business coalition that wanted to establish global intellectual property standards.⁵²⁴ This resulted in a conflicting overlap with AEM norms.

As detailed in the introductory chapter (Chapter 1), the conflict between AEM norms under the right to health and TRIPS is that TRIPS requires the establishment of minimum standards for the protection of pharmaceutical patents in countries where such

⁵²² Mara, 'Concerns Continue Over Generic Drug Seizures as Legality Debates Begin'.

⁵²³ F Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 (2) *Journal of International Economic Law* 469, p. 474; E Stein, 'International Integration and Democracy: No Love at First Sight' (2001) 95 *American Journal of International Law* 489.

⁵²⁴ This international business coalition was known as the 'Intellectual Property Committee' and was comprised of various prominent global corporations, such as Johnson & Johnson, Bristol-Myers Squibb, Digital Equipment Corporation, General Electric, IBM, Merck, Pfizer, among others. See Sell, 'TRIPS and the Access to Medicines Campaign', p. 481.

intellectual property rights did not previously exist (e.g. numerous developing countries). Patents, due to their creation of a market monopoly, allow companies to charge much higher prices than they could otherwise achieve. This can create daunting problems of affordability for poorer developing countries and, as a result, leads to an access to medicines conflict. Proponents of the TRIPS agreement argue that the protection of intellectual property rights help to foster product innovation (e.g. research and development) and that 'inadequate' protection of these rights would serve as a 'barrier to legitimate trade' internationally.⁵²⁵ Essentially, corporations would not have an incentive to create and develop new products if they feel they cannot reap the benefits. Public health proponents, on the other hand, counter that essential medicines are 'not simply another commodity', but a core component of the right to health.⁵²⁶ In addition, while recognizing that incentives for innovation are important, public health supporters argue that it is not certain that pharmaceutical companies will invest in the necessary medicines – especially those for the poor.⁵²⁷

The tensions between TRIPS and public health (especially AEM) has been formally recognized at the WTO via TRIPS Council meetings⁵²⁸ and eventually led to the

⁵²⁵ *ibid.*, p. 486.

⁵²⁶ WHO, *WHO Policy Perspectives on Medicines*

⁵²⁷ *ibid.* This is because there is a well-recognized market failure in developing treatments for the diseases of the poor, also known as the 'neglected diseases'. Pharmaceuticals usually do not find such treatments to be profitable and prefer not to invest their R&D resources in such areas. (Despite the establishment of TRIPS and claims that it would foster greater innovation for health, Ellen 't Hoen has observed that the agreement 'has not kick-started research on neglected diseases, for which product development is not seen as profitable, and which often occur in developing countries'. Ellen 't Hoen is the former advocacy director of Médecins Sans Frontières' Access to Essential Medicines Campaign. W New, 'Views Mixed On WTO Doha Declaration On Public Health After Five Years ' (2006) Intellectual Property Watch <<http://www.ip-watch.org/weblog/2006/11/16/views-mixed-on-wto-doha-declaration-on-public-health-after-five-years/>> (16 November 2006).)

⁵²⁸ For example, a special session of the TRIPS Council on Intellectual Property and Access to Medicines was held in June 2001. G Velásquez, CM Correa and T Balasubramaniam, 'WHO in the Frontlines of the

establishment of the Doha Declaration on TRIPS and Public Health to affirm and clarify the use of certain TRIPS ‘flexibilities’ (e.g. compulsory licensing and parallel importation). A subsequent ‘waiver’, which is currently pending formal adoption as an amendment to TRIPS, was also established to address the restriction on generic importation for countries lacking the manufacturing capacity to exercise compulsory licensing.

Despite these normative adjustments in the WTO to address the conflicts between the health and trade institutions on AEM, the implementation of these rules by developing countries has proved difficult. Those countries that might attempt to implement TRIPS flexibilities are deterred by their complexity⁵²⁹ and, when countries do attempt to exercise them, they have faced political challenges from other powerful countries (such as the EU or US).⁵³⁰ While WTO members have the option of filing a dispute before the DSB, the disputes actually filed by developing countries are few to none.⁵³¹ The heavy cost and political⁵³² concerns involved in filing a dispute have served as a serious deterrent for poor developing countries.

Access to Medicines Battle: The Debate on Intellectual Property Rights and Public Health' in JAZ Bermudez and MA Oliveira (eds) *Intellectual Property in the Context of the WTO TRIPS Agreement: challenges for public health* (WHO/PAHO Collaborating Center for Pharmaceutical Policies, National School of Public Health Sergio Arouca and Oswaldo Cruz Foundation, Rio de Janeiro 2004), p. 85.

⁵²⁹ This problem is described a bit later in this section.

⁵³⁰ This is discussed in Chapter 5.

⁵³¹ In the past, there have been moves by developing countries toward bringing a dispute against a developed country on the matter of access to medicines, but they were resolved before reaching the stage of dispute settlement panel formation. It remains to be seen if the current dispute brought by India and Brazil against the EU will reach the DSB panel stage, as described earlier.

⁵³² This is illustrated and discussed in Chapter 5.

The WTO's Dominance of the Institutional Overlap with WHO

As the WTO becomes increasingly intertwined in global health affairs through issue overlap, such as AEM, there is a belief that '[i]nternational law on public health in the first half of the twenty-first century will, in large part, be driven by the WTO and its multilateral agreements'.⁵³³ This belief is substantiated by the fact that its agreements have a significant impact on health, as illustrated by the TRIPS agreement. Furthermore, in contrast to the policies and laws of other international institutions, WTO agreements are actually enforceable by its powerful dispute settlement mechanism. Hence, from an international legal perspective, David Fidler argues that 'the cent[re] of power for [global health governance] has shifted from WHO to the WTO'.⁵³⁴ This shift is troubling for several reasons.

First, the WTO was not designed to address health matters and holds no formal duty to protect health. As M. Gregg Bloche points out, '[t]he WTO's framers paid little heed to health policy. ... however, politics and the AIDS pandemic have pushed to centre stage as a trade issue.'⁵³⁵ On the matter of AEM, Frederick Abbott observed that the WTO 'took on the role of developing and regulating patent policy, but neglected to exercise its mandate with attention to its broader implications'.⁵³⁶ The governance approach that the WTO has taken, with regard to health, is one of 'heightened deference' to national health policies whereby it has not sought to establish health policies and does

⁵³³ Fidler, *Global Health Governance: Overview of the Role of International Law in Protecting and Promoting Global Public Health*, p. 26.

⁵³⁴ *ibid.*, p. 26.

⁵³⁵ M Bloche, 'WTO Deference to National Health Policy: Toward an Interpretive Principle' (2002) 5 (4) *J Intl Economic L* 825, p. 825.

⁵³⁶ Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 505.

not require its member states to do so either.⁵³⁷ Essentially, the WTO is an institution for trade and not health.

Second, there is concern about the bias in priorities and expertise applied by the WTO in dispute settlement decisions involving health issues. As R. Labonte argues:

[T]he basic political question of whether free market practices are compatible with human development and public health objectives is rendered into technical disagreements over the interpretation of this or that exemption or exception, interpretations that inevitably will be left to dispute panels dominated by experts in trade policy and law, not in development or public health.⁵³⁸

Keisuke Iida indicates WTO activity will likely be driven by private corporations and industry associations as these actors are able to 'speak the loudest' and, therefore, 'most likely to be heard' by countries in raising disputes or endorsing acts of retaliation.⁵³⁹ In response to this problem, some suggest a need to subordinate trade agreements to the health priorities of developing countries. This could be achieved by granting developing countries special exemptions from trade obligations for the purposes of health, and also by establishing a new dispute settlement panel with health expert representation to address conflicts.⁵⁴⁰ Others advocate for the incorporation of nontrade concerns through WTO legislative reform.⁵⁴¹

A third concern about the WTO pertains to the structure of the dispute settlement system in favour of richer countries. This structural bias arises because the dispute

⁵³⁷ Bloche, *WTO Deference to National Health Policy: Toward an Interpretive Principle*., p. 844-45.

⁵³⁸ R Labonte and M Sanger, 'Glossary on the World Trade Organization and Public Health: Part 2' (2006) 60 *J Epidemiol Community Health* 738, p. 743.

⁵³⁹ Iida, p. 218.

⁵⁴⁰ Labonte and Sanger., p. 743.

⁵⁴¹ Iida, p. 220.

settlement process can be expensive.⁵⁴² The costly process of discovery in preparation for a case could be beyond what a developing country can afford to bring a case to the DSB, thus leading to the underrepresentation of grievances brought by poor developing countries.⁵⁴³ In response to this problem, civil society organizations have played an active role in advising and assisting developing countries on this and TRIPS implementation-related matters.⁵⁴⁴ Civil society organizations can also support developing countries through the submission of *amicus curiae* submission to the dispute settlement panel (or Appellate Body, if an appeal is made to a panel ruling). According to the WTO, the panel can ‘accept and consider or to reject [such] information and advice’; however, if a dispute participant attaches an *amicus curiae* submission during an appeal, the Appellate Body will need to consider it.⁵⁴⁵

Fourth, a concern has been raised about the uncertain legal authority of the Doha Declaration.⁵⁴⁶ While it is widely believed that the Doha Declaration can be used to

⁵⁴² Shaffer, p. 471.

⁵⁴³ Iida, p. 216. See also Shaffer, p. 470. (Shaffer suggests that countries that are able to utilize the WTO’s dispute settlement system hold an advantage in shaping WTO jurisprudence. This is because ‘those governments that are able to participate most actively in the WTO dispute settlement system are the best positioned to effectively shape the law’s interpretation and application over time. Not surprisingly, the [US] and [EC] remain by far the predominant users of the system They attempt to shape judicial interpretation of the WTO rules over time.’)

⁵⁴⁴ See Shaffer, p. 477. (Alternatively, Shaffer proposes three strategies for developing countries in overcoming the structural bias of the WTO. He recommends: ‘pooling government resources at the national, regional, and international levels; coordinating with private parties in the United States and Europe to undercut industry pressure in the formation of US and EC negotiating positions and litigation strategies; and working with generic producers of pharmaceuticals in political negotiations and judicial disputes’.)

⁵⁴⁵ WTO, ‘Participation in Dispute Settlement Proceedings: Dispute Settlement System Training Module’ (2003) <http://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c9s3p1_e.htm> (12 June 2008). (According to the WTO, it considers such material to be an ‘integral part of the submission of that participant’.)

⁵⁴⁶ James Gathii finds that there are at least three possibilities in explaining the legal status of the Doha Declaration: (1) ‘as a subsequent agreement under Article 21 Section 3(a) of the Vienna Convention on the Law of Treaties regarding the interpretation of the TRIPS agreement’; (2) ‘as evidence of subsequent practice establishing the understanding of WTO members regarding interpretation of the TRIPS

defend public health measures taken by member states, it is uncertain whether the WTO dispute panels and Appellate Body will actually draw guidance from the declaration when deciding upon complaints.⁵⁴⁷ Hence, the legal uncertainty in applying Doha Declaration-affirmed TRIPS flexibilities may deter developing countries from using them. This concern appears to be reinforced by the fact that only one country to date has utilized the ‘Paragraph 6’ system to import medicines since the establishment of this procedure in 2003.⁵⁴⁸

A final concern pertains to the implementation of TRIPS flexibilities, as specified by the Doha Declaration. In addition to the issue of legal uncertainty, there are beliefs that ‘[the] current flexibilities [are] too complex to be used in practice’ and ‘the right of countries to use the public health safeguards provided for in the TRIPS Agreement [may not be] sufficiently recognized and accepted’.⁵⁴⁹ In recent years, the WTO has hosted a series of workshops, which it states are aimed ‘to help [member states] make use of the pharmaceutical patent flexibilities in the [TRIPS agreement]’ through greater

agreement’; or (3) ‘as a declaration of commitment and intent that does not constitute an enforceable legal obligation’. See JT Gathii, ‘The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties’ (2002) 15 (2) *Harvard Journal of Law & Technology* 292, p. 299. (In a report published by WHO, Carlos Correa observes that the Doha Declaration’s ‘clearly stated purpose’ of public health ‘establishes a specific rule of interpretation that gives content to the general interpretative provisions of the Vienna Convention on the Law of Treaties on which GATT/WTO jurisprudence has been built up’. Hence, the WTO should ‘opt for interpretations that are effectively “supportive of WTO Members’ right to protect Public Health” in situations of ambiguity.’ C Correa, ‘Implications of the Doha Declaration on the TRIPS Agreement and Public Health’ (2002) *World Health Organization* <https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf> (12 June 2008), p. vii.)

⁵⁴⁷ Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’.

⁵⁴⁸ Rwanda filed to use the ‘Paragraph 6’ system on 19 July 2007 and is the only country (as of August 2010) WTO, ‘Notifications by importing WTO Members’ (2010) *World Trade Organization* <http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm> (10 July 2010)

⁵⁴⁹ A Jack, ‘WTO head flags trade rules as a way to reduce drug costs’ *Financial Times* (12 October 2006).

information.⁵⁵⁰ The meetings, however, have covered topics beyond patents. As the WTO publicized on its website, the workshops have been conducted ‘[w]ith a view to putting the issue of TRIPS and public health in the context of a wider action to address problems related to public health’ and have covered issues such as ‘quality control and effectiveness of medicines’ and ‘competition and procurement’.⁵⁵¹ It is interesting to note that the WTO appears to be channelling attention and discussion amongst its member states towards activities beyond TRIPS and patents. While it headlines press releases with statements of helping developing countries utilize patent flexibilities, there has been a concerted effort by the WTO to shift attention to other medicines concerns. (This effort will be described in further detail in the next section on ‘managing interactions’.) Despite the WTO’s TRIPS flexibility workshops, concerns about the implementation of the TRIPS agreement in relation to public health still persist.⁵⁵² In response, other groups (such as NGOs, WHO, etc.)⁵⁵³ have come forward to offer their services in helping developing countries navigate the use of TRIPS flexibilities while meeting compliance standards.

⁵⁵⁰ WTO, 'TRIPS and Public Health: 5th Geneva workshop helps officials use health patent flexibilities (Press Release)' (2009) World Trade Organization
<http://www.wto.org/english/news_e/news09_e/heal_05nov09_e.htm> (5 Nov 2009). (Five workshops on the use of TRIPS flexibilities have been hosted by the WTO to date.)

⁵⁵¹ *ibid.*

⁵⁵² WTO, 'TRIPS Council Meeting - Members ask: Is the 'Par.6' system on intellectual property and health working?' (2010) World Trade Organization
<http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm> (2 March 2010) (This has also been mentioned in my conversations with developing country delegates of the WHO, such as Thailand.)

⁵⁵³ Examples include Knowledge Ecology International (KEI), the South Centre, IQsensato, and the WHO’s Globalization, Trade and Health team.

Efforts by the WHO and WTO to Address the Institutional Tensions⁵⁵⁴

The array of interactional concerns noted above is now well recognized by the WHO and WTO. While there is ‘no formal arrangement between the WTO and WHO’ on matters of health and trade,⁵⁵⁵ these institutions have attempted to become more visible and involved in each other’s official functions when an interrelated matter arises. For example, the institutions will participate in each other’s annual meetings (i.e. the WTO Ministerial meeting and the World Health Assembly) in an ‘observer’ capacity. The WHO has also granted WTO observer status for various WHO technical meetings (such as the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property).⁵⁵⁶ At present, WHO has only been granted *ad hoc* observer status for the WTO TRIPS Council.⁵⁵⁷ In their capacity as observers, the WHO and WTO are allowed to attend discussions and provide expert advice (upon request) at the meetings.

Beyond the more official institutional settings, the two organizations have engaged in an array of ad hoc, collaborative projects – such as joint research, country training / missions, and policy consultations (including high level and informal consultations). Much of this, however, appears to be driven by WHO as directed by a variety of different World Health Assembly mandates over the years (see Appendix table 2 and the discussion later in this section). WTO has also been increasingly pressured, by its developing country member states, to address the tensions between public health and

⁵⁵⁴ The findings reported in this section are drawn from my interviews and observation while based at the WHO.

⁵⁵⁵ WTO, ‘Work With Other International Organizations: The WTO and the World Health Organization’ (2010) World Trade Organization <http://www.wto.org/english/thewto_e/coher_e/wto_who_e.htm> (10 July 2009).

⁵⁵⁶ The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property will be discussed in detail in Chapter 6 (Emerging Trends in AEM Governance).

⁵⁵⁷ WTO, ‘Work With Other International Organizations: The WTO and the World Health Organization’

trade – most notably on the issue of access to medicines. The increased efforts to manage the inter-organizational interactions by WHO and WTO has not been a smooth process and some lingering problems appear to persist.

Efforts by WHO to manage the apparent tensions between trade and health began shortly after the passage of TRIPS in 1994. As described in Chapter 3 and Chapter 5, developing country concerns about the impact of TRIPS on access to medicines were raised for the first time at WHO through the 1996 resolution on the Revised Drug Strategy (WHA 49.14).⁵⁵⁸ This resolution reaffirmed and added to the 1986 version of the WHO Revised Drug Strategy (WHA 39.27) with the purpose of ‘enabl[ing] WHO to address current pharmaceutical issues’.⁵⁵⁹ Specifically, the 1996 WHA resolution requested that the WHO:

... report on the impact of the work of the World Trade Organisation (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between the WTO and WHO, as appropriate.⁵⁶⁰

It is generally considered that WHA 49.14 gave WHO the initial mandate to look into the impact of the WTO agreements (namely TRIPS) on public health.⁵⁶¹ Hence in 1997, in response to developing country demands, WHO developed policy guidance for its member states on the implementation of TRIPS and published them in a report titled

⁵⁵⁸ ‘t Hoen; Velásquez, Correa and Balasubramaniam, p. 86. (According to Velasquez and his colleagues, concerns about intellectual property rights ‘had been voiced by many developing countries during the Uruguay Round negotiations, [but] this resolution marked the first time these concerns were broached in the international public health agenda.’); WHA 49.14.

⁵⁵⁹ The WHA 39.27 was a ‘policy to ensure equitable access to essential drugs of acceptable quality and to promote the rational use of drugs’. See ‘t Hoen; WHA 39.27.

⁵⁶⁰ WHA 49.14

⁵⁶¹ Velásquez, Correa and Balasubramaniam, p. 86.

Globalization and Access to Drugs (which was nicknamed ‘the red book’).⁵⁶² According to one of the report’s authors, the WHO guide:

... examined TRIPS from a public health perspective, [and] ... identified the safeguard provisions in the Agreement that enabled countries to protect health and promote access to medicines [which included compulsory licensing, parallel importation, limited exceptions to patent rights, and transitional periods].⁵⁶³

It is also noted that WHO held ‘[a] number of training seminars regarding TRIPS implementation ... with public health, patent office, and trade officials’; however, these seminars were generally not publicized due to concerns about the reaction from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).⁵⁶⁴

The WHO mandate to address trade-related concerns on public health was later defined to include cooperation with other international organizations. For example, in the 1999 WHA resolution on the Revised Drug Strategy (WHA 52.19), it asks the WHO:

... to cooperate ... with *international organizations* in monitoring and analyzing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that member states can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements.⁵⁶⁵ (emphasis added)

This resolution was controversial and significant for WHO. The draft version of this resolution was initially met with opposition by developed countries due to statements that

⁵⁶² G Velásquez and P Boulet, *Globalization and access to drugs (First Edition)* (World Health Organization, Action Programme on Essential Drugs 1997).

⁵⁶³ Velásquez, Correa and Balasubramaniam, ‘WHO in the Frontlines of the Access to Medicines Battle: The Debate on Intellectual Property Rights and Public Health’, p. 87.

⁵⁶⁴ Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’; WHO Medicines Strategy: Perspectives on TRIPS and Access to Drugs, Warsaw Sept 2001. (The concern about IFPMA was that the this industry association would complain to the developed countries, which would likely result in negative political repercussions upon the WHO.)

⁵⁶⁵ WHA 52.19

WHO should ‘assist Member States to analyze the pharmaceutical and public health implications of [WTO] agreements ... and to develop appropriate policies and regulatory measures’.⁵⁶⁶ Developed countries felt WHO was ‘not [a] competent authority to interpret trade agreements’.⁵⁶⁷ Instead, the resolution was passed with more toned down language (as in shown in the excerpt above). The resolution, despite being watered down, is considered significant in that it broadened and strengthened WHO’s role on matters of international trade relating to health.⁵⁶⁸

The resolution’s mandate to ‘cooperate’ with other international organizations suggests requiring that WHO work constructively with WTO. This would indicate building a practice of communications and openness to assist its member states on TRIPS. On the surface, the institutions appeared to be moving towards greater ‘cooperation’ through joint activities, such as the development of a policy guide on trade agreements and public health. Yet, it appears that problems between the two institutions lurked beyond public view. For example, in the time period leading up to the WTO Doha Round of negotiations, the WTO and WHO had begun developing a joint guide on WTO’s trade agreements and public health (including access to medicines). The WTO secretariat, according to insiders, was ‘less than entirely cooperative’ with the WHO.⁵⁶⁹ This is evidenced by a private communication by Adrian Otten (the WTO Director of Intellectual Property),⁵⁷⁰ which expressed his ‘doubts about the wisdom and feasibility of

⁵⁶⁶ Velásquez, Correa and Balasubramaniam, ‘WHO in the Frontlines of the Access to Medicines Battle: The Debate on Intellectual Property Rights and Public Health’, p. 88.

⁵⁶⁷ *ibid.*, p. 89.

⁵⁶⁸ ‘t Hoen.

⁵⁶⁹ Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’, p. 475.

attempting a joint guide with WHO ...' and his 'strong' belief that WTO's work on the guide should not be sent to WHO before the Doha Round started.⁵⁷¹ Otten states that his reasons against sending it to WHO are: (1) the 'unnecessar[y] ris[k] for the WTO Secretariat to share texts on the TRIPS Agreement's provisions on pharmaceuticals with WHO at [that] stage' and (2) '[his] concern ... that [TRIPS] does not, as yet, contain a section which discusses the positive impact of [the Agreement] on public health, namely through promoting research and development into new drugs'. In his concern about the risk, Otten expressed a lack of trust in the WHO secretariat with statements that 'nothing that is given to WHO can be relied upon to remain confidential' and 'misleading information about the actions of the WTO Secretariat have been given by individuals in the WHO Secretariat to delegations and which have caused [WTO] problems'.⁵⁷² He also emphasized that 'it is only wise to keep [WTO] focus[ed] on the need for not doing anything that could put in jeopardy the process of developing language on the issue of access to drugs prior to the Doha Ministerial'. (The guide was eventually released in 2002, which was almost a year after Otten's comments came to light.⁵⁷³) In addition, it has been observed by WHO insiders that there was a 'practic[e] [by] certain WTO members of excluding representatives of organizations such as WHO from informal

⁵⁷⁰ Adrian Otten was the Director of Intellectual Property at WTO until 2008. A private communication from Mr. Otten was accidentally included in a TRIPS Council submission by Australia and then leaked to the public.

⁵⁷¹ M Palmedo, 'Adrian Otten Missive on WTO/WHO Cooperation [IP-Health List Serve] ' (2001) IP-Health <<http://lists.essential.org/pipermail/ip-health/2001-September/001900.html>> (8 July 2008).

⁵⁷² *ibid.*

⁵⁷³ WHO and WTO, 'WTO Agreements & Public Health: A joint study by the WHO and the WTO Secretariat'. (The joint guide was eventually released in August 2002 and it continues to serve as the official reference guide used and recommended by WHO for its Member States. I noticed in my field work at WHO that the Globalization, Trade and Health team uses the joint guide in country missions and training sessions.) The WHO includes a link on its website to the joint guide, which can be viewed at: <http://www.who.int/trade/resource/wtoagreements/en/index.html>. The WTO website features the joint guide, which can be viewed at: http://www.wto.org/english/news_e/pres02_e/pr310_e.htm.)

meetings relating to access to medicines'.⁵⁷⁴ Frederick Abbott believes that a part of the WTO's lack of cooperation can be attributed 'to normal inter-institutional competition for jurisdictional primacy'.⁵⁷⁵ As noted earlier in this chapter, competition is a potential implication of overlapping institutions.

Given the growing developing country agitation about access to medicines at WTO leading up to the Doha Round, it is understandable that WTO would be concerned about potential distractions or diversions from the institution's main agenda.⁵⁷⁶ The WTO Intellectual Property Division's intention to withhold information for the joint study from WHO may constitute an effort to prevent access to medicines concerns from impeding negotiations for the Doha Round. Concerns about access to medicines were raised at the WTO meetings prior to Doha, which eventually forced WTO to hold a special June 2001 session of the TRIPS Council on intellectual property and access to medicines. This session is credited with leading to '[an] emergent consensus ... that international trade rules should not undermine the legitimate right of WTO members to formulate their own public health policies and adopt measures to safeguard public health'.⁵⁷⁷ In the end, public health proponents were able to achieve a key milestone for AEM with the passage of the Doha Declaration on TRIPS and Public Health in November 2001. This helped to solidify recognition of public health norms (namely AEM) and the use of TRIPS flexibilities within an official WTO document. Concerns

⁵⁷⁴ Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', p. 491.

⁵⁷⁵ *ibid.*, p. 475.

⁵⁷⁶ In fact, to date, the WTO negotiations for the Doha Round are still not complete.

⁵⁷⁷ Velásquez, Correa and Balasubramaniam, 'WHO in the Frontlines of the Access to Medicines Battle: The Debate on Intellectual Property Rights and Public Health', p. 86.

linger, however, over the legal authority of this document in relation to the WTO's dispute settlement mechanism (as discussed earlier).

In the years following the WTO's Doha Declaration on TRIPS and Public Health in November 2001, the interactions between the WTO and the WHO have remained a priority at WHO. As recently as 2006 and 2007, the WHA resolutions have called again for collaboration between WHO and other organizations (including WTO). In the WHA 59.26 on *International Trade and Health*, WHO was requested:

... to *continue collaborating with the competent international organizations* in order to support policy coherence between trade and health sectors at regional and global levels, including generating and sharing evidence on the relationship between trade and health.⁵⁷⁸ (emphasis added)

The establishment of a WHO 'Globalization, Trade and Health' team, which works solely on matters of health and trade and collaborates with WTO, is attributed to WHA 59.26.

Also, in WHA 59.24 on *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action*, the WHO was called upon:

... to convene immediately the *intergovernmental working group* and to allocate the necessary resources to it; (emphasis added)

and

... to *invite, as observers* at the sessions of the intergovernmental working group, representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the United Nations system, of *intergovernmental organizations with which WHO has established effective relations*, and of nongovernmental organizations in official relations with WHO, who shall attend the sessions of the working group in accordance with the relevant Rules of Procedure and resolutions of the Health Assembly.⁵⁷⁹ (emphasis added)

⁵⁷⁸ WHA 59.26

⁵⁷⁹ WHA 59.26

The WHA 59.24 established the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property,⁵⁸⁰ which permitted WHO to act as a new forum for the deliberation of intellectual property rights. Among the intergovernmental organizations in attendance, WTO was granted an 'observer' role during these meetings and was permitted to speak only when requested by official meeting participants. It was observed, however, that the mere entry into the meeting (even as an observer) permitted the WTO to exert influence on member state delegates during the meeting due to the frequent informal conversations that occurred outside the meeting hall and electronically through email or text messaging.⁵⁸¹

In addition, WHA 60.30 on *Public Health, Innovation and Intellectual Property* mandated WHO:

[T]o provide as appropriate, upon request, *in collaboration with other competent international organizations*, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products, and to implement *the Doha Ministerial Declaration on the TRIPS Agreement and Public Health* and other WTO instruments.⁵⁸² (emphasis added)

Here, the WHO is directed to work with the WTO in the provision of support on TRIPS flexibilities and the implementation of the Doha Declaration. This indicates a significant about-face from the 1997 'Red Book' controversy that WHO was faced with about 10 years ago. In its collaboration with WTO, WHO has been working on a variety of activities pertaining to trade and health (as mentioned in the beginning of this section).

The WHO's main project in the area of technical guidance, which engaged WTO,

⁵⁸⁰ The Intergovernmental Working Group will be covered in depth in Chapter 6 (Emerging Trends in the Governance of AEM).

⁵⁸¹ This is based on my observation of and conversation with meeting participants at the Intergovernmental Working Group's 2nd Session in Nov 2007.

⁵⁸² WHA 60.30

appeared to be a ‘policy tool’ and workbook aimed at assisting member states with ‘formulat[ing] better national policies and strategies ... [on] health and trade’ as well as ‘structur[ing] their requests for capacity building ... [on] trade and health’.⁵⁸³ In terms of capacity building, WHO reports that it has engaged with the WTO on almost ten occasions (between 2004-2006) for training sessions related to TRIPS. According to the WHO, it has participated in the WTO’s regional training workshops aimed at trade, patent, and health officials on the ‘implementation of the TRIPS agreement and the Doha Declaration’ as well as a WTO seminar on the ‘Implementation of Paragraph 6 of the Doha Declaration’ through WHO-led session. The WHO and WTO have also held a joint policy module for WHO staff on TRIPS and access to medicines.⁵⁸⁴

In recent years the collaboration appears to have continued,⁵⁸⁵ however, the general direction of activities between the two organizations leads one to wonder if they are aligned. The WTO has taken a recent defensive stance on TRIPS ‘implementability’, especially in relation to the ‘Paragraph 6 system’. In response to developing country concerns that the system might not be ‘working’,⁵⁸⁶ since the system has only been used

⁵⁸³ This was determined through observation of and conversations with the WHO’s Globalization, Trade and Health staff (August 2007). See also WHO, ‘Interagency work on the interface between trade, intellectual property and public health (Report by the Secretariat, A/PHI/IGWG/2/INF.DOC./5)’ (2007) World Health Organization <http://apps.who.int/gb/phi/pdf/igwg2/PHI_IGWG2_ID5-en.pdf> (31 October 2007), p. 3. (This report was developed by the Globalization, Trade and Health Team. In addition to WTO, WHO states that it was working on this tool in collaboration with the ‘World Bank, UNCTAD, bilateral development agencies, academia, centres of excellence and civil society’. It is noted, however, that the level of participation by these various groups varied.)

⁵⁸⁴ *ibid*; WTO, ‘Technical Cooperation Activities: Information From Other Intergovernmental Organizations (Submission by the World Health Organization)’ (2005) World Trade Organization - TRIPS Council <[http://www.who.int/medicines/areas/technical_cooperation/WHOTechCoop\(Oct05\)W456A1.pdf](http://www.who.int/medicines/areas/technical_cooperation/WHOTechCoop(Oct05)W456A1.pdf)> (19 October 2005).

⁵⁸⁵ This is based on a review of WTO press releases on its website regarding WTO and WHO joint activities.

⁵⁸⁶ TWN, ‘TRIPS Council discusses Art. 27.3(b) review, “Para 6” system’ (2010) Third World Network <<http://www.twinside.org.sg/title2/health.info/2010/health20100701.htm>> (6 July 2010)

once (despite its inception in 2003), the WTO Director-General Pascal Lamy has argued that this could be due ‘[i]n part ... from the limited patent coverage of needed medicines in key exporting countries’.⁵⁸⁷ In addition, WTO has been promoting efforts to adopt a ‘broader view on access to medicines’ with a joint inter-organizational⁵⁸⁸ symposium held on 16 July 2010. The focus of the symposium was on pricing and procurement practices, which included topics such as tariffs and regulation ‘to ensure the quality, safety and efficacy of medicines’.⁵⁸⁹ At the meeting, WTO Director-General Pascal Lamy set the tone for the symposium by ‘indicat[ing] that substantive discussion of the WTO’s [TRIPS agreement] was not on the table for discussion’ and that this session was not ‘to establish a parallel policy forum, nor to assess or debate existing legal instruments, [and] not to come up a with policy recommendation’.⁵⁹⁰ Based on the symposium’s press release, one of the key messages from the meeting was that ‘prices are not the only factor determining whether the sick in poor countries can receive medicines’ and that ‘the prices themselves can be affected by [other factors]’.⁵⁹¹ WTO critics argue, however, that ‘[p]atents are a major issue for access, a bigger issue than we have been led to believe [at the symposium]’.⁵⁹² Some civil society organizations fear a broader move by trade

⁵⁸⁷ WTO, ‘Lamy urges multilateral cooperation to advance public health "in the real world"' (2010) World Trade Organization <http://www.wto.org/english/news_e/sppl_e/sppl131_e.htm> (14 July 2009).

⁵⁸⁸ The symposium was sponsored by the WTO and included the participation of the WHO and the World Intellectual Property Organization (WIPO).

⁵⁸⁹ WTO, ‘WHO, WIPO, WTO join forces to put access-to-medicines under the microscope’ (2010) World Trade Organization <http://www.wto.org/english/news_e/news10_e/trip_16jul10_e.htm> (16 July 2010).

⁵⁹⁰ C Saez, ‘Agencies talk cooperation on medicines access; stakeholders cautious’ (2010) Intellectual Property Watch <<http://www.ip-watch.org/weblog/2010/07/19/agencies-talk-cooperation-on-medicines-access-stakeholders-cautious/>> (25 July 2010)

⁵⁹¹ WTO, ‘WHO, WIPO, WTO join forces to put access-to-medicines under the microscope’ . The other factors discussed at the symposium include: ‘poor procurement practices, marketing policies such as differential pricing (where different prices are set in different markets), mark ups (the profit margins companies add to the cost), and border measures such as tariffs, other government charges, import licences (which can also affect availability)’.

⁵⁹² Saez, ‘Agencies talk cooperation on medicines access; stakeholders cautious’.

proponents of a developed country and industry agenda to ‘cynically’ use public safety ‘as a pretext to promote [the IP enforcement]’ through methods such as the Anti-Counterfeiting Trade Agreement (which is discussed further in Chapter 6).⁵⁹³

This section introduced the key aspects of the international institution for trade (i.e. WTO) in relation to AEM and analyzed the critical institutional overlaps between the WTO and WHO. As discussed, there have been a number of serious tensions between the two institutions in terms of conflicting norms and operations. Normative concerns remain, despite the establishment of the Doha Declaration, due to the prevailing power of the WTO’s dispute settlement mechanism and the threat of trade sanctions. (The legal uncertainty of utilizing TRIPS flexibilities, such as the ‘paragraph 6’ system, is illustrated by the recent EU complaint against India.) While the WTO and WHO appear to be addressing the operational tensions through more frequent informal collaboration, there is concern about the WTO’s ability to drive and frame the discussion related to TRIPS (as illustrated by the recent joint symposium).

The Institutional Interactions between International Health and Development

Interactions have also occurred over AEM between the institutions for health and development, particularly in the context of the global HIV/AIDS pandemic. Without clear leadership from the WHO, the international response to major global health issues (such as HIV/AIDS) has been ad hoc and fragmented.⁵⁹⁴ A proliferation of actors (e.g.

⁵⁹³ *ibid.*

international organizations, bilateral programs, and philanthropic organizations) appeared on the global health scene armed with differing agendas and a selective set of health initiatives, but there was initially almost no coordination between them. Access to essential medicines, such as antiretrovirals for HIV, was addressed as part of these initiatives; however, the larger problems associated with the institutional interactions between health and development caused a number of complications for the achievement of AEM.

The interactions between the institutions for health and development present a very different set of issues for the governance of AEM and the implementation of international assistance and cooperation by states, in comparison to the interactions between the institutions for trade and health. As this section will show, through the same analytical framework (i.e. interaction characterization, implications, and management), there is a complex relationship between the main institutions for health and development. Though their goals generally align, the institutions have found themselves in competition for power and resources. In addition, this section will reveal that new institutions could emerge in the midst of interactions with the aim to address coordination and cooperation; however, such new institutions are not always successful and can lead to further complexity. Understanding these interactions will help to shed light on where IAC for AEM stands today and how it arrived at this state.

The complexity of analyzing these institutional interactions requires a focus on a particular area of major concern for both health and development – HIV/AIDS.⁵⁹⁵

⁵⁹⁴ Gostin; Fidler, 'The Challenges of Global Health Governance. International Institutions and Global Governance Program Report'

⁵⁹⁵ As presented in the introduction, my research analyzed institutional interactions on AEM in the health and development space by tracing institutional activities on the HIV/AIDS disease. The health and

HIV/AIDS provides an illustrative study on the issue of AEM and now the growing attention and activity on IAC for AEM, more specifically. Even within the HIV/AIDS space of institutional interactions, there are still a wide variety of actors involved.⁵⁹⁶ This study, however, focuses on the interactions between the most powerful intergovernmental institutions on HIV/AIDS in the pursuit of a deeper understanding of the critical relationships in these interactions. The chapter will begin with an introduction to the World Bank's role in HIV/AIDS (with an emphasis on AEM activities) as well as an analysis of its interactions with WHO. It will then discuss the emergence of the two relatively new institutions, the Joint UN Programme on HIV/AIDS (UNAIDS) and the Global Fund on the Fight Against AIDS, Tuberculosis and Malaria (the Global Fund), and how their involvement has affected the dynamics of institutional interactions between health and development.

The World Bank

The combination of the World Bank's financial power and aggressive health initiatives had led to the belief that the World Bank would displace the WHO as the 'premier global health agency'.⁵⁹⁷ During the 1990s, such prospects were possible for the World Bank because the WHO had become stagnant in its international role. Reports of 'cronyism, a lack of direction and cohesion, a reluctance to shift its focus away from prevention of

development sector has become so complex over the years (with a proliferation of different actors), it would be very difficult to capture all of the institutional interactions on the topic of AEM. Hence, I found it necessary to select a particular disease for study and HIV/AIDS was chosen. (The reasons for this selection were covered in Chapter 1.)

⁵⁹⁶ These actors include a broad array of issue-focused intergovernmental organizations (such as UNICEF), nongovernmental organizations (including philanthropic organizations), multinational corporations, etc.

⁵⁹⁷ G Yamey, 'WHO in 2002: Why does the world still need WHO?' (2002) 325 *British Medical Journal* 1294, p. 1294; I Kickbusch, 'The Development of International Health Policies - Accountability Intact?' (2000) 51 *Social Science & Medicine* 979, p. 982. (See also K Lee, *The World Health Organization* (Global Institutions, Routledge, Abingdon 2009), p. 111-112.)

infectious diseases, and a reluctance to tarnish its image with governments',⁵⁹⁸ were crippling problems that plagued the WHO under the leadership of then Director-General Hiroshi Nakajima. As a result, WHO was sidelined to the supporting role of providing 'medical expertise' and 'technical support' while the World Bank worked on health initiatives with the ministries of health, finance, and planning in developing countries.⁵⁹⁹

While many non-health focused IGOs, such as UNICEF and UNDP, have crossed into the realm of global health;⁶⁰⁰ none have had the same level of influence upon this area as the World Bank. The World Bank, a UN specialized agency, operates under a very different governance structure compared to most other UN intergovernmental organizations. As a 'bank', it is owned by 186 countries with the largest shareholdings traditionally held by the world's most industrialized nations.⁶⁰¹ In consequence, this has allowed the richer countries to exert greater influence upon the World Bank as they possess greater voting power due to their holdings of capital shares.⁶⁰² The largest shareholder, which is currently the U.S., holds the traditional power of nominating the World Bank president but the nominee's appointment is subject to the approval of the

⁵⁹⁸ K Abbasi, 'The World Bank and World Health: Changing Sides' (1999) 318 *British Medical Journal* 865, p. 868.

⁵⁹⁹ *ibid*, p. 868.

⁶⁰⁰ R Dodgson, K Lee and N Drager, 'Global Health Governance: A Conceptual Review' (2002) *World Health Organization* <http://libdoc.who.int/publications/2002/a85727_eng.pdf> (June 15, 2008)

⁶⁰¹ Up until 2010, the five largest shareholders of the World Bank were the United States, the United Kingdom, France, Germany, and Japan. The voting powers changed, however, in 2010 when the World Bank changed reformed the voting powers in order to 'better reflect the realities of a new multi-polar global economy where developing countries are now key players'. The countries with the top voting powers are the United States (15.85%), Japan (6.84%), China (4%), Germany (4%), the United Kingdom (3.75%), and France (3.75%). See *World Bank*, 'World Bank Reforms Voting Power, Gets \$86 Billion Boost' (2010) *The World Bank* (Press Release) <<http://go.worldbank.org/VOCHUCZQL0>> (25 April 2010); L Wroughton, 'China gains clout in World Bank vote shift' *Reuters* (U.S. Edition 25 April 2010)

⁶⁰² Kohlmoorgen, p. 135-136.

World Bank's board of governors.⁶⁰³ The board of governors, which represents the government shareholders at annual meetings, have the ultimate decision-making authority in the World Bank.⁶⁰⁴ Today, the World Bank's agenda is driven by the goals of sustainable economic development and the reduction of poverty in low and middle-income countries.⁶⁰⁵ To achieve this objective, the World Bank functions as an intermediary that attracts financial support from developed countries as well as private capital markets and then allocates the funds as either grants or loans to developing nations.⁶⁰⁶ Its ability to provide such financial resources to developing countries is a significant source of influence on national policies.⁶⁰⁷

Since the 1990s, the World Bank has become known for its comparatively large financial investments in health initiatives in developing countries.⁶⁰⁸ Upon recognizing the connection between public health and its mission of 'reducing poverty and improving living standards' in developing countries,⁶⁰⁹ the World Bank moved beyond its core financier operations and launched the implementation of 'a whole array of health

⁶⁰³ World Bank, 'World Bank Approach paper: Evaluation of the World Bank's Assistance for Health, Nutrition, and Population' Independent Evaluation Group, World Bank Sector, Thematic and Global Evaluations Unit (27 July 2007). (There is a 'handshake agreement that has for more than 60 years given the president of the United States the right to select the World Bank chief while allowing Europe to pick the head of the International Monetary Fund'. See PS Goodman, 'Bush to Pick Zoellick for World Bank' *The Washington Post* (Washington, DC 30 May 2007).)

⁶⁰⁴ World Bank, 'World Bank Approach paper: Evaluation of the World Bank's Assistance for Health, Nutrition, and Population'

⁶⁰⁵ C Gilbert and D Vines, *The World Bank* (Cambridge University Press, Cambridge, UK 2000), p. 10

⁶⁰⁶ *ibid.*

⁶⁰⁷ *ibid.*

⁶⁰⁸ From a historical perspective, it is interesting to note that the World Bank went from 'virtually no presence in global health to [becoming] the world's largest financial contributor to health-related projects It is also one of the world's largest supporters in the fight against HIV/AIDS, with commitments of more than \$1.6 billion in [the early 2000s]'. See JP Ruger, 'The Changing Role of the World Bank' (2005) 95 (1) *American Journal of Public Health* 60, p 61.

⁶⁰⁹ Abbasi.

initiatives ... bringing new money and fresh ideas to tackle disease'.⁶¹⁰ In terms of access to essential medicines, the World Bank's efforts have mainly focused on treatments for HIV/AIDS, tuberculosis, and malaria in developing countries. This section will focus on the World Bank's efforts on HIV/AIDS.

The World Bank's Mission and Agenda

The World Bank has played a critical role in facilitating access to essential medicines for HIV, though not in the same sense as the WHO. While the WHO agenda is directed to uphold the 'right to health', the World Bank's current agenda is driven by development assistance for the reduction of poverty in low and middle-income countries.⁶¹¹

Specifically, it functions as an intermediary that attracts financial support from developed countries (and now also emerging economies) and then distributes the funds in the form of grants or loans to support developing countries. Antiretrovirals for HIV has been deemed one such worthy cause by the World Bank, as discussed later in this section.

The World Bank has come to elevate and incorporate health issues in its work through the Comprehensive Development Framework (CDF) approach,⁶¹² which 'views development as a holistic and multidimensional process that focuses on people in the

⁶¹⁰ Yamey, p. 1294.

⁶¹¹ N Poku, 'The Global AIDS Fund: Context and Opportunity' (2002) 23 (2) *Third World Quarterly* 283, p. 289 (The World Bank's Health, Nutrition and Population sector, which is described a bit later, defines 'investments in [health as] constitut[ing] an investment in human capital, and are necessary for enhanced welfare, reduced poverty, and sustainable growth'. See R Govindaraj, MR Reich and JC Cohen, 'World Bank Pharmaceuticals' (2000) World Bank Health, Nutrition and Population (HNP) Discussion Paper <<http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/Govindaraj-WBPharmacuetical-whole.pdf>> (10 July 2008), p. 6.)

⁶¹² The Comprehensive Development Framework was introduced under the term of World Bank president John Wolfensohn, who served from 1997 to 2005.

societies in which it operates'.⁶¹³ More specifically, the CDF is used to develop national poverty reduction strategies for borrowing governments and then operationalized through the Poverty Reduction Strategy Paper (PRSP).⁶¹⁴ According to a WHO analysis, the investments by PRSPs in health tend to be 'based on assumptions about what works to reach the poor, rather than a systematic evaluation of the specific needs in the local situation'.⁶¹⁵ HIV/AIDS, for example, has been framed by the World Bank as 'a development problem that can threaten human welfare, socioeconomic advances, productivity, social cohesion, and even national security'.⁶¹⁶ (As discussed a bit later, the World Bank's HIV/AIDS programmes embraced the CDF philosophy.)

Health operations at the World Bank are guided by its Health, Nutrition and Population (HNP) sector's 'strategy papers', which have appeared in 1997 and then in 2007. These strategy papers present the set of objectives that the institution seeks to achieve. For example, in 1997, the HNP strategy paper stated the aims of: (1) improving the health, nutrition, and population outcomes of the poor and protect the population from the impoverishing effects of illness, malnutrition and high fertility; (2) enhancing the performance of health care systems; and (3) securing sustainable health care financing.⁶¹⁷ In addition, it sought to leverage the Bank's strengths of global expertise, multisectoral, and macro-level country focus as well as its 'ability to mobilize large financial resources,

⁶¹³ Ruger, 'The Changing Role of the World Bank', p.61.

⁶¹⁴ See World Bank, 'Comprehensive Development Framework' (2010) <<http://go.worldbank.org/N2NDBE5QL0>> ; WHO, 'Comprehensive Development Framework (CDF)' (2010) World Health Organization <<http://www.who.int/trade/glossary/story009/en/index.html>>

⁶¹⁵ WHO. Poverty Reduction Strategy Papers. <http://www.who.int/trade/glossary/story075/en/index.html>

⁶¹⁶ M Görgens-Albino and others, 'The Africa Multi-Country AIDS Program (2000–2006)' (2007) The Global AIDS Monitoring and Evaluation Team of the Global HIV/AIDS Program (the World Bank) <<http://siteresources.worldbank.org/EXTAFRREGTOPHIVAIDS/Resources/717147-1181768523896/complete.pdf>> (10 July 2009), p. 11.

⁶¹⁷ World Bank, *Healthy Development* (The World Bank Strategy for HNP Results 2007)

either directly or through partnerships'.⁶¹⁸ The 2007 HNP strategy paper states that the World Bank's new objectives are to: (1) improve the level and distribution of key HNP outcomes, outputs, and system performance at the country and global levels in order to improve living conditions, particularly for the poor and vulnerable; (2) prevent poverty due to illness; (3) improve financial sustainability in the HNP sector and its contribution to sound macroeconomic and fiscal policy and to country competitiveness; and (4) improve governance, accountability and transparency in the health sector. While it may appear that the HNP objectives between the 1997 and 2007 strategy papers seem similar,⁶¹⁹ the World Bank appears to be following the 2007 strategy more carefully this time around.

The World Bank's Financial Power and Influence on HIV/AIDS

In the resource constrained environment of international health, it has been observed that the World Bank's 'main advantage [or power] compared with other intergovernmental institutions is its ability to mobilize financial resources'.⁶²⁰ The World Bank, as the largest health funder, has tremendous influence on global health through an array of 'loans, credits, and grants'.⁶²¹ In particular, it has been one of the largest funders of global HIV/AIDS efforts with a total allocation of \$4.5 billion over the past twenty years.⁶²²

⁶¹⁸ *ibid.*

⁶¹⁹ World Bank, 'Evaluation of the World Bank's Assistance for Health, Nutrition, and Population' (2007) Independent Evaluation Group, World Bank <<http://www.oecd.org/dataoecd/52/11/39598722.pdf> > (As pointed out by this analysis, both strategy papers place emphasis on 'improving health system performance and inter-sectoral approaches'.)

⁶²⁰ Ruger, 'The Changing Role of the World Bank', p. 67.

⁶²¹ *ibid.*, p. 67-69; Kohlmorgen, p. 136.

⁶²² World Bank, 'As Fight Against AIDS Intensifies, World Bank Reaffirms Role in Global Response' (2010) World Bank <<http://go.worldbank.org/WLGORY56B0> > (July 15, 2010).

The World Bank, however, was not initially involved in a full-scale effort to address the HIV/AIDS crisis. By some accounts, the World Bank (like the WHO) was considered late in recognizing and addressing the epidemic occurring in many developing countries.⁶²³ Between 1986 and 1997, the World Bank engaged in some lending to countries on HIV/AIDS; however, there was not a great sense of concern about the subject within the institution. It has been described that the World Bank exhibited ‘a scattershot approach rather than determined action [on HIV/AIDS] ... [as] [s]ome in the Bank wanted to do more; others were not sure’.⁶²⁴ In addition, a number of borrowing countries either expressed reluctance or denial on the subject of HIV/AIDS; thus disincentivizing the World Bank’s loan officers from developing loans that a client would not want.⁶²⁵

While the regional offices of the World Bank were recognizing the growing HIV/AIDS crisis occurring in their areas of responsibility,⁶²⁶ the World Bank’s HNP sector central office (at the Washington, D.C. headquarters) was not enthusiastic about addressing an issue that would challenge its newly formulated 1997 HNP strategy. According to a World Bank account, ‘mobilizing resources to fight any single disease, including HIV/AIDS, was seen by the [World] Bank’s health sector leadership as a lower

⁶²³ S Mallaby, *The World's Banker* (Penguin Press, New York 2004), p. 318.

⁶²⁴ *ibid*, p. 318.

⁶²⁵ *ibid*, p. 316-318; World Bank, 'Committing to Results: Improving the Effectiveness of HIV/AIDS Assistance ' (2005) The World Bank Operations Evaluation Department <http://siteresources.worldbank.org/EXTHIVAIDSIEG/Resources/hiv_complete_report.pdf> (10 July 2009), p. 13-14.

⁶²⁶ World Bank, 'Committing to Results: Improving the Effectiveness of HIV/AIDS Assistance ', p. 13. (During the 1990s, there were four early AIDS strategies developed in the Africa region and more informal efforts on AIDS occurring in the East Asia and Pacific region as well as the Latin America and Caribbean region.)

priority than reforming weak health systems’ and there was concern that ‘address[ing] the AIDS epidemic might somehow compete with this agenda, given scarce capacity’.⁶²⁷ In fact, the Africa region was ‘cautioned that an expanded role of the [World] Bank in AIDS should not be allowed to overtake the critical agenda for strengthening health systems’.⁶²⁸ Overall, the World Bank gave the impression that HIV/AIDS was not a major priority as institutional leadership appeared ‘indifferent’ about the subject and continued with ‘business pretty much as usual’.⁶²⁹

Things began to change in the late 1990s within the World Bank after an internal crusade to bring attention to HIV/AIDS by Debrework Zewdie (a doctor working in the central HNP sector on AIDS) and Hans Binswanger (a prominent, HIV-positive World Bank economist).⁶³⁰ Through a series of talks, Zewdie gained the support of the Africa region’s top management about the devastation being caused by the HIV/AIDS pandemic and was charged with developing an AIDS strategy for the Africa region. This strategy eventually became known as the Multi-Country AIDS Program (MAP). There was internal disagreement, however, between the World Bank’s economists and AIDS proponents over the appropriate World Bank strategy on HIV/AIDS. Based on their research, the economists endorsed a top-down approach that targeted high-risk and

⁶²⁷ *ibid*, p. 15.

⁶²⁸ *ibid*, p. 15.

⁶²⁹ Mallaby, p. 319. (It is noted that the World Bank’s World Development Report mentioned that AIDS ‘should be prioritized because it kills people in their prime’; however, the ‘leadership of the health sector within the [World] Bank remained reluctant to elevate AIDS above other diseases’. See Mallaby, p. 436.)

⁶³⁰ Mallaby, p. 320-322; S Harman, ‘The Causes, Contours and Consequences of Multi-Sectorialism’ (2007) University of Warwick - Conference on the Governance of HIV/AIDS Responses: Making Participation and Accountability Count <<http://www2.warwick.ac.uk/fac/soc/csgr/events/conferences/2007/hiv aids/papers/harman.doc>> (9 July 2008). (Sophie Harman argues that Zewdie and Binswanger’s internal campaign on HIV/AIDS ‘would no[t] (sic) have been possible at a different time in Bank practice and Presidency’ given the World Bank’s bureaucratic and top-down nature of management.)

marginalized populations which contrasted with the opinion of the AIDS community-at-large (including Zewdie and Peter Piot⁶³¹) to adopt a ‘comprehensive strategy’ that involved a ‘broad social mobilization’ (including the grassroots community).⁶³² (It is interesting to note that the latter proposal is also strongly aligned with the then-World Bank President James Wolfensohn’s Comprehensive Development Framework approach and that he backed the HIV/AIDS plan proposed by Zewdie.)⁶³³ These internal disagreements triggered Zewdie to develop a strategy known as *Intensifying Action Against HIV/AIDS in Africa: Responding to a Development Crisis*⁶³⁴ and press for a ‘freestanding AIDS department’ in the Africa region, so that the Bank’s HIV/AIDS efforts would not get ‘mired in trade-offs against other public health crises’, which she won.⁶³⁵ The World Bank’s shareholder approval for Zewdie’s MAP was also granted after the institution placed the issue of HIV/AIDS on the agenda and urged them to pass it.⁶³⁶ The shareholders agreed to support the HIV/AIDS program in Africa by committing an initial \$500 million in 2000 and then another \$500 million two years later for the second stage of the programme.⁶³⁷ In the World Bank’s broader operations, the urgency of the HIV/AIDS crisis was also embraced by the World Bank president James

⁶³¹ Peter Piot was the first appointed leader of the UN Joint Programme on HIV/AIDS (UNAIDS). UNAIDS will be described later in this chapter.

⁶³² Mallaby, p. 324-326.

⁶³³ Harman, p. 5.

⁶³⁴ Görgens-Albino and others, p. 12. (The World Bank notes that the strategy was developed in partnership with UNAIDS and African governments and that it aimed ‘to put HIV/AIDS at the center of the development agenda in Africa’. The strategy endorsed four actions by the World Bank: (1) to ‘increase advocacy to boost demand for action against HIV/AIDS as a central development issue’; (2) to ‘strengthen the Bank’s capacity to meet the anticipated increase in demand’; (3) to ‘expand resources for AIDS programs’; and (4) to ‘expand knowledge about the epidemic and how to respond effectively’.)

⁶³⁵ Mallaby, p. 327.

⁶³⁶ *ibid*, p. 328-329.

⁶³⁷ Görgens-Albino and others, p. 13.

Wolfensohn, who triggered attention to this issue under his leadership for other borrowing countries such as Russia and India.⁶³⁸ As explained by this brief history, the World Bank's leading role in HIV/AIDS eventually arose out of international urgency in 1999 and its response was shaped by the World Bank's new vision for development (i.e. the CDF).⁶³⁹

World Bank Operations on HIV/AIDS and Access to Essential Medicines Activities

From 1999, the World Bank was active in bringing HIV/AIDS to the forefront of international attention. According to a World Bank account, the institution 'play[ed] a leadership and advocacy role at high levels, engaged international audiences about HIV, and put HIV/AIDS on the agenda of the annual spring meetings with finance ministers'.⁶⁴⁰ The World Bank's Multi-Country HIV/AIDS Program (MAP) for Africa, which was launched in 2000, became an important feature of the institution's response to the global HIV/AIDS crisis. The programme leveraged the World Bank's advantage of financial mobilization when it was granted the authority 'to approve individual country or subregional International Development Association (IDA) credits and grants on a fast, "no objection" basis, up to a total of \$500 million [for the first stage], to support national and regional HIV programs'.⁶⁴¹ Overall, the MAP received a commitment from the World Bank of \$1.286 billion from fiscal year (FY) 2001-2006.

⁶³⁸ Mallaby, p. 320. (By 1999, the impact of AIDS was unavoidable for the World Bank. AIDS had become the leading cause of death in Africa.); World_Bank, 'Committing to Results: Improving the Effectiveness of HIV/AIDS Assistance '

⁶³⁹ Görgens-Albino and others, p. 11-12.

⁶⁴⁰ *ibid*, p. 12.

⁶⁴¹ Görgens-Albino and others, p. 13.

MAP was envisaged by the World Bank to have three phases whereby each would last approximately four to five years; hence, the programme would be completed between 2012 and 2015.⁶⁴² In relation to AEM for HIV/AIDS, each phase has a critical role to play. The first phase sought to ‘scale up ... treatment programs’ and was envisioned ‘to lay the foundation for long-term, country-specific responses to HIV’ through activities such as treatment and care capacity building.⁶⁴³ The next phase aimed to ‘expand ... treatment interventions’ and to ‘attempt to include all interested countries that did not take part in the first phase’. Finally, in the third phase, MAP expected a decline in infections and would place ‘a sharper focus on areas or groups where spread of the disease continued’. In the World Bank’s MAP accounting for the period of FY 2001-2006, the institution observed that the MAP was focused on being ‘fast’ and ‘comprehensive’ through ‘flexibility’, ‘learning by doing’, and ‘project modification’.⁶⁴⁴ It also claimed that the MAP programme has helped to ‘lay the groundwork for other donors’ and ‘by committing half a billion dollars, with more to come, it raised the funding benchmark for other donors’.⁶⁴⁵ This account appears to portray the World Bank’s inexperience (and, perhaps, lack of technical expertise) in HIV/AIDS programmes in a positive light, but it has undoubtedly played a pioneering role by channelling large-scale funds to address the disease.

⁶⁴² *ibid*, p. 15.

⁶⁴³ It is worth noting that the World Bank’s Board of Directors ‘endorsed [MAP] funding for [ARV] procurement as part of comprehensive AIDS programming’ in 2002. See UNAIDS, ‘UNAIDS: The First Ten Years’ (2008) UNAIDS <http://data.unaids.org/pub/Report/2008/JC1579_First_10_years_en.pdf> (10 June 2009), p. 163.

⁶⁴⁴ Gørgens-Albino and others, p. 13.

⁶⁴⁵ *ibid*, p. 14.

MAP provides a significant example of the World Bank's involvement in addressing the international HIV/AIDS emergency, which included funding for 'medicines procurement and supply'.⁶⁴⁶ The World Bank has also supported AEM through medicines policy development and procurement financing across all six regions of its operations and for other diseases.⁶⁴⁷ It is worth noting the World Bank, itself, does not engage directly in 'the production, procurement or purchasing of pharmaceuticals, nor does it have any regulatory capacity'.⁶⁴⁸ Rather, its influence on AEM is established through its policies and financing for pharmaceuticals. Most analyses of the World Bank's pharmaceutical lending indicate that a substantial amount of the funds were used for medicines procurement.⁶⁴⁹ In addition, the pharmaceutical loans can take a variety of project forms. For example, according to a study by Ramesh Govindaraj and his colleagues, it found that the World Bank's lending practices in relation to medicines included: (1) '[Health, Nutrition and Population] projects that finance drug procurement for specific diseases'; (2) 'pharmaceutical standalone [p]rojects'; (3) 'pharmaceutical components as part of broader health reform projects'; and (4) 'projects linked to non-health-specific activities, such as structural adjustment, critical investment, and private

⁶⁴⁶ Leach, Paluzzi and Munderri, p.14.

⁶⁴⁷ *ibid*, p.14; Govindaraj, Reich and Cohen, p. 6.

⁶⁴⁸ J Rovira, 'Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries' (2004) 4 (2) *Yale Journal of Health Policy, Law & Ethics* 401, p. 408.

⁶⁴⁹ Rovira; R Rodriguez-Monguio, J Rovira and E Seoane-Vazquez, 'Analysis of the World Bank's pharmaceutical lending' (2007) 81 *Health Policy* 102; T Falkenberg and G Tomson, 'The World Bank and Pharmaceuticals' (2000) 15 (1) *Health Policy and Planning* 52; Govindaraj, Reich and Cohen. (It is worth noting that, in addition to drug procurement, the World Bank's pharmaceutical lending can also encompass: 'laboratory equipment for biomedical and drug quality control laboratories'; 'civil works related to restoration of pharmaceutical warehouses, hospitals, pharmacies or drug retail facilities and vehicles for drug distribution'; 'purchase of computer systems and programmes to be used for drug registration, drug inspection, drug price and market monitoring or procurement'; 'training, education and information in the fields of pharmaceutical management, national drug policy development, rational use of drugs, drug seller training, essential drug programmes, inspection and quality control'; and 'technical assistance in relation to, for example, procurement arrangements, legislation and regulation, distribution policy, cost recovery, pricing policy and operational research'. See Falkenberg and Tomson, p. 53.)

sector investment loans'.⁶⁵⁰ All of this helps to illustrate the expansive level of involvement that the World Bank has had on the issue of AEM.

In terms of the World Bank's medicines procurement procedure, the borrower country governments are 'responsible for purchasing [the medicines] for World Bank financed projects' and the World Bank then holds the task of 'monitor[ing] [country] procurement to ensure it is conducted efficiently and in an open, competitive and transparent manner'.⁶⁵¹ The World Bank's procurement guidelines indicate that there are several methods available for procurement, but the process of International Competitive Bidding is the preferred method for non-patented essential drugs and vaccines.⁶⁵² The alternative methods of National Competitive Bidding (NCB)⁶⁵³ and Limited International Bidding (LIB)⁶⁵⁴ are permitted when 'the characteristics of the products and the markets, the nature and size of the procurements, the likelihood of interests by foreign bidders, the critical dates for delivery, or the administrative or financial burden involved would make

⁶⁵⁰ Govindaraj, Reich and Cohen, p. 6. (The researchers also note that the World Bank has been involved in non-lending activities related to pharmaceuticals; these activities include: 'policy dialogue with governments on developing national drug policies'; 'drug pricing strategies'; and UN pharmaceutical partnership efforts through the Interagency Pharmaceutical Coordination.)

⁶⁵¹ Rodriguez-Monguio, Rovira and Seoane-Vazquez, p. 103. (The authors note that according to the 'Articles of Agreement', the World Bank 'must "...ensure that the proceeds of any loan are used only for the purposes for which the loan was granted, with due attention to considerations of economy and efficiency and without regard to political or other non-economic influences or considerations"'. If a country were to succumb to political pressures against the procurement of generics, this could provide a basis from which the World Bank can react.)

⁶⁵² R Rodriguez-Monguio, J Rovira and E Seoane-Vazquez., p. 103.

⁶⁵³ NCB is the process of bidding only within the borrowing country without foreign competition.

⁶⁵⁴ LIB applies the process of ICB, but through a direct invitation to bidders and no open advertisement. It is also interesting to note that the World Bank encourages 'the development of domestic contracting and manufacturing industries in the borrowing countries' and will permit the borrowing country to 'grant a margin of preference in the evaluation of bids under certain procedures to bids offering goods manufactured in the country of the borrower' with the World Bank's agreement. See R Rodriguez-Monguio, J Rovira and E Seoane-Vazquez., p. 103.

difficult or inefficient the use of ICB procedures'.⁶⁵⁵ When the World Bank began to address the HIV/AIDS emergency (including treatment), it did not have an 'explicit strategy to guide its policy dialogue and funding in the pharmaceutical sector'.⁶⁵⁶ More specifically, the World Bank did not clearly dictate how to handle the procurement of generic antiretrovirals (ARVs) for the treatment of HIV (which were still on patent).⁶⁵⁷ In the case of many antiretrovirals, due to the 'supply limitations resulting from patents and registration requirements', the procurement of these pharmaceuticals are usually considered single-source or limited-source products.⁶⁵⁸ This means that there tends to be only a single or limited number of suppliers of the medicine.

In 2000, the then-Director of the HNP sector (Christopher Lovelace) and then-sector leader of the Health, Nutrition and Population (HNP) Africa Region (Ok Pannenborg) issued a joint statement on essential medicines:

The timely provision of good quality essential drugs to those in need, and particularly to the poor and the vulnerable, is an important component of the World Bank's mission "... to fight poverty with passion and professionalism for lasting results". ... Access by the poorest communities to essential medicines at the right time, the right place, and the right price remains an enormous efficiency challenge for most low- and many middle-income countries. ... Ultimately, of course, these pharmaceutical sector challenges are not mainly economic or technical in nature, but are part of the larger moral and equity concerns which are at the core of the development mandate of the Bank ...⁶⁵⁹

Clearly, as indicated by this statement, the HNP leadership has come to view the issue of AEM as a key part of the World Bank's development mandate. It is also important to note

⁶⁵⁵ *ibid.*, p. 103.

⁶⁵⁶ Govindaraj, Reich and Cohen, p. 1.

⁶⁵⁷ Rovira, p. 410.

⁶⁵⁸ L Gable and others, 'Legal Aspects of HIV/AIDS: A Guide for Policy and Law Reform' (2007) The World Bank (Global HIV/AIDS Program and Legal Vice Presidency) <<http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1103037153392/LegalAspectsOfHIVAIDS.pdf>> (10 June 2009), p. 211.

⁶⁵⁹ Govindaraj, Reich and Cohen, p. 1.

that this statement aligns well with the WHO's requirements for essential medicines (as defined in Chapter 1), in terms of medicines being available 'at the right time, right place, and the right price'.⁶⁶⁰ Operationalizing the idea, however, was another story. A former member of the World Bank's 'pharmaceuticals group', which operates within the Health Systems Development section of the HNP sector,⁶⁶¹ recounts that:

Uncertainties on the part of both the [World] Bank and country ministers regarding the implications of TRIPS for developing countries sometimes resulted in countries choosing [the] originator⁶⁶² product aimed at ensuring conformity with a country's domestic legislation and with international agreements.⁶⁶³

The World Bank has since made an effort to adopt an official position on the issue of generics ARVs.⁶⁶⁴ In 2004, the World Bank released a technical guide on HIV/AIDS medicines procurement, which specifically addressed the issue of generic ARVs. The World Bank's policy for the MAP programme states:

... recipient countries may use those funds to procure ARVs in any circumstances that are legal. So long as the said ARVs are manufactured and distributed in accordance with relevant standards of quality, safety, and efficacy, there is no preference regarding whether such ARVs are purchased from a patent holder with respect to such medicine or from a vendor of the same medicine that produces and

⁶⁶⁰ The World Bank and WHO collaborated on essential medicines policy issues as part of the Interagency Pharmaceutical Coordination (IPC) group, along with other intergovernmental organizations (such as UNICEF, UNFPA, the Global Fund, and FAO), International Federation of Pharmaceutical Manufacturers (IFPMA), Médecins Sans Frontières (MSF), and others. Leach, Paluzzi and Munderrri, p.14; Govindaraj, Reich and Cohen, p. 1; WHO, 'Essential Medicines Biennial Report: 2006-2007' (2008) WHO/PSM/TCM/2008 <http://www.who.int/medicines/areas/access/EssentialMedsBiennialReport06_07.pdf> .

⁶⁶¹ The 'pharmaceuticals group' within the HNP sector works on pharmaceutical issues as they relate to health systems development. Through interviews with former World Bank staff and former associates, it was determined that the group conducts analyses of various pharmaceutical issues; monitors World Bank support on pharmaceuticals; provides guidance and strategy (on topics such as pharmaceutical policies, essential drug lists, procurement, regulation, and pricing) to internal management and country clients; designs the 'pharmaceutical components' for World Bank projects; and liaises with other intergovernmental organizations to share information, discuss issues, and harmonize pharmaceutical-related procedures.

⁶⁶² The term 'originator' basically refers to the patent-holder.

⁶⁶³ Rovira, p. 410.

⁶⁶⁴ It is interesting to note that a 2000 New York Times op-ed by a then-Managing Director and then-Chief Economist of the World Bank encouraged broader access to generic medicines beyond HIV/AIDS, malaria and TB. They stated 'ensuring continued legal access to generics for the poorest countries is vital to improving [developing country] health care systems...'. See Ramphele and Stern.

sells under circumstances in which the consent of the patent holder is not required.⁶⁶⁵

The World Bank also offers the following general guidance to its borrowers on generic HIV/AIDS medicines:

To sum up, a government may issue a compulsory licence to its procurement authority to acquire generic HIV/AIDS medicines, including by import, despite the presence of a local patent by stating that it is doing so to address a national emergency or circumstance of extreme urgency. As a matter of general practice, it is preferable that national patent or public health laws or regulations expressly provide a basis for such action. But if such laws or regulations are not in place, this does not prevent a government from taking this action. Inherent in the sovereignty of every government is the right to protect the public interest in a national emergency or circumstance of extreme urgency, and the government does not need to refer to specific national legislation to exercise this authority. Nothing in the TRIPS Agreement requires that the steps a government takes in these circumstances be laid out in advance.⁶⁶⁶

It is interesting to note that this policy not only brings attention to the use of TRIPS-flexibilities (i.e. compulsory licensing), but it also sets out to clarify the application of TRIPS for developing countries. The World Bank's policy guidance was reportedly welcomed by access to medicines activists.⁶⁶⁷ Theoretically, the World Bank's tacit endorsement of generic medicines in procurement (along with its requirement of competitive bidding procedures) could influence the medicines market by encouraging competition and, thus, lowering prices.⁶⁶⁸ Juan Rovira, a former World Bank economist from the pharmaceuticals group, observes that although the World Bank's impact on the market is 'limited by the relatively modest amount of its own pharmaceutical lending', it could lead to 'a strong demonstration effect on countries and other institutions, such as

⁶⁶⁵ World Bank, 'HIV/AIDS Medicines and Related Supplies: Contemporary Context and Procurement (Technical Guide)' (2004) World Bank
<<http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Technical-Guide-HIV-AIDS.pdf>> (1 April 2008), p. 24.

⁶⁶⁶ *ibid.*, p. 89.

⁶⁶⁷ Rovira, p. 408.

⁶⁶⁸ *ibid.*, p. 408.

[the Global Fund], based on the prestige and leverage that the [World] Bank has on economic and policy issues in the international arena'.⁶⁶⁹ He also suggests that the World Bank's approach to HIV/AIDS medicines could be expanded to other medicines where intellectual property rights currently hinder access. Interestingly, it does not seem that the World Bank's latest positions on generics have created issues with its major shareholders (which are predominantly rich industrialized countries) nor has it been altered or revoked under the latest World Bank President – Robert Zoellick.⁶⁷⁰

Analyzing the Institutional Interactions between International Health and Development

The Parallel Relationship between WHO and World Bank Aims

Obvious similarities in the missions of the World Bank and the WHO have emerged over the past two decades. As discussed earlier, the World Bank has been seeking to address economic development and the problem of poverty from a more 'holistic' and multisectoral approach. This naturally broadened the World Bank's work into the realm of health as a contributing factor. The WHO, ever since the term of Director-General Brundtland, has paid growing attention to concept of the 'social determinants of health', which includes economic conditions.⁶⁷¹ In fact, Director-General Brundtland has publicly stated that 'health is central to development' and worked to 'demonstrat[e] a

⁶⁶⁹ *ibid*, p. 411.

⁶⁷⁰ Robert Zoellick, the current World Bank president, was appointed as the World Bank President in 2007. Prior to joining the World Bank, he served as the U.S. Trade Representative from 2001 to 2005. See J Love, 'Bob Zoellick and Medicine Patents in Poor Countries' (2007) *The Huffington Post* <http://www.huffingtonpost.com/james-love/bob-zoellick-and-medicine_b_49929.html> (1 Sept 2009).

⁶⁷¹ JP Ruger and D Yach, 'The Global Role of the World Health Organization' (2009) 2 (2) *Global Health Governance* 1, p. 5.

strong link between health and economic development' during her time at WHO.⁶⁷² It has been argued, however, that DG Brundtland used this link as a strategy to 'elevat[e] the status of health-related investment' and, thus, attract donor funds.⁶⁷³ Interestingly, HIV/AIDS has emerged as the 'poster child' of health and development efforts due, in part, to institutional interactions on the matter. Both the international institutions for health and development have championed the issue and shaped the way it is addressed (including the promotion of access to antiretrovirals). The fact that the WHO was embroiled in an internal political struggle over the issue (as described in Chapter 3) allowed the World Bank to step in and take the lead from WHO on efforts to battle the disease. The WHO has since returned to addressing the HIV/AIDS epidemic, most notably with its '3 by 5' campaign,⁶⁷⁴ and thus both institutions were addressing the issue of AEM for HIV/AIDS. The convergence in the aims of World Bank and the WHO helps to characterize the institutional interactions between the two as a 'parallel', which means that the two institutions are likely to compete with each other on the same issue but also hold the potential to work together synergistically as their objective (e.g. promoting AEM for HIV/AIDS) does not directly conflict.

The Expansion of the World Bank's Mission into the WHO's Domain

Despite the World Bank's efforts to spearhead health initiatives in developing countries, its institutional competence has been challenged when it failed to reach promised goals and was accused of reporting false outcomes.⁶⁷⁵ One major criticism of the World Bank

⁶⁷² JP Ruger, 'Health and Development' (2003) 362 *Lancet* 678, p. 678. (See also Lee, p. 113-114.)

⁶⁷³ Ruger, 'Health and Development', p. 678.

⁶⁷⁴ The '3 by 5' campaign was discussed in Chapter 3.

⁶⁷⁵ A Attaran and others, 'The World Bank: false financial and statistical accounts and medical malpractice in malaria treatment' (2006) 9531 (368) *The Lancet* 247-52.

has been its lack of technical expertise necessary to implement health programs.⁶⁷⁶ While the World Bank tried to make up for this by recruiting help from WHO, it has been argued that borrowing staff from the already staff-constrained WHO was an inadequate solution.⁶⁷⁷ Another criticism of the World Bank pertains to its ‘institution[al] unsuit[ability] to deliver excellence on [health initiatives]’.⁶⁷⁸ Critics argue that the World Bank holds ‘no compelling advantage’ in working with the health ministries, whereas other ‘health-focused’ institutions (such as the WHO) do.⁶⁷⁹ Instead, these critics call upon the World Bank to ‘revert strictly to its core competence as a financier – a bank – and deposit the pledged commitments ... into a dedicated fund for the exclusive use of other, more technically competent and transparent agencies’.⁶⁸⁰

The World Bank’s expansive mission on development has been a major point of contention in the past decade. The institution’s work in a wide variety of areas, beyond even health, has raised concern for those who feel the World Bank is undertaking too many tasks because they all can be ‘subsumed ... under “development” to fall within the [World] bank’s charter’ and there is a need for money in these various areas.⁶⁸¹ It has been observed that this could be attributed to the demands of its major government shareholders, which are ‘forever driving the bank into new areas – sometimes against the judgment of its leaders and staff’ ; thus, the World Bank often finds itself called upon by

⁶⁷⁶ *ibid.*, p. 251.

⁶⁷⁷ *ibid.*, p. 251; K Abbasi, ‘The World Bank and World Health: Healthcare Strategy’ (1999) 318 *British Medical Journal* 933, p. 935.

⁶⁷⁸ *ibid.*, p. 251.

⁶⁷⁹ *ibid.*, p. 251.

⁶⁸⁰ *ibid.*, p. 251.

⁶⁸¹ J Einhorn, ‘The World Bank’s Mission Creep’ (2001) 80 (5) *Foreign Affairs* 22, p. 32.

these governments, regardless of other existing international institutions in an area, because it is considered ‘more effective than [other] bodies’ (such as the WHO).⁶⁸² While this might be the case in many areas of the World Bank’s operations, it was not apparent in this review of the World Bank’s move to address HIV/AIDS as a distinct unit – apart from the HNP sector. (Also, though the HNP sector was officially formed in 1997, the World Bank has actually been engaged in some health-related projects since 1979 - under the then-World Bank President Robert MacNamara. Hence, the World Bank’s recent operations in health do not seem to be driven by its shareholders in this case.) The World Bank’s aggressive move on the issue of HIV/AIDS as an independent area, however, was driven by internal staff (and, specifically, the efforts of Debrework Zewdie and Hans Binswanger). Some observe that ‘the [World] [B]ank’s strength paradoxically undercuts its effectiveness. The bank is so diverse in its expertise, so professional in its staffing, and so strong in its financial structure that all the interested parties want to control it for their own purposes’.⁶⁸³ In a sense, Zewdie saw the opportunity to engage the institution on the issue of HIV/AIDS through the World Bank’s financial power – even though it may not have intended to (from the HNP perspective).

According to a former World Bank managing director, Jessica Einhorn, ‘[the institution’s] mission has become so complex that it strains credulity to portray the bank as a manageable organization. The bank takes on challenges that lie far beyond any institution’s operational capabilities.’⁶⁸⁴ She even suggests the idea that the World Bank ‘scale back its activities’ and ‘distribut[e] some of its programs to other existing

⁶⁸² S Mallaby, 'Saving the World Bank' (2005) 84 (3) Foreign Affairs .

⁶⁸³ Einhorn, p. 31.

⁶⁸⁴ *ibid*, p. 22.

institutions with overlapping missions’ or ‘devolv[e] some of [its] functions to new institutions’.⁶⁸⁵ Such growing awareness within the World Bank and amongst its outside critics, including those from the health realm, have had an impact on the direction that the World Bank is now taking on HIV/AIDS. In a number of recent World Bank strategy documents on the issue of HIV/AIDS, the World Bank often acknowledges the changed circumstances in the global health environment in terms of the new proliferation of actors and funds that are now addressing the problem. This has forced the World Bank to assess its ‘comparative advantage’ on the issue and re-evaluate its level and means of engagement.

The complexity of the new operating environment for HIV/AIDS and the World Bank’s involvement requires a look at the formation of two relatively new institutions – the UN Joint Programme on HIV/AIDS (UNAIDS) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund). These institutions hold major implications in the institutional interactions between health and development and, hence, it is necessary to consider their role in this space. Before proceeding to the final part of the institutional interaction analysis (i.e. on ‘managing interactions’), the next section describes the reasons behind the entry of the two new institutions and why this added to the complexity of AEM governance in the context of HIV/AIDS.

⁶⁸⁵ *ibid*, p. 23 and 34.

The New Institutions on HIV/AIDS at the Intersection of International Health and Development

The Joint United Nations Programme on HIV/AIDS (UNAIDS)

The urgency of the global HIV/AIDS crisis during the 1990s and the UN's lack of confidence in the WHO as the 'lead agency' through its Global Programme on AIDS (GPA) led to the establishment of a new UN institution called the Joint UN Programme on HIV/AIDS (also known as 'UNAIDS') in 1996. UNAIDS provides an illuminating example of how intergovernmental and organizational coordination within the UN system has been attempted through the formation of a new institution.

UNAIDS became an organization under the perfect storm of a rather timely and unique set of circumstances. As the HIV/AIDS epidemic became a growing and undeniable global problem, the formation of this organization occurred against a backdrop of major international institutional tensions that began in the late 1980s and a change in the donor country attitudes toward the UN. The departure of the charismatic and popular Jonathan Mann from the WHO Global Programme on AIDS (GPA) led to a substantial decline in the programme's funding levels and a 'considerable demoralization among the staff'.⁶⁸⁶ There were concerns that the new GPA, under Michael Merson, was shifting from its former multisectoral approach and becoming too 'medicalized'; although, Merson has denied this and claims that the accusation was being made by those who wanted 'their agencies to be more prominent in the pandemic and to have more money'.⁶⁸⁷

⁶⁸⁶ UNAIDS p. 18; The reasons behind Jonathan Mann resignation as the director the WHO's Global Programme on AIDS (GPA) was covered in Chapter 3 (on the WHO).

⁶⁸⁷ *ibid*, p. 18.

The UN agencies' access to donor funds became increasingly tight. A major economic recession had hit a number of the donor countries and the post-Cold War attitude towards the UN was unfavourable.⁶⁸⁸ The U.N. was viewed as suffering from 'bureaucratic arthritis' and there were growing calls for U.N. reform by its member states.⁶⁸⁹ The former U.S. ambassador to the U.N., Madeleine Albright, publicly commented that the U.N. needed to 'reform or die'.⁶⁹⁰ Interest in funding GPA, along with other U.N. multilateral efforts, was waning amongst the donors and there was marked shift towards funding AIDS efforts bilaterally.⁶⁹¹

The problem of UN 'infighting', which commonly occurred between the WHO and other key agencies (i.e. the World Bank, UNICEF, and UNDP), triggered an external review⁶⁹² requested by country donors that uncovered the 'inefficiency of coordination between different UN agencies' due to the duplication of efforts and 'territorial rivalries'.⁶⁹³ The external review resulted in two subsequent ad hoc working groups to propose solutions to the perceived collaboration problem on AIDS with the UN system.⁶⁹⁴ The first working group, under the GPA Management Committee,⁶⁹⁵

⁶⁸⁸ G Behrman, *The Invisible People* (Free Press, New York 2004), p. 168

⁶⁸⁹ *ibid.*

⁶⁹⁰ *ibid.*

⁶⁹¹ C Jonsson, 'From 'Lead Agency' to 'Integrated Programming': The Global Response to AIDS in the Third World' in HO Bergeson and G Parmann (eds) *Green Globe Yearbook* (Oxford University Press, Oxford 1996).

⁶⁹² The external review was conducted by a 'committee of ten members, representing the five major donor countries and five recipient countries.' See Jonsson., p. 67.

⁶⁹³ UNAIDS, p. 19-20. (The WHO GPA was perceived by donors as 'hamstrung by its place within WHO and unable to work effectively with other UN agencies ...'. Poku, p. 288.)

⁶⁹⁴ UNAIDS; Jonsson, p. 68-69.

⁶⁹⁵ The GPA Management Committee was comprised of 'members representing 30 [WHO] Member States and 6 intergovernmental organizations (i.e. UNICEF, UNDP, UNESCO, UNFPA, the World Bank, and the

commented that ‘no single agency is capable of responding to the totality of the problems posed by AIDS’ and ‘a cooperative effort ... is essential’.⁶⁹⁶ Structure-wise, the working group proposed the establishment of a yearly AIDS coordination forum that would ‘includ[e] representatives of the UN system agencies, bilateral donors, and NGOs’.⁶⁹⁷ The UN donors were dissatisfied with this idea and pushed for an alternative solution. This led to the use of a second working group, which recommended the formation of a task force comprised of representatives from donor and developing countries, UN agencies, and civil society. It was charged with the ‘design of a new body’ that would coordinate the UN’s work on HIV/AIDS.⁶⁹⁸

Ultimately, the task force endorsed a new joint and cosponsored programme, which would possess a secretariat and have ‘the ownership of a broad set of UN agencies’.⁶⁹⁹ In parallel, a group of donors held a meeting in London where they discussed Canada’s similar idea of a joint and co-sponsored UN programme on AIDS.⁷⁰⁰ An agreement on the idea was not reached among the donors, but the Canadian delegation decided to take the initiative of presenting it to the WHO World Health Assembly that year. It has been described that the WHO secretariat was ‘up in arms’ over the idea;⁷⁰¹ however, the idea devolved into a request for the WHO ‘to work out a proposal for a joint and co-sponsored UN programme on HIV/AIDS in close consultation

Commission of the European Community)’. The represented Member States included both developing and developed countries. See WHO, ‘Report of the Tenth Meeting of the Management Committee’ (1994) WHO Global Programme on AIDS (24-26 May 1994).

⁶⁹⁶ UNAIDS, p. 20

⁶⁹⁷ Jonsson, p. 68.

⁶⁹⁸ UNAIDS, p. 20.

⁶⁹⁹ *ibid.*, p. 21.

⁷⁰⁰ Jonsson, p. 68

⁷⁰¹ *ibid.*; UNAIDS.

with the executive heads of UNDP, UNICEF, UNFPA, UNESCO, and the World Bank'.⁷⁰² The proposal was to include 'several options ... in order to avoid watered-down attention to UN consensus formulations'.⁷⁰³ The task force continued its role in this 'interagency bargaining process' and three options were presented with 'different balances between the central secretariat and the co-sponsors'.⁷⁰⁴ In a symbolic gesture of support for new body, the UN Secretary-General convened a meeting with the leaders of the six UN organizations and voiced his preference for the 'most far-reaching' option proposed. This option was revolutionary in the sense that it would establish a new standalone secretariat within the UN system that would be underpinned by the idea of co-ownership, or the more used UN phrase of co-sponsorship, by other agencies involved in the work of HIV/AIDS.⁷⁰⁵ Hence, WHO was effectively displaced as the lead agency on HIV/AIDS work within the UN system.

The Joint UN Programme on HIV/AIDS (hereafter referred to as UNAIDS) was established by a UN Economic and Social Council (ECOSOC) resolution in 1994 and officially launched in 1996.⁷⁰⁶ It is governed by a Programme Coordinating Board (PCB) comprised of: representatives from 22 governments, its UN co-sponsors (including WHO, UNDP, UNICEF, UNFPA, UNESCO, and the World Bank), and five NGOs.⁷⁰⁷ Early

⁷⁰² UNAIDS., p. 21. (Insiders of the process recount that 'WHO spent many months ... attempting to impose language saying it would "administer" the program rather than offer "administration in support" of it'. This has been considered a fundamental struggle over power. See B Gellman, 'Death Watch: The Global Response to AIDS in Africa' *The Washington Post* (Washington, D.C. 5 July 2000).)

⁷⁰³ Jonsson, p. 69.

⁷⁰⁴ *ibid.*

⁷⁰⁵ *ibid*; Behrman, p. 167.

⁷⁰⁶ It is interesting to note that although it is called a 'programme', in essence, it became an organization.

⁷⁰⁷ UNAIDS, 'Governance' (2010) UNAIDS
<<http://www.unaids.org/en/AboutUNAIDS/Governance/default.asp>> (10 June 2009).

accounts of the organization describe the internal challenges of a vague mission (which had to be redefined by the UNAIDS Executive Director Peter Piot), a dwindling budget, and an inexperienced leader.⁷⁰⁸ It soon became clear to Piot, however, that he would be ‘on the hook’ to sorting the organization’s role and that ‘his real mandate ... [was] [m]aking sure that the UN agencies are doing more on AIDS, and that they do it in a better way, qualitatively, and that they do it in a coherent way’.⁷⁰⁹ In the eyes of others, including the UN and its member states, UNAIDS was seen as an ‘experiment’ for UN reform. There was an ‘appetite’ to attempt something new and, as one early insider recalled, ‘AIDS just happened to be there’.⁷¹⁰ At the national level, UNAIDS operated through UN Theme Groups comprised of country-level representatives of UNAIDS co-sponsors and other UN agencies. These groups served as a ‘forum to plan, manage and monitor a coordinated response’.⁷¹¹

The appearance of UNAIDS on the global health landscape did not sit well with existing actors, such as the WHO and the World Bank. The external challenges faced by the organization, in relation to its interactions with the cosponsors, could be characterized by resistance, tension, and painfully slow progress. In fact, Jonathan Mann (former WHO GPA director) once commented that coordinating the six UN Co-Sponsors is akin to ‘walking six cats on a leash’.⁷¹² It was observed that after the launch of UNAIDS, ‘its ostensible partners cut back sharply on the resources and personnel they devoted to

⁷⁰⁸ Behrman, p. 169. (Peter Piot was described as a ‘novice in the realm of international political advocacy’.)

⁷⁰⁹ *ibid.*, p. 168-9.

⁷¹⁰ *ibid.*, p. 168

⁷¹¹ UNAIDS, *Resource Guide for UN Theme Groups on AIDS* (2005), p. 45.

⁷¹² M Balter, ‘United Nations: global program struggles to stem the flood of new cases’ (1998) 280 (5371) *Science* 1863, p. 1863.

AIDS' and that within UNAIDS there was talk of a 'syndrome of abdication'.⁷¹³ For the WHO, according to Peter Piot, the split of HIV/AIDS power from WHO was 'like a really bad divorce. There was a fantasy of bringing UNAIDS back into WHO'.⁷¹⁴ Piot felt there was a need for WHO 'to redefine itself' given the changes in the global health architecture; however, the fighting between the organizations (as well as others, including the World Bank) continued over 'territory and policies, with WHO claiming it was the controller, that they were in charge'.⁷¹⁵ The World Bank, for its part, was considered to have 'acceded [to UNAIDS] with bad grace'⁷¹⁶ for it 'emphasized that it would "assume no liability" for UNAIDS and wished to have "as little involvement as possible" in the new unit', according to memos from a World Bank legal advisor and the then-Human Development director.⁷¹⁷

Operationally, UNAIDS consists of a secretariat based in Geneva (along with the PCB and Committee of Cosponsoring Organizations⁷¹⁸) at the international level and operates through the UN Theme Group on HIV/AIDS (as a collaborative mechanism to work with its UNAIDS cosponsors) at the country level. UNAIDS has played a major

⁷¹³ Gellman, 'Death Watch: The Global Response to AIDS in Africa'. (It was reported that the 'World Bank loans dropped from \$50 million to less than \$10 million, WHO spending dropped from \$130 million to \$20 million, UNICEF from \$45 million to \$10 million, and so on'.) See also UNAIDS, 'UNAIDS: The First Ten Years', p. 22. (Hans Moerkerk, Chair of the GPA Management Committee, has stated that 'we in the Task Force wanted [UNAIDS] to be a funding agency, like the Global Fund is now, but UNICEF, UNDP and the World Bank were too powerful and would not allow it to be more than a coordinating and advocacy organization'.)

⁷¹⁴ G Yamey, 'Faltering Steps Towards Partnerships' (2002) 325 (7374) *British Medical Journal* 1236, p. 1237.

⁷¹⁵ *ibid*, p. 1237.

⁷¹⁶ Mallaby, *The World's Banker*, p. 319.

⁷¹⁷ Gellman, 'Death Watch: The Global Response to AIDS in Africa'.

⁷¹⁸ The Committee on Cosponsoring Organizations provides a forum for the cosponsor representatives to meet twice a year to review UNAIDS matters and provide input.

role in access to ARVs over the years. For example, it had launched two initiatives (i.e. the Drug Access Initiative [DAI] in 1997 and the Accelerating Access Initiative [AAI] in 2000) in an effort to promote access to ARVs in developing countries through differential pricing arrangements with the pharmaceutical industry.⁷¹⁹ It is interesting to note that the UNAIDS approach was not without controversy. When DAI was first launched, there were ‘few generic suppliers of ARVs’ at the time.⁷²⁰ By 1999, there was increased recognition among DAI participants that ARVs could be sourced at a lower price through generic versions. In an effort to maintain a favourable position with UNAIDS, the pharmaceutical industry proposed an idea that would further reduce prices through individual pricing arrangements, but it required that the UN ‘commit to mobilising support for the controlled use of their products and sustainable financing for them’ in return.⁷²¹ UNAIDS (along with WHO, the World Bank, and a few other UN agencies) agreed to the arrangement and the AAI was formed. It was observed, in hindsight, that the ‘roll out [for the AAI] was slow and hindered by individual countries having to negotiate prices and conditions’.⁷²²

The Global Fund to Fight AIDS, TB, and Malaria (‘the Global Fund’)

The Global Fund to Fight AIDS, TB, and Malaria (also known as the ‘the Global Fund’) was established by the Group of 8 (G8)⁷²³ countries in 2002 as a new type of organization to mobilize financing to prevent and treat the three major diseases affecting developing

⁷¹⁹ Schwartlander, Grubb and Perriens, p. 541-542; UNAIDS, ‘UNAIDS: The First Ten Years’, p. 163-165.

⁷²⁰ Schwartlander, Grubb and Perriens, p. 541.

⁷²¹ *ibid.*, p. 542.

⁷²² *ibid.*, p. 542.

⁷²³ The G8 countries consist of: Japan, Italy, Canada, U.S., France, Germany, Russia, and the U.K.

countries. According to the Global Fund's founding director, the organization's motto was to 'raise it, spend it, [and] prove it'.⁷²⁴ It was intentionally established outside of the UN due to donor concerns about the ongoing turf battles, bureaucracy, and inefficiency within the UN system.⁷²⁵ As the second largest funder of HIV/AIDS programs, the Global Fund is a unique joint endeavour between governments, civil society, and the private sector that has established itself as one of the most prominent global public-private partnerships today.⁷²⁶ The Global Fund, which is governed by a board of representatives (comprised of developing and developed countries, NGOs, affected communities, and the private sector), holds the power of approving grants made. It also holds partnerships with WHO, UNAIDS, the World Bank, and a few public-private partnerships.⁷²⁷

The model of the Global Fund is also unique in the sense that it possesses no in-country or technical assistance expertise because it strictly operates as a financing mechanism without involvement in national-level implementation activities.⁷²⁸ This created a problematic dynamic between the Global Fund and the UN agencies involved in HIV/AIDS (such as WHO, UNAIDS, and the World Bank). The tension between the

⁷²⁴ S Bartsch, 'The Global Fund to Fight AIDS, Tuberculosis and Malaria' in W Hein, S Bartsch and L Kohlmorgen (eds) *Global Health Governance and the Fight Against HIV and AIDS* (Palgrave Macmillan, Basingstoke 2007), p. 157-158.

⁷²⁵ *ibid.*, p. 149. Other accounts detail tensions in the talks between the UN bodies and donors leading up to the formation of the Global Fund, as these bodies had hoped to keep funding within the system. (UNAIDS, 'UNAIDS: The First Ten Years', p. 130.); Nana Poku described the formation of the Global Fund as arising under 'a swirl of rumors, whispers and backroom intrigue driving the process forward'. (Poku, p. 294).

⁷²⁶ Bartsch; M Bernstein and M Sessions, *A Trickle of a Flood: Commitments and Disbursement for HIV/AIDS from the Global Fund, PEPFAR, and the World Bank's Multi-Country AIDS Program (MAP)* (2008).

⁷²⁷ The Global Fund, 'The Global Fund' (2010) <<http://www.theglobalfund.org/en/board/?lang=en>>.

⁷²⁸ Bernstein and Sessions., p. 12.

organizations was apparent in the Global Fund's introduction of the Country Coordinating Mechanism (CCM) (based within developing countries),⁷²⁹ which has created a number of problems at the national and global level in terms of its lack of coordination with extant governance structures. Under Global Fund procedures, CCMs were established for the distribution of grants at the national level. In particular, CCMs function in the capacity of developing and submitting grant proposals as well as overseeing implementation.⁷³⁰ The establishment of CCMs, however, has been 'in addition' to extant national coordinating institutions (e.g. the National AIDS Councils, which are used by the World Bank, and the UN Theme Groups, which are used by UNAIDS).⁷³¹ This has resulted in problems of duplication and confusion for developing countries as well as greater political competition for power and influence between the different coordinating authorities.⁷³² In a 5 year external review of the Global Fund, the organization was advised to 'emphasize CCM functions rather than [the] CCM entity' and to 'incorporate the CCM functions into other "CCM-like mechanisms" ...'.⁷³³

The CCMs have also been a source of conflict at the global level between the Global Fund and the WHO and UNAIDS. Because the Global Fund endorses a 'bottom-up' approach to health initiatives, it does not have an in-country presence nor does it house technical expertise to assist CCMs in developing countries with their proposals. CCMs, as a result, rely on technical assistance from bilateral and other multilateral

⁷²⁹ CCMs, as described by the Global Fund, are 'country-level partnerships' which support local ownership and participatory decision-making. The Global Fund, 'Country Coordinating Mechanisms' The Global Fund <<http://www.theglobalfund.org/en/apply/mechanisms>> (15 June 2008).

⁷³⁰ *ibid.*

⁷³¹ Bartsch., p. 166.

⁷³² *ibid.*, p. 166.

⁷³³ The Global Fund, 'The Global Fund'.

organizations. This dependency has added to the workload of other organizations, such as WHO and UNAIDS, which supported the CCMs without compensation. (This issue was later resolved through a revision in grant proposals to allow for technical assistance compensation.) An interesting dynamic created by this dependent relationship is that other organizations can influence country proposals through the provision of technical assistance.⁷³⁴ Though the Global Fund was created outside the purview of the UN system, in order to avoid the bureaucracy of the UN system and shift power away, WHO and UNAIDS can still find ways to exert control.⁷³⁵

The sustainability of the Global Fund approach, however, has been an issue of contention. The Global Fund faces an increasing shortage of funds due to the challenges of donor fatigue, difficult economic times, and competition with other organizations for funding.⁷³⁶ For example, the Global Fund has been ‘side-stepped’ by the US (a key donor of the Global Fund) through the creation of the President’s Emergency Plan for AIDS Relief (PEPFAR). With the increasing shortage of funds from donors, some wonder whether the Global Fund’s approach to supporting disease programs can continue as it would have to ‘mobilize enough resources to run treatment programs [for] as long as they are needed’.⁷³⁷ Recently, the Global Fund has indicated interest in addressing a broader range of fundamental health concerns, such as health systems and the MDGs,⁷³⁸ but they express concern about ‘whether [they] are ready to take on more’. The Global

⁷³⁴ Bartsch., p. 161-162.

⁷³⁵ *ibid.*; Kohlmorgen., p. 131-132.

⁷³⁶ Bartsch.

⁷³⁷ *ibid.*, p. 170.

⁷³⁸ For example, in 10th round of the Global Fund grant applications, health systems strengthening was added as a criterion.

Fund Board Chairman (Tedros), has stated that the Global Fund is ‘not worried that [they] are leaving the core mandate [for discussion], but still with an eye to the core’.⁷³⁹

To address the current funding difficulties posed by the current economic climate and the issue of bilateral programmes, the Global Fund has been engaging in active outreach to the donor countries in an effort to ‘build trust’ and ‘a relationship’ with each one.

From Parallel Interactions to Institutional Complexity: Lessons and Future Considerations for the Institutional Interactions between Health and Development

The institutional interactions between international health and development over HIV/AIDS have been further transformed by the creation of UNAIDS and the Global Fund. The entry of these two new institutions have moved the institutional interactions of the WHO and World Bank beyond that of parallel interactions to institutional complexity. The interactions between the institutions vary and have evolved over time. For example, the initial tensions between WHO and the World Bank could be characterized by the competition for funds and staff resources to address the HIV/AIDS epidemic.⁷⁴⁰ The entry of UNAIDS created institutional tensions with WHO in terms of norm setting, staff resources, and the assertion of leadership over HIV/AIDS. The later establishment of the Global Fund created an array of tensions with all three institutions.⁷⁴¹ For example, the Global Fund’s lack of in-country presence and developing countries’ reliance on technical assistance from UNAIDS and WHO created inter-organizational problems. In

⁷³⁹ Christoph Benn, Global Fund (Presentation at the Center for Strategic and International Studies (CSIS), 12 March 2010).

⁷⁴⁰ Kohlmorgen; Abbasi.

⁷⁴¹ Bartsch.

addition, the Global Fund's preferred use of its Country Coordination Mechanism as opposed to the World Bank's established use of National AIDS Councils created another set of problems in developing countries and between the two institutions. Overall, the institutional interactions on HIV/AIDS assistance were considered fragmented, redundant, and inefficient.⁷⁴²

'3 by 5' – A WHO Partnership Gone Awry?

The '3 by 5' initiative, as discussed in Chapter 3, was an effort by WHO to re-position itself as a leader in the HIV/AIDS health response by addressing the emergency issue of the lack of access to antiretrovirals. (The initiative aimed to put three million people on antiretrovirals by 2005, but fell short of this goal with only 1.3 million people on treatment at its conclusion.⁷⁴³) The initiative, officially, was intended to be partnership launched by WHO in conjunction with international partners, such as the UNAIDS and its co-sponsors, the Global Fund, and donors.⁷⁴⁴ The WHO's methods in leading and managing the initiative, however, left it in a general state of confusion amongst these groups. For example, there were 'varied interpretations' of what the '3 by 5' actually entailed⁷⁴⁵ as well as uncertainty regarding the nature of the WHO's partnerships with

⁷⁴² L Garrett, 'The Challenge of Global Health' (2007) 86 (1) Foreign Affairs.

⁷⁴³ WHO, 'Global access to HIV therapy tripled in past two years, but significant challenges remain' (2006) World Health Organization (press release) <<http://www.who.int/hiv/mediacentre/news57/en/index.html>> (28 March 2006).

⁷⁴⁴ Nemes and others, p. 83.

⁷⁴⁵ *ibid*, p. 60. (According to an external evaluation of the '3 by 5' initiative, it found that perceptions of the '3 by 5' initiative included: 'a "slogan"; "a marketing and fundraising strategy"; an initiative"; "an indicator"; "a mindset"; "a wake-up call"; "an advocacy strategy"; "a programme of work"; "a very ambitious plan"; "a global political declaration"; as well as "the WHO strategy for treating 3 million people by the year 2005"'.)

others.⁷⁴⁶ In general, the WHO's so-called 'partnerships' for the initiative were mainly an array of 'loosely managed arrangements' that lacked consensus building, which left the partners with the unenthusiastic impression that '3 by 5' was 'a WHO initiative'.⁷⁴⁷ Essentially, WHO's effort to play a leading role on HIV/AIDS through partnership was considered a failure by some despite its attempt to build up its HIV/AIDS capacity and assert itself in the new role of coordinating access to ARVs.⁷⁴⁸ Overall, the WHO's problems in leading '3 by 5' can be attributed to an array of key factors (according to an external evaluation), which include an ill-conceived strategy, lack of programme structure, lack of upfront financial commitment, delayed disbursement of funding (leading to late recruiting of country officials), a lack of interdepartmental collaboration, a lack of a sense of 'ownership' by the WHO regional offices, a lack of involvement and consensus building with its external partners, and poorly defined partnerships (in terms of its form and extent).⁷⁴⁹

Over time, the various health and development institutions began to see the problems in HIV/AIDS governance. The conflicting policies, misaligned priorities, competition and turf battles, redundant operations, and functional gaps (as discussed earlier in this chapter) became recognized within the UN system as key problems.⁷⁵⁰ The

⁷⁴⁶ There was a lack of understanding about the 'parameters and explicit expectations ... for [the] collaborations' and a lack of distinction between 'strategic, scientific, and operational partnerships'. See *ibid.*, p. 89.

⁷⁴⁷ *ibid.* p. 25-26 and p. 34; Schwartlander, Grubb and Perriens, p. 545.

⁷⁴⁸ Nemes and others, p.34.

⁷⁴⁹ *ibid.*, p. 60-68.

⁷⁵⁰ UNAIDS, 'Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors' (2005) <http://www.unaids.org/unaids_resources/images/GTT/GTT_Brochure.pdf> ; UNAIDS, 'Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors – Final Report' (2005) UNAIDS (14 June 2005) <http://data.unaids.org/Publications/IRC-pub06/JC1125-GlobalTaskTeamReport_en.pdf>.

institutional complex that had emerged between the institutions was raising concerns from developed states about the inefficient use of funds and from developing countries about the tedious and complicated variety of grants applications and reporting procedures that was straining its limited resources.⁷⁵¹ Technical assistance from the WHO and UNAIDS was needed by the Global Fund, but not financed. Multiple national coordinating mechanisms, favoured by different international bodies, existed in recipient countries. The UN agencies and the Global Fund, as described in Chapter 6 (on Emerging Changes in Governance), came together to form the ‘Global Task Team on improving AIDS coordination among multilateral institutions and international donors’ in an effort to manage the institutional problems that they faced. It is interesting to note that the U.S. added to this institutional complexity with the formation of a bilateral programme known as the President’s Emergency Plan for AIDS Relief (PEPFAR), under former President George W. Bush. Upon its creation, PEPFAR became the largest funder of HIV/AIDS programmes and it gave special emphasis to the funding for treatment.

Conclusion

This chapter analyzed the institutional interactions in the governance of AEM in terms of: (1) international health and trade and (2) international health and development. On the institutional interactions between health and trade, though it appears that the WTO and WHO have made some progress in building cooperation over the course of their troubled history, the institutional tensions still appear to exist between the two organizations due to

⁷⁵¹ UNAIDS, 'The Global Response to AIDS: 'Making the Money Work' The Three Ones in Action' (2005) Communiqué from the High Level meeting <<http://www.aidsportal.org/store/292.pdf>> (9 March 2005); , 'Improving Coherence Among Multilateral Institutions and International Donors to Develop and Support Effective AIDS Programmes' (2005) Discussion Document at "Making the Money Work: The Three Ones in Action Conference" <<http://www.aidsportal.org/store/295.pdf>> (9 March 2005).

differing priorities. A major priority of the WTO is to overcome the problematic stalemates in the ongoing Doha Round negotiations and, given its focus, it would want to avoid any other complications to its completion. Current developing concerns about ‘paragraph 6’ system implementation could divert attention from the WTO’s main agenda. In addition, further discussions and reports about problems with TRIPS implementation would only add to the workload of the small staff in the WTO’s Intellectual Property division and the already full meeting schedule of its member states. WHO, on the other hand, continues to be pressed by its developing country member states to address TRIPS flexibility issues. WHO’s recent passage of the Global Strategy and Plan of Action through the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (discussed in Chapter 6) is viewed as a potential move by developing countries to better position WHO in governing trade-related health issues through the regime shifting of intellectual property matters from WTO.⁷⁵²

On the institutional interactions between health and development, there have been significant improvements in addressing HIV/AIDS (including AEM) over the past decade. Yet, despite the progress made, the resulting complexity of these institutional interactions and the persisting lack of coordination undermine the possibility of greater success. As illustrated by this set of key organizations (i.e. WHO, the World Bank, UNAIDS, and the Global Fund), while they may all hold the ultimate objective of reducing the prevalence of HIV/AIDS, they have not sought to work together historically and a power struggle has ensued. A growing recognition of the governance problem by these organizations, along with external pressure from states (i.e. both developed and

⁷⁵² Kohlmorgen.

developing countries), has prompted an effort led by UNAIDS to coordinate the various UN institutions and the Global Fund. (This will be described further in Chapter 6.)

Chapter 5: THE IMPLEMENTATION OF INTERNATIONAL ASSISTANCE AND COOPERATION FOR ACCESS TO ESSENTIAL MEDICINES BY DEVELOPED COUNTRIES

Introduction

As mentioned in my discussion of the implementation framework (in Chapter 2 – Theoretical Framework), the implementation of norms involves two levels – the international and national levels. The previous chapters considered the role of the international order in governance and the challenges faced by the intergovernmental institutions involved, notably the WHO, WTO, World Bank, UNAIDS, and the Global Fund. The aim of this chapter is to consider the national progression towards the implementation of international AEM standards and its interactions with the international level. To help illustrate this process, I selected the United Kingdom as a case study.

In the introductory chapter of this thesis (Chapter 1), it was established that a set of international standards on international assistance and cooperation (IAC) for AEM exists. Yet, to consider the level of international influence necessary to facilitate national implementation, it helps to assess the level of state receptivity to the international norm (e.g. access to essential medicines). The core content of access to essential medicines (AEM) can be derived from the right to health and, hence, belongs to the broader category of economic, social and cultural rights. A look at the country attitude towards the right to health provides a general barometer of state receptivity to AEM's international standards.

As an individual country, the U.K. has not shown outward resistance to AEM norms but the European Commission (EC) has openly challenged AEM on the trade front. While the model by Thomas Risse and his colleagues is not designed for regional study, his phases of denial, tactical concessions, and prescriptive status can be considered in the context of the regional trade bloc's activities during the years before and after the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. I will trace the EC's position on AEM through these stages to understand how the EC's views on AEM have evolved and where it stands on the issue today. Distinct from its trade-related policies, the U.K.'s health assistance and development activities have been lauded as some of the most progressive approaches to helping developing countries achieve greater access to medicines. I will provide a historical analysis of the U.K.'s health and development agencies' positions on AEM to illustrate the U.K.'s generally consistent stance on AEM and discuss the government's future plans for AEM in the context of U.K. global health policy.

Case Study of the United Kingdom

The U.K. presents an interesting study on AEM recognition and its handling of AEM issues in health, trade, and development policies and laws as a matter of state implementation. From a human rights perspective, the U.K. government appears to be a more willing supporter of the realization of the right to health in developing countries as indicated by the following statement from the U.K. Department of Health in 2008:

We believe that every individual – whatever part of the world they come from or live in – is of equal value. The UK Government, as one of the original 1948 signatories, remains committed to the provisions of the Universal Declaration of Human Rights. 'Human rights belong to every individual in every part of the world ...'⁷⁵³

The U.K. is a signatory⁷⁵⁴ to the ICESCR but it has gone further in its recognition of economic, social and cultural rights through the ratification of the covenant in 1976.⁷⁵⁵ Despite the ratification of the ICESCR, the U.K. still has ‘never incorporated it into domestic law’ under the country’s dualist approach to the adoption of international law.⁷⁵⁶ Legal scholars, such as Ed Bates, comment that the U.K. has historically taken the position of recognising the ICESCR as principles, programmatic objectives, or guidelines, which ‘consequently ... cannot be given legislative effect’.⁷⁵⁷ In other words, U.K. government believes that many of the ICESCR’s provisions do not ‘lend themselves to translation into legislation or justiciable issues [for British court adjudication]’.⁷⁵⁸ When asked to report to the UN ESCR Committee on the incorporation of the rights of the ICESCR under domestic law in 1996 and 2001, the U.K. government responded by pointing to its ‘[sectoral] policies and programmes’ relating to the principles of the ICESCR.⁷⁵⁹ For instance, Bates observes that the U.K. government has exhibited the general belief that ‘foreign policy objectives on ESC rights were covered by the government's commendable commitment to the relief of poverty and sustainable

⁷⁵³ UK, 'Health is Global' (2008) UK Department of Health
<http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_088753.pdf >, p. 16. (Quote from David Miliband, Foreign Secretary)

⁷⁵⁴ Signed on 16 Sep 1968.

⁷⁵⁵ UN, 'UN Treaty Collection' (2010)
<http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en >

⁷⁵⁶ As Bates explains, the UK’s ‘dualist’ approach ‘require[s] an international treaty to be specifically incorporated into domestic law for it to take full legal effect’. E Bates, 'The United Kingdom and the International Covenant on Economic, Social and Cultural Rights' in M Baderin and R McCorquodale (eds) *Economic, Social, and Cultural Rights in Action* (OUP, Oxford 2007), p. 259.

⁷⁵⁷ *ibid.*, p. 260.

⁷⁵⁸ *ibid.*, p. 259 and p. 268-269.

⁷⁵⁹ *ibid.*, p. 259, 264-265, 269.

development⁷⁶⁰ rather than to a need to incorporate the rights of the ICESCR in domestic law.⁷⁶¹ The government's position on economic, social and cultural rights appears consistent with its approach towards meeting IAC standards for AEM as well as the broader demands of the right to health. As detailed later in this section, the U.K. established a number of policy objectives and embarked on a number of programmes pertaining to its support of AEM.

Yet, even with recognition of the human right to health and AEM, the U.K.'s membership in the European Union (EU) poses an added level of complexity to its stance on health and trade-related matters – namely AEM. The U.K.'s membership in the EU means that its representation at the international level is subsumed under the European Commission in fora such as the WTO and WHO. This means that the European Commission votes as one body on international matters (e.g. international trade or health agreements) rather than as individual states. As a result, the U.K.'s position on AEM matters will have to be considered in this context with regard to international health and trade policies and laws. The health and trade agency bodies within the U.K. that have been active at the international level on AEM issues include: the Department of Health and the UK Intellectual Property Office (known as the UK Patent Office until 2007).

In addition to these particular U.K. agencies, the Department for International Development (DFID) is another state-level body that has also been heavily involved in AEM issues on the international health and development front. DFID, as an agency, was given the broad mandate of 'provid[ing] aid for sustainable development and welfare'

⁷⁶⁰ *ibid*, p. 265.

⁷⁶¹ *ibid*, p. 265-266.

with the goal of ‘reducing poverty’.⁷⁶² One of the driving forces of DFID’s agenda is the Millennium Development Goals (MDGs), which includes two health-related targets (as noted in Chapter 1). DFID’s broad mandate, the health-related MDGs, and the general understanding that good health is an underlying factor of economic development, all contribute to DFID’s involvement and leading role in U.K. activities pertaining AEM (as described later in this section).

The remainder of this section will trace and analyze the U.K.’s acceptance and involvement on AEM. To understand the U.K., as an EC member, it is necessary to assess the EC’s actions in the health and trade realms in relation to AEM. Given the EC’s initial resistance to recognizing AEM standards, this allows for an analysis of how the EC as a regional bloc was socialized into norm implementation through the spiral model’s phases of denial, tactical concessions, and prescriptive status. The section concludes with a review of the U.K. health and development agencies’ actions on AEM to shed light on the country’s individual stance towards AEM and why it is considered to be much more progressive on the norm’s recognition and implementation than other developed countries.

Phase I. EC Denial

The European Commission’s initial stance on AEM in international trade prompts an analysis of ‘regional denial’ within the spiral model. Here, the EC’s collaboration with the U.S. in the creation of the TRIPS agreement and its defence of intellectual property rights over developing country AEM concerns is detailed.

⁷⁶² DFID, ‘Who we are and what we do’ (2010) UK Dept. for International Development <<http://www.dfid.gov.uk/About-DFID/Quick-guide-to-DFID/Who-we-are-and-what-we-do/>>

WTO TRIPS Agreement

As discussed in the previous case study, the U.S. government took a lead role in introducing the ideas of an intellectual property rights agreement (later known as TRIPS) to the WTO. The U.S. realized, however, that the passage of this agreement would require strong backing by some of the other powerful country groups within the WTO and it worked to establish a powerful coalition of like-minded developed countries known as the 'Quad' to support the intellectual property rights agenda.⁷⁶³ The Quad consisted of the U.S., European Commission (EC), Japan and Canada. Soliciting support from the EC was not a significant hurdle for the U.S. considering the number of prominent pharmaceutical companies based in Europe (e.g. U.K., France, and Germany). Hence, following the U.S.-led efforts in the creation of TRIPS at the WTO during the Uruguay Round (1986-1994), the Quad was able to lock developing countries into an international legal agreement that would limit medicines options in developing countries due to newly imposed base standards for patent protection.

Despite the EC's support of TRIPS, the E.U. business community is considered to have held a 'relatively low profile' on TRIPS lobbying in comparison to the highly 'proactive approach' taken by companies based in some other developed countries. Intellectual property expert, Duncan Matthews, believes that this is because the E.U. businesses are 'generally ... less well informed on the significance of issues raised [pertaining to TRIPS]', which can be attributed to the fact that Europe possesses fewer

⁷⁶³ P Drahos, 'When the Weak Bargain with the Strong: Negotiations in the World Trade Organization' (2003) 8 (1) *International Negotiation* 79.

patent attorneys and a more cumbersome lobbying process in comparison to the U.S.⁷⁶⁴ Because the EC operates as a representative who speaks on behalf of its member states, the countries ‘normally have [to adopt] a common position and coordinated ... response prior to the TRIPS Council meeting’.⁷⁶⁵ This procedure creates a complex process for European business lobbies as they would ‘need to approach national officials who, in turn, seek to influence [EC] policy decisions ...’.⁷⁶⁶ In the U.K., lobbying at the national level is viewed as problematic by a number of businesses due to: (1) the government’s use of a rather ‘inflexible’ formal committee structure to hear industry views and (2) the belief that the government ‘collects comments on policy proposals that it itself initiates, rather than being responsive to the views generated by UK companies’.⁷⁶⁷ The U.S. Trade Representative, in comparison, is known to allow direct and informal contact from business groups and to rely on U.S. industry ‘advice and expertise’ due to internal resource limitations.⁷⁶⁸ Hence, Matthews finds that ‘it is ... common for [international pharmaceuticals] to bypass the European-level representation ... going instead directly to the USTR via global networks’.⁷⁶⁹ These procedural obstacles help to illustrate why pharmaceutical business lobbying has been less intensive within Europe; however, the availability of other avenues within the ‘Quad’ has allowed the corporations to push their intellectual property rights agenda and ultimately garner EC support.

Other Trade-Related Activities and the Growing Criticism of Trade Policies

⁷⁶⁴ D Matthews, *Globalising intellectual property rights: the TRIPs Agreement* (Routledge, London 2002), p. 85.

⁷⁶⁵ *ibid.*, p. 86.

⁷⁶⁶ *ibid.*, p. 86.

⁷⁶⁷ *ibid.*, p. 86-87.

⁷⁶⁸ *ibid.*, p. 85 and 87.

⁷⁶⁹ *ibid.*, p. 87.

In another act of outright ‘denial’ of AEM by the European Commission, the EC Directorate General for Trade (DG Trade) announced that ‘[n]o priority should be given to health over intellectual property considerations’ in response to the draft Revised Drug Strategy at the WHO.⁷⁷⁰ (The Revised Strategy was discussed earlier in Chapter 3 – International Institution for Health.) The Revised Drug Strategy was a key WHO resolution, which was eventually passed at the World Health Assembly and expanded the WHO’s mandate to address issues that interface between health, trade, and intellectual property rights. The EC’s DG Trade statement illustrates an attempt to pre-empt the significance of the WHO’s influence on trade and IP issues by attempting to delegitimize the importance of health concerns. This attempt by the EC, however, did not prevent the WHA from passing a number of subsequent resolutions addressing the WHO’s role and member states’ responsibilities in relation to AEM and trade.

The European Union also supported efforts to pressure South Africa on its Medicines and Related Substances Control Amendment Act in 1998 (as described in the U.S. case study). The European Union, however, eventually backed down in its pressure upon South Africa due to a widespread activist and celebrity media campaign that slammed the developed country governments for denying AEM for HIV/AIDS patients. When the U.K. government was questioned about its stance on the South African court case, its response displayed reluctance to criticize the pharmaceutical industry position. For example, when asked about the South African government’s case, the Secretary for International Development at the time (Clare Short) said:

I believe that [South Africa’s] negotiations with pharmaceutical companies on price and licensing offers the best way of balancing the need for affordable access

⁷⁷⁰ ‘t Hoen, p. 48.

to drugs with the need for intellectual property protection to encourage future research. The legal action is regrettable, but it is a matter between the pharmaceutical companies and the Government of South Africa.⁷⁷¹

The Select Committee on International Development (in the House of Commons) has also commented on the South African court case and tried to take a neutral position on the issue by stating that they ‘do not intend to come to a view on the merits of that case nor how in detail to interpret the TRIPS agreement of the WTO’.⁷⁷² Yet, in its explanation of the issue, the government committee revealed a rather inconsistent stance. It initially tried to downplay the significance of the South African Court case and the growing AEM movement by stating that ‘[i]t is too easy ... to create a single identifiable enemy (the pharmaceutical companies) and a single identifiable solution (cheaper drugs)’.⁷⁷³ Then, when responding to accusations by a UK-based NGO (Action for Southern Africa) that ‘the European Union and the UK Government intervened and tried to persuade South Africa to drop its challenge to TRIPS’, the report begins to acknowledge AEM norms and re-position the government’s stance on the controversial issue by stating:

The provisions of TRIPS under which a country can use parallel importing or compulsory licensing in a national emergency were put in for a purpose. Progress in agreeing [upon] concessional prices with the pharmaceutical companies is to be encouraged. This should not be at the expense of developing countries also pursuing alternative solutions permissible under WTO rules. We do not believe the United Kingdom Government, the European Union or any other developed country should put pressure on developing countries not to make use of available TRIPS provisions.⁷⁷⁴

⁷⁷¹ U.K. Parliament, 'Commons Hansard Written Answers text for Thursday' (2001) Volume No. 364 Part No. 47 <<http://www.publications.parliament.uk/pa/cm200001/cmhansrd/vo010308/text/10308w07.htm>> (8 Mar 2001)

⁷⁷² U.K. Parliament, 'House of Commons. International Development - Third Report. Session 2000-01' (2001) <<http://www.publications.parliament.uk/pa/cm200001/cmselect/cmintdev/354/35415.htm>> para. 191.

⁷⁷³ *ibid*, para. 191.

⁷⁷⁴ *ibid*, para. 198.

Despite the U.K.'s attempt at a somewhat neutral stance on the South African court case, the increasingly negative public perception of the pharmaceutical industry caused the U.K. to move towards adopting a stance that acknowledges the existence of TRIPS flexibilities for AEM. Eventually, the the pharmaceutical companies withdrew their suit in response to public pressure.

Domestic UK Politics

As noted earlier, the European Commission (EC) acts to represent its member states in multilateral fora on international matters such as trade and health. The Commission is comprised of '20 Commissioners appointed for a five-year term by Member States' governments and an EU civil service of approximately 14,000 officials'.⁷⁷⁵ The U.K. is allocated two Commissioners within the EC. The EC's delegation to the WTO TRIPS Council, however, is also supplemented by national representatives from the EC member states. In order to allow the EC to lead and represent the member states in international fora, the EC member states usually reach a consensus on their position before attending the TRIPS Council meeting.⁷⁷⁶

The U.K.'s national representatives to TRIPS are provided by the U.K. Intellectual Property Office (formerly known as the U.K. Patent Office).⁷⁷⁷ The U.K. Intellectual Property Office is the state-level body charged with 'establishing and maintaining the national framework of intellectual property rights' as well as assisting

⁷⁷⁵ EURIM, 'EURIM Guide to Decision-Making in the European Union after Amsterdam' (1998) <<http://www.eurim.org/EURGUIDE.html>>

⁷⁷⁶ Matthews, *Globalising intellectual property rights: the TRIPs Agreement*, p. 86

⁷⁷⁷ *ibid*, p. 86

businesses ‘make the most of their IP and be better prepared to compete in national and international markets’.⁷⁷⁸ A former executive officer of the UK Patent Office has recounted his experience as a U.K. representative on IP matters (during the WTO Uruguay and Doha Round negotiations) as being ‘all about politics’ and that his personal role was about ‘pragmatism ... getting things [that the government wanted] done’.⁷⁷⁹ He observed that his superior was ‘pro-innovation’ and that, as a UK delegate, central government often directed him not to ‘scar[e] off the [pharmaceutical companies]’ and that what was being done about IP strengthening was ‘not enough’ due to the ‘very powerful’ voice that the pharmaceutical industry held in the country. In terms of development influence on the U.K.’s foreign policy, he felt that it was there but it was ‘not major’ because DFID was not considered a ‘big hitter in the political hitting order’.

As the South African court case entered the international spotlight, the U.K. government found itself having to account to its public on the health considerations of the WTO TRIPS Agreement. For example, Baroness Amos asked to respond for the government about how it was ensuring that the WTO’s TRIPS agreement would ‘not harm the health and well-being of the people of the developing countries by prohibiting or inhibiting ... generic versions of life-saving drugs’.⁷⁸⁰ She stated that the government ‘believe[s] that the TRIPS agreement provides WTO members with sufficient flexibility to implement domestic patent regimes that take account of their national circumstances’; however, the U.K.’s position on ‘the best way forward’ was for developing countries to

⁷⁷⁸ See UK Intellectual Property Office, <http://www.ipo.gov.uk/>.

⁷⁷⁹ Roundtable Presentation at Univ. of Oxford, UK (13 March 2009).

⁷⁸⁰ U.K. Parliament, ‘Commons Hansard Written Answers text for Thursday’

negotiate with the pharmaceutical companies ‘on price and licensing’.⁷⁸¹ Similarly, when Lord David Sainsbury (former Minister of Trade) was asked ‘[w]hy the [TRIPS] agreement was negotiated without reference to the World Health Organization’, he responded that ‘the [WHO] has observer status on the TRIPS Council, which administers the [TRIPS] agreement and plays an active role in discussions on the application of the agreement to medicines’.⁷⁸² Given the limited level of engagement permitted for WTO ‘observers’ (as discussed in Chapter 4) and WHO’s actual absence during the Uruguay Round negotiations,⁷⁸³ Lord Sainsbury’s response does not appear to address whether the WHO held any true role in relation to the TRIPS agreement. Instead, he only points to the physical presence of the WHO in current negotiations.

Initial ‘denial’ has been a major hurdle for the recognition of AEM norms by the EC. Because the U.K. is subsumed within EC group, it has also played a role in tacitly denying AEM norms on the trade front. An analysis of domestic U.K. politics, however, shows that the government was not in opposition to the promotion of intellectual property rights at the international level and actually worked to support it – along with its EC counterparts. Yet, public mobilization against the South African lawsuit through shaming and moral-consciousness raising were a key turning point in changing the EC’s hard-line position against AEM norms and forcing the U.K. to account for its inconsistent stance on the issue.

⁷⁸¹ *ibid.*

⁷⁸² *ibid.*

⁷⁸³ F Abbott and J Reichman, ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions’ (2007) 10 (4) *J Intl Economic L* 921–987, p. 967.

Phase II. EC and U.K. Tactical Concessions

WTO Doha Round and the Doha Declaration on TRIPS and Public Health

In the subsequent round of international trade negotiations (i.e. the Doha Round), however, some developed countries found that it was ‘not always able to count on its Uruguay Round partner for unwavering support in the WTO and WHO negotiations’.⁷⁸⁴ The European Commission was faced with increased pressure from a coalition of international NGOs (INGOs) prior to the Doha Round, and it responded by holding ‘several meetings ... to which position papers were prepared and circulated by the Commission and interested groups’.⁷⁸⁵ This was a critical move by the INGOs to influence the EU’s position in the lead up to the ‘special’ WTO session requested by the African delegation. The European Commission prepared a paper for submission that ‘noted with some sympathy the bases for concerns that developing Members had expressed regarding interpretation of provisions on compulsory licensing’, although other aspects of the Commission’s stance on intellectual property still took a ‘fairly hard line industry-oriented perspective’.⁷⁸⁶ Yet, when it came time to submit the European Commission paper at a TRIPS Council Meeting in 2001, the Commission had prepared a report that reflected a position more aligned with a hardline stance on TRIPS and AEM. This was seen as a significant ‘departure from ... earlier attempts to occupy a middle ground’.⁷⁸⁷ An excuse to withdraw the paper, however, was suddenly presented to the

⁷⁸⁴ Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’, p. 478.

⁷⁸⁵ *ibid.*, p. 478 and p. 480-481.

⁷⁸⁶ *ibid.*, p. 482.

⁷⁸⁷ *ibid.*, p. 486.

WTO by the EC. Eventually, the remaining texts evolved into what is now known as the Doha Declaration on TRIPS and Public Health (described in Chapter 4) in 2001.

UK Department for International Development (DFID) Meetings on Access to Medicines and Intellectual Property Rights

Shortly before the Doha Declaration was adopted at the WTO in late 2001, the then U.K. Prime Minister Tony Blair decided to ask the Secretary of State for International Development Clare Short to establish ‘a small high level working group ... to find ways of improving access to medicines in developing countries’.⁷⁸⁸ This working group was comprised of representatives from the pharmaceutical industry, IGOs (i.e. WHO and WTO IP division), and the European Commission (i.e. DG Trade and DG Development) as well as ministers from other UK departments (i.e. Department of Health, HM Treasury, and Department of Trade and Industry). PM Blair launched his call for the working group with a public statement that the U.K. government is ‘committed to working together in partnership to improve access to medicines to help meet health targets’ and that the working group would work ‘to facilitate international discussions and actions around this vital international public health agenda’.⁷⁸⁹

The working group, on recognizing that ‘[t]he price of medicines is one of the key obstacles keeping people from the drugs they need’, issued a main recommendation for

⁷⁸⁸ UK Government, 'Prime Minister's Statement on Access to Medicines' (2001) <<http://www.dfid.gov.uk/Documents/publications/accessmedicines-report281102.pdf>>

⁷⁸⁹ C Short, 'Report to the Prime Minister. UK Working Group on Increasing Access to Essential Medicines in the Developing World. Policy Recommendations and Strategy.' (2002) Secretary of State for International Development <<http://www.dfid.gov.uk/Documents/publications/accessmedicines-report281102.pdf>> (28 Nov 2002)

the establishment of ‘an international framework ... [of] differential pricing as the operational norm’. Though the working group recognizes that this approach ‘alone would not be a panacea’, their recommendations stop short of touching upon the controversial issues of compulsory licensing and parallel importation that would be raised during the Doha Round. The U.K.’s promotion of a differential pricing system was consistent with the European Commission’s move towards the idea of a ‘global tiered pricing system for pharmaceuticals’, which was proposed by the EC as an alternative ‘middle ground’ option to the individual proposals put forth by the U.S. and developing countries at the WTO Doha Ministerial.⁷⁹⁰ The working group also saw the ‘urgent need for stepped up investments in new and improved technologies to address diseases of the poor’ and believed that ‘[c]reative public investment policies can help resolve market failure and re-shape incentives for industry’, such as the U.K.’s policy of corporate tax relief⁷⁹¹ for the research and development on HIV/AIDS, TB and malaria medicines and the Vaccines Research Relief.⁷⁹²

At about the same time, UK Government launched an independent Commission on Intellectual Property Rights based on a proposal from DFID’s White Paper – ‘Eliminating World Poverty: Making Globalisation Work for the Poor’. The Commission consisted of a panel of ‘international experts on [intellectual property rights]’ and it was charged with ‘look[ing] at the ways that intellectual property rules need to develop in the future in order to take greater account of the interests of developing countries and poor

⁷⁹⁰ S Muralidharan, 'A Compromise Deal.' (2001) 18 (24) *Frontline*

⁷⁹¹ Short.

⁷⁹² DFID, 'Increasing Access to Medicines in the Developing World: UK Government Policy and Plans' (2004) <<http://www.dfid.gov.uk/Documents/publications/accessmedicines.pdf>> p. 17

people'.⁷⁹³ The Commission reported to DFID on the completion of its study in late 2002, and the UK government responded to the Commission's report through a joint comment from Clare Short and the Secretary for Trade and Industry (Patricia Hewitt). While the UK Government 'did not endorse the entirety of the Commission's report or its recommendations', it 'broadly considered that the report had raised important issues that the international community should continue to debate'.⁷⁹⁴ For example, in response to the Commission's recommendation that '[d]eveloping countries should establish workable laws and procedures to give effect to compulsory licensing ...', the UK government responded that it:

[A]grees that legislation and procedures should be established by developing countries to allow the effective use of compulsory licensing and government use, as provided for in TRIPS and in line with the Doha Declaration. ... The Government considers that the principal purpose of this recommendation is to bolster the ability of developing countries to negotiate effectively with potential providers of patented medicines. But the actual use of compulsory licensing should be sparing and should follow the rules set out in Article 31 of TRIPS.⁷⁹⁵

The comment illustrates the UK's cautious acknowledgement and growing acceptance of TRIPS flexibilities for use by developing countries. Because the Doha Declaration was passed in late November 2001, the UK found itself being engaged through subsequent discourse with the public to align with the growing acceptance of the Declaration's provisions – such as compulsory licensing. Among the recommendations from the report accepted by the UK government, 'a number' found their way into DFID's subsequent Intellectual Property Rights strategy.⁷⁹⁶ It is interesting to note that, despite the fact that

⁷⁹³ DFID, 'Eliminating World Poverty: Making Globalisation Work for the Poor' (2000) <<http://www.dfid.gov.uk/Documents/publications/whitepaper2000.pdf>>

⁷⁹⁴ UK Government, 'The UK Government Response to the Report of the Commission on Intellectual Property Rights "Integrating Intellectual Property Rights and Development Policy' (2003) <http://www.iprcommission.org/papers/text/govt_response/govt_response.htm>

⁷⁹⁵ *ibid.*

intellectual property rights primarily lie within the domain of the Department of Trade and Investment, as well as the Patent Office, ‘the strategy highlight[ed] a specific role for DFID ... in the areas of technical assistance research specific to developing countries’.⁷⁹⁷ The UK’s international development agency was taking a unique approach that is unmatched by its developed country peers – notably the US. (DFID’s role in IP technical assistance is discussed further later in this section.)

WTO’s ‘Paragraph 6’ Waiver Decision – A temporary compromise

Following the passage of the Doha Declaration at the WTO, discussion amongst member states turned to the unresolved problem of developing countries without production capacity and their inability to exercise the TRIPS flexibility of compulsory licensing due to this limitation. There were concerns that the TRIPS provision requiring that compulsory licensing be used strictly for the domestic market would prohibit developing countries without production capacity from importing generics from other production-capable countries. Hence, Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health called upon the ‘Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002’.⁷⁹⁸ To address this issue, the EC tabled two potential solutions at the WTO: (1) ‘an amendment to Article 31(f) of the TRIPS Agreement that would create an exception to the requirement that a compulsory licence is predominantly for the domestic market’ and (2) ‘the option of allowing production for export as a limited exception under Article 30’.⁷⁹⁹ However,

⁷⁹⁶ DFID, ‘DFID Access to Essential Medicines Policy & Strategy’ (2004) <<http://webarchive.nationalarchives.gov.uk/+http://www.dfid.gov.uk/aboutdfid/organisation/accessmedicines.asp>>

⁷⁹⁷ *ibid.*

⁷⁹⁸ Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/2

both EC proposals exercised caution in the adjustment to the original TRIPS agreement as they were ‘subject to conditions with regard to eligible countries and scope of diseases’.⁸⁰⁰

Due to a lack of consensus between the country groups, the Chairman of the TRIPS Council took forward the task of developing a compromise text (known as the ‘Perez Motta text’) for consideration by the WTO member states. The text permits ‘countries to export patented medicines to [developing countries without manufacturing capacity], by making use of compulsory licences’, but also includes certain measures that are intended to appease the developed countries.⁸⁰¹ For example, the text includes ‘substantial safeguards’ to prevent the trade diversion of goods, whereby ‘the system ... provide[s] cheap medicines to the poor people, not to create parallel markets’.⁸⁰² The EC also requested that the text include a provision that use be ‘subject[ed] to the principle of proportionality’ whereby its use ‘must be reasonable and proportional to the administrative capacities of the country concerned’.⁸⁰³ Following these additions, the EC accepted to the text in December 2002 and praised it as ‘provid[ing] for a fair, balanced and flexible framework that can be effectively implemented in view of providing low priced medicines to countries in need’ and ‘constitut[ing] a key element in the fight

⁷⁹⁹ E ‘t Hoen (ed), *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond* (Economics of AIDS and Access to HIV Care in Developing Countries: Issues and Challenges ANRS Editions France 2003), p. 58.

⁸⁰⁰ ‘t Hoen, p. 58.

⁸⁰¹ European Commission, ‘Access to Essential Medicines: Background Info on the TRIPS Health Deal.’ (2003) <http://ec.europa.eu/trade/issues/global/medecine/bginfo_en.htm>

⁸⁰² *ibid.*

⁸⁰³ *ibid.*

against communicable diseases'.⁸⁰⁴ The EC followed this with the following statement to publicise its support of AEM:

The EU has been one of the driving forces behind the WTO debate on TRIPS and Public Health, and has sought throughout to find a compromise solution to this difficult question. The EU will continue its work to make sure that the deal is effectively implemented in a full and timely fashion in order to make it work to the benefit of those who need access to affordable drugs.⁸⁰⁵

The Chairman of TRIPS Council worked to resolve the differences between countries by holding talks between the two sides and moving them towards a compromise.⁸⁰⁶ The text was adopted at last on 30 August 2003 by the WTO's General Council and became known as the 'Decision on the Implementation of Paragraph 6 of the Declaration of the TRIPS Agreement and Public Health'.⁸⁰⁷ This decision, however, only 'takes the [legal] form of a provisional "waiver"' until a formal amendment to TRIPS Article 31 is reached.⁸⁰⁸ Discussions between countries over the transformation of the waiver into an amendment, however, were problematic. An agreement for the amendment of TRIPS Art. 31 was eventually reached in December 2005,⁸⁰⁹ but it requires ratification by two-thirds under WTO rules. A deadline for its ratification was set for Dec 2007, but then later re-extended until Dec 2012. The U.K. has voiced its support for an amendment.⁸¹⁰

EU Regional Free Trade Agreements (FTAs) and TRIPS-Plus Provisions

⁸⁰⁴ *ibid.*

⁸⁰⁵ *ibid.*

⁸⁰⁶ *ibid.*

⁸⁰⁷ See also Chapter 4 (section on the WTO).

⁸⁰⁸ European Commission, 'Access to Essential Medicines: Background Info on the TRIPS Health Deal' (2003) <http://ec.europa.eu/trade/issues/global/medecine/bginfo_en.htm>

⁸⁰⁹ Amendment of the TRIPS Agreement (6 December 2005) WT/L/641

⁸¹⁰ DFID, 'DFID Access to Essential Medicines Policy & Strategy ', p. 27.

In the years following the TRIPS agreement, bilateral and regional free trade agreements (FTAs) have arisen as a new problem for AEM. Developed countries found that they could use FTAs to incorporate trade measures that they could not achieve in the WTO negotiations, such as stronger patent protections and other related provisions. The EU has not been as active in its pursuit of more stringent intellectual property (IP) standards through FTAs and has generally applied the rules set out by TRIPS. However, recent EU trade policies indicate growing alignment with certain trade practices. In its regional trade negotiations with the Caribbean Forum of African, Caribbean and Pacific States (CARIFORUM), the EU incorporated 'TRIPS-Plus' measures (i.e. standards that go beyond TRIPS requirements) and this has raised concerns for the potential EU FTAs with the African region, Caribbean and Pacific (ACP) region, the Andean region, Central American region, and the Association of Southeast Asian Nations (ASEAN).⁸¹¹

Such measures, however, are inconsistent with the EC's growing practice of referring to 'access to medicines' as well as public health needs and implications in WTO talks.⁸¹² The EC has sometimes tried to appear to take a 'moral' path while attempting to shift the blame for failed multilateral compromises upon other actors. For example, in recounting its negotiating strategy for the WTO Hong Kong ministerial session, the EC stated:

It was agreed in Doha that WTO members would revise the TRIPS Agreement, to ensure that WTO rules on intellectual property would not impede access to affordable medicines. The end-2002 deadline for agreeing on the outline of an amendment was missed, due to opposition by the USA alone, and in spite of a proposal on how this could be achieved, tabled by the Africa Group. ... The

⁸¹¹MS Cruz, 'Intellectual Property Provisions in European Union Trade Agreements' (2007) Issue Paper No. 20 ICTSD Intellectual Property and Sustainable Development Series

⁸¹²HD Banta, 'Worldwide Interest in Global Access to Drugs ' (2001) 285 The Journal of the American Medical Association 2844, p. 2845.

promise to solve this problem was a key factor to persuading developing countries to agree to a new Round. Now it is just another broken promise.⁸¹³

Though the EC may have tried to work with the other WTO countries to reach a mutually acceptable consensus on the TRIPS amendment, the pursuit of TRIPS-Plus measures outside of the WTO does not indicate a true concern for AEM and public health needs. Hence, the EC's compromises made within the WTO forum (such as the amendment to TRIPS) could be a tactical concession to push for other objectives within the WTO, such as another round of trade talks. The inconsistency in the EC's behaviour on AEM recognition is apparent in its parallel pursuit of TRIPS-Plus measures outside of the WTO. To deal with this issue, the WHO and various NGOs have played a watchdog role in monitoring TRIPS-Plus activities and trying to help developing countries understand the possible implications of FTAs on AEM through the provision of technical assistance (e.g. country advising and regional workshops on TRIPS-Plus) and knowledge sharing (e.g. reports). Such efforts have helped to pressure developed countries, such as the EC, to modify their TRIPS-Plus provisions. To some degree, it could be argued that the efforts of the WHO and NGOs may also help to dissuade developed countries from including TRIPS-plus provisions in the future. As a growing number of bilateral and regional FTAs are modified due to public disapproval, this could help acculturate the developed countries from pursuing further TRIPS-plus measures in future FTAs.

As public and developing country sentiments turned against the WTO trade talks in the Doha Round, the EC found itself forced to give in to the tactical concessions of supporting the Doha Declaration on TRIPS and Public Health and the Paragraph 6 Waiver in order to move the trade talks forward. Yet, the EC's inconsistency on

⁸¹³ European Commission, *EV84 – European Commission's Negotiating Strategy for the WTO Hong Kong* (2006)

supporting AEM norms is apparent in its use of EU FTAs with developing countries as a means to pursue TRIPS-Plus provisions. The UK, on the other hand, tried to address the problem of acknowledging some, but not all, AEM norms. The government established a high-level working group to explore and recommend a solution to its internal dilemma. A tactical concession is made by the government to endorse the concept of differential pricing (also supported by the EC), but the passage of the Doha Declaration forces the U.K. to move beyond this small step and embrace the broader set of AEM norms, namely the use of TRIPS flexibilities.

Phase III and IV. EC and U.K. Prescriptive Behaviour and Habitualization

As the EC became increasingly socialized into accepting the criticality of AEM norms, it began to adopt a new set of legislative and policy measures to support the implementation of AEM by its member states. The EC's move towards prescriptive behaviour is apparent in the example measures discussed in this section. The U.K., in particular, has increasingly been recognized for its progressive domestic measures to implement AEM norms in its health and development activities. Like other countries, the implementation of AEM has been imperfect at times but the U.K. has become more consistent and committed in its approach to AEM.

The EC's Passage of a Regulation Allowing Compulsory Licensing for Export

An indication of a more formal commitment by the European Union towards AEM is exhibited by its passage of Regulation (EC) No 816/2006 of the European Parliament and

of the Council on 17 May 2006.⁸¹⁴ This regulation establishes a system within the EU that grants compulsory licences to European companies intending to export 'pharmaceutical products' to developing countries without production capacity.⁸¹⁵ It has been observed by former MSF activist, Ellen t'Hoen, that the European Parliament's 'approach ... is consistent with the position of the WHO in the TRIPS Council'.⁸¹⁶ Notably, the regulation 'does not impose any restrictions with regard to the pharmaceutical products and illnesses covered', which was a requirement that the developing countries had championed during the Paragraph 6 discussions.⁸¹⁷ On its role in the EC's passage of the regulation, the UK has reported that it worked closely with the EC to ensure that 'discussions on substantive issues' of the compulsory licensing decision were 'not reopened' by other EU members and that the 'totality of the [decision's] package [was] preserved'.⁸¹⁸ The U.K. has also gone on to amend its national patent legislation in accordance with the EC's regulation to permit compulsory licensing for the export of medicines.⁸¹⁹ This prescriptive move by the EU allows it to join several other countries (i.e. Canada, Norway, and India), which have changed their laws to support compulsory licensing for export.⁸²⁰

⁸¹⁴ Commission Regulation 816/2006, Compulsory Licensing of Patents relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, OJ (L 157) 1–7

⁸¹⁵ Europa, 'Compulsory licensing system for the production and export of generic medicinal products to developing countries' (2007)
<http://europa.eu/legislation_summaries/development/sectoral_development_policies/121172_en.htm>

⁸¹⁶ t'Hoen (ed), p. 60.

⁸¹⁷ Europa.

⁸¹⁸ DFID, 'Increasing Access to Medicines in the Developing World: UK Government Policy and Plans'.

⁸¹⁹ *ibid.*

⁸²⁰ WTO, 'Compulsory Licensing of Pharmaceuticals and TRIPS'

The EU's Adoption of the Programme for Action to Confront HIV/AIDS, TB, and Malaria

In 2005, the EU adopted a health and development-related policy framework known as the Programme for Action (PfA) to Confront HIV/AIDS, TB, and Malaria Through External Action (2007-2011) to guide the European Community's approach to address the three specified diseases in developing countries.⁸²¹ One of the PfA's main objectives is to scale up effective interventions to meet the treatment needs of these countries. To achieve this objective, the PfA calls upon the EU countries to take the following actions: (1) 'aim for a contribution that helps to fill the financing gap for the three diseases', (2) 'provide further technical support to improve countries' capacities to develop pharmaceutical policy', (3) 'encourage WHO to identify key issues that pharmaceutical policy needs to address', and (4) 'support countries in developing sound and efficient procurement policies and practices for pharmaceutical products ... [including] anti-retrovirals'.⁸²² In addition, the PfA's endorsement of affordable pharmaceutical products requires the EC to: promote the registration of 'a wide selection' of products under Regulation (EC) No 816/2006 by European businesses, endorse the transparency of product prices and publish the information to facilitate price comparisons, 'uphold' the Doha Declaration's principles as well as the WTO's August 2003 Decision, and 'actively participate in negotiations to change the August 2003 Decision into a formal amendment'.⁸²³

⁸²¹ Europa, 'Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis (2007-2011)' (2005) <http://europa.eu/legislation_summaries/development/sectoral_development_policies/r12537_en.htm>

⁸²² Europa, 'Communication from the Commission to the Council and the European Parliament - A European Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011)' (2005) <http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2005&nu_doc=179>

⁸²³ *ibid.*

Prescriptive Behaviour in the U.K. Government's Health and Development Activities

Over the years, the U.K. government has recognized AEM as part of the right to health in its efforts to 'contai[n] and progressively eliminat[e]' critical diseases (such as HIV/AIDS) that are affecting the developing world.⁸²⁴ The U.K. government's activities and policies in relation to AEM have featured prominently in the following areas: (1) the U.K.'s G8 and EU presidency in 2005, (2) the work of the U.K. Department for International Development (DFID), and (3) the U.K.'s Global Health Strategy for 2008-2013.

The U.K., in 2005, held the presidency for the G8 and EU. This gave the U.K. the opportunity to promote greater and more effective foreign aid for HIV/AIDS. Among the G8 and EU, the U.K. rallied for the replenishment of the Global Fund to Fight AIDS, TB and Malaria and was able to get donors to commit \$3.7 billion for 2006-07.⁸²⁵ The U.K. doubled its own commitment to 200 million pounds for the same period.⁸²⁶ Also during 2005, the U.K. led a campaign among the G8 countries at the Gleneagles Summit to rapidly increase HIV treatment with the target to achieve 'universal access by 2010'.⁸²⁷ To address the problem of aid effectiveness for HIV/AIDS, the U.K. co-hosted a high-level meeting (along with UNAIDS, the U.S., and France) called 'The Three Ones in Action: Making the Money Work', which called for the creation of the Global Task Team

⁸²⁴ UK Foreign and Commonwealth Office, 'Human Rights Annual Report' (2007) <<http://www.fco.gov.uk/resources/en/pdf/human-rights-report-2007>> , p. 25.

⁸²⁵ DFID, 'EU confirms its leadership in the fight against major diseases' (2005) <<http://webarchive.nationalarchives.gov.uk/+http://www.dfid.gov.uk/news/files/pressreleases/presidency-global-fund.asp>>

⁸²⁶ Stop AIDS Campaign, 'Universal access by 2010 – the UK Government's role in making it happen' (2006) <www.aidsconsortium.org.uk/2010/2010docs/SACpolicybriefing06.pdf>

⁸²⁷ *ibid.*

to improve coordination amongst international and multilateral donors (as discussed in Chapter 6).

The work of the U.K.'s Department for International Development (DFID) has also played a prominent role in the country's recognition and commitment to AEM. The importance of AEM norms is evident in DFID's work as the Secretary of State for International Development has acknowledged that the government believes that treatment for HIV/AIDS 'needs to be available, accessible and affordable worldwide'.⁸²⁸ In follow-up to the high-level working group on improving access to medicines (mentioned earlier in this section), DFID established an Access to Medicines team to focus on this issue and led a cross-governmental process to develop the U.K.'s policy and plans to increase access to essential medicines in the developing countries.⁸²⁹ This process involved consultations with an array of relevant government departments (such as the Department of Health, the Department of Trade and Industry, the Patent Office, and the Foreign and Commonwealth Office) as well as various actors from outside the UK government (including developing countries, international agencies, pharmaceutical companies, and NGOs). The process resulted in policy and plans centred on the government's development assistance programme, trade policy, pharmaceutical engagement and best practice guidelines, and research and development incentives and partnership, and the ways in which access to medicines could be better addressed or enhanced.⁸³⁰

⁸²⁸ UK House of Commons, 'Observations by the Secretary of State for International Development on the Petition [19th January] from the Stop AIDS Campaign for better global provision of medicines against AIDS, TB and malaria' (2006) Supplement to the House of Commons Votes and Proceedings (Session 2005 - 06) <<http://www.publications.parliament.uk/pa/cm/cmvotesupp/60217vs01.htm>> .

⁸²⁹ DFID, 'Increasing Access to Medicines in the Developing World: UK Government Policy and Plans', p. 18.

⁸³⁰ *ibid*, p. 17.

DFID has also been directly involved in health and trade-related matters. In 2005, DFID supported the WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) through 'the secondment of an official to lead the secretariat of the Commission'.⁸³¹ Also, in contrast to most other developed countries which provide IP-related technical assistance solely through their patent office, the U.K. also involves its international development agency (DFID). Intellectual property expert, Duncan Matthews, has observed that such agency involvement has resulted in 'IP-related technical assistance activities [that] tend to be more development oriented'.⁸³² Furthermore, based on DFID's Access to Medicines Strategy, the U.K. has committed government funding to the following initiatives: (1) a resource book on IP strategies for countries at different levels of development, (2) regional dialogues for developing countries on the formulation of IP legislation that meets their development aims, and (3) 'research and capacity to overcome [TRIPS flexibility] challenges'.⁸³³

The involvement of DFID on the matter of AEM has not been without controversy within the UK. DFID's efforts to take the lead on cross-governmental policies and activities on AEM have sometimes conflicted and overshadowed the U.K. Department of Health's intended role as the leader on the country's global health policies. Watchdog groups have found that DFID's HIV/AIDS programmes in developing countries were 'poorly organized' and the department itself has admitted to 'lack of support in dealing with complex technical issues'.⁸³⁴ In 2002, Richard Horton (the editor

⁸³¹ UK Parliament, 'Intellectual Property Rights' (2005)
<<http://www.publications.parliament.uk/pa/cm200506/cmhansrd/vo051208/text/51208w16.htm>>

⁸³² D Matthews and V Munoz-Tellez, 'Bilateral technical assistance and TRIPS' (2006) 9 (6) *Journal of World Intellectual Property* 629, p. 644.

⁸³³ DFID, 'Increasing Access to Medicines in the Developing World: UK Government Policy and Plans'

of the influential medical journal, *The Lancet*) criticized the DFID's undue influence upon the WHO both monetarily, as a major donor, and policy-wise, through its WHO strategy paper. Horton stated that DFID's strategic review of WHO wrongly 'defines WHO's work almost entirely within the context of human development' and that DFID's 'intention to improve co-ordination of UK government policy with WHO's work ... [puts] pressure on WHO to follow [its] narrow agenda'.⁸³⁵ He also went on to criticize DFID for not having consulted with the necessary U.K. health officials in developing the strategy paper and for lacking a broader view of the WHO's role in global health. DFID has responded to this criticism by stating that there was a 'misunderstanding of the purpose' of their report and that they vouch for the Department of Health's role as the 'overall lead for UK relations with WHO'.⁸³⁶ Hence, DFID explained that the report was only covering 'one aspect of the UK government's overall engagement with WHO'.⁸³⁷

To overcome concerns of inconsistencies and conflicts in the U.K.'s approach to global health matters, the Department of Health led and issued a comprehensive government strategy (for 2008-2013) called 'Health is Global'.⁸³⁸ Here, the U.K.'s approach to global health is very clearly underpinned by health as a human right as one of its guiding principles, whereby a clear reference is made in 'Health is Global' to the U.K.'s binding commitment to international human rights law (e.g. UDHR and ICESCR). Through this approach, the U.K. government seeks to create a 'clear and unified voice'

⁸³⁴ H Ashraf, 'Watchdog slams UK government's AIDS policy' (2004) 4 *The Lancet Infectious Diseases* 481, p. 481.

⁸³⁵ R Horton, 'WHO's mandate: a damaging reinterpretation is taking place' (2002) 360 *The Lancet* 960, p. 960.

⁸³⁶ C Short and A Milburn, 'UK Government and WHO' (2002) 360 (8343) *The Lancet* 1422., p. 1422.

⁸³⁷ *ibid.*

⁸³⁸ D Primarolo, M Malloch-Brown and I Lewis, 'Health is global: a UK government strategy for 2008-2013' (2008) 373 *The Lancet* 443.

on global health-related issues to multilateral agencies (such as the WHO and the WTO) and to create greater coherence in its foreign policies in areas such as trade, development, and health.

The EC and U.K.'s legislative and policy measures discussed here illustrate the growing consistency in the recognition of AEM through the establishment of substantial, formal commitments to AEM implementation. Though the implementation of these measures may sometimes be less than ideal, they indicate a deliberate move towards habituating the EC and UK's attitudes towards AEM norms. As the laws become more fully utilized and the programmes mature, this will help indicate the extent to which the UK government has become habituated on AEM.

Conclusion

This chapter set out to study the process of national progression towards the implementation of international standards on access to essential medicines (AEM) through the a case study of the United Kingdom. It also sought to understand how the international order influences this process and how the international and national levels interact with each other.

Through the spiral model, I was able to trace and understand the historical events in a country on AEM. The EC exhibited a changing attitude towards AEM as it progressed through the phases of denial, tactical concessions, and prescriptive status. Initially, there appeared to be a pattern of mimicry as the EC often followed the lead of other developed countries on matters of intellectual property rights in the trade forum by supporting the establishment of the TRIPS agreement and then pursuing TRIPS-Plus

provisions through bilateral and regional FTAs. Yet, the EC eventually broke away on a number of AEM-related issues (such as the Doha Declaration and pricing matters) as it was 'socialized' into giving AEM norms greater recognition. The phases of prescriptive behaviour by the EU indicates that the EU (and UK) have taken a set of much more progressive measures, both legislative and policy, than other country governments.

The case study also revealed the limited control of international institutions (i.e. WHO and WTO) over the countries, as its guidance can often be either ignored or circumvented. Even the powers of the WTO's DSB could be avoided by some, if it was able to persuade or intimidate the other party to resolve the dispute privately. Instead, the main drivers of state change appeared to be domestic and international NGOs' use of shaming, argumentation, and persuasion. Through the use of such moral dialogue, the NGOs were able to entrap and persuade governments to behave in accordance with its public statements and conform to international standards.

Though the international institutions have been more hesitant to apply 'socialization' processes (such as the use of coercion through penalties or openly engage in shaming and argumentation) to influence developed countries, this does not suggest that international institutions had no role in these processes. There are instances of shaming or persuasion partnerships or networks between the institutions and NGOs that were effective in bringing country offences to light. For example, this can be seen in the EC's adoption of Regulation (EC) No 816/2006, which closely follows the WHO's advocated position on compulsory licensing for export as indicated during the WTO TRIPS Council. As for the UK's move towards accepting AEM in a 'habitualized' manner, the future remains uncertain. The UK has made a deliberate move towards more

fully recognizing and implementing AEM norms – from its initially inconsistent stance to its currently progressive approach amongst the developed countries. The outlook on the UK's implementation of AEM norms appears promising, but whether the momentum of the UK's progressive approach to AEM can be maintained is subject to political considerations within the greater EC body and financial considerations in terms of foreign assistance.

Chapter 6: EMERGING CHANGES IN THE GOVERNANCE OF ACCESS TO ESSENTIAL MEDICINES

Introduction

The issue of AEM does not exist in a static world. In recent years, the institutions and states alike have come to recognize the problems of conflict and disorganization that are obstructing governance in this area. AEM, as discussed in the previous chapters, is an issue area that sits at the intersection of several different institutional realms – health, trade and development. There presently is no clear governance structure or hierarchy of rules to deal with the institutional overlaps and disconnects mentioned earlier. At the intersection between trade and health, there is a strong tension between the right to health and the present legal system for international intellectual property rights. The intersection between health and development presents a very different type of problem. While health and development efforts can be mutually reinforcing, this has not been the case for many initiatives due to misaligned priorities, a lack of coordination, and the competition for resources. In addition, the basis of access to essential medicines on the right to health can allow it to summon the institutional support of the broader human rights regime, namely the powers of the UN Committee on Economic Social and Cultural Rights (CESCR). Thus, it is important to consider the role that the CESCR UN could play a role in supporting the governance of AEM and urging developed countries to meet their IAC obligations.

Following from the earlier discussions about the current state of governance and implementation, this chapter considers three approaches that have emerged in recent years to address the weaknesses and inconsistencies of IAC for AEM amongst

the key international institutions. The first two approaches deal with the institutional tensions that exist for AEM in terms of its intellectual property and health financing dimensions. On the intellectual property dimension of AEM, the approach involved the formulation of a 'Global Strategy and Plan of Action' through an ad hoc structure known as the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property at WHO. The second approach, which addresses the HIV/AIDS health financing and technical assistance dimension, involved the establishment of a UNAIDS-led 'Global Task Team on improving AIDS coordination among multilateral institutions and international donors' and the creation of several governance mechanisms. After evaluating these two ad hoc structures, the chapter turns its attention to the role of the UN's Committee on Economic, Social and Cultural Rights and considers how it could better address the issue of IAC for AEM.

WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)

Recent activity at the WHO may indicate a significant change from the institution's past approach to the issue of access to medicines.⁸³⁹ Most notably, the WHO recently served as the forum for a series of formal negotiations on intellectual property and innovation with regard to medicines by WHO member states. These negotiations were conducted through a series of meetings known as the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, which has been abbreviated as the 'IGWG' by participants.

⁸³⁹ The WHO, as detailed in the earlier chapters, has mainly taken a territorially 'safe' and, typically, non-controversial approach towards the issue of access to medicines – especially in relation to international trade and intellectual property. Ellen 't Hoen, a former Access to Medicines advocate at MSF, observes that the 'WHO ... has tended to focus on "lofty goals" such as the "3 by 5" initiative ... but not how to get there'. See 'WHO Board Wrestles With IP And Public Health Report, R&D Proposal' *Intellectual Property Watch* (Online 27 January 2006).

The Origins of the IGWG

The IGWG originated from a chain of key events at WHO. The first event was the report of the WHO Commission on Intellectual Property Rights and Public Health (CIPIH), which was released in April 2006. The report was developed by a WHO assembled team of independent experts who were tasked with developing a set of recommendations to help improve the innovation and accessibility of medicines needed in developing countries based upon available evidence and different stakeholder perspectives.⁸⁴⁰ Concerns about the report's findings about the present lack of innovation and the impact of patent protection on AEM by developing countries and public health activists led to the merging of two existing global movements. One movement had been focused on the need for greater research and development (R&D) into medicines that targeted neglected diseases, such as tropical diseases, which predominantly affect the developing world. The other movement was concerned with the impact of intellectual property rights (IPRs) on access to existing medicines. These two movements, known respectively as the 'innovation' and 'access' movements, joined forces to push for a global strategy or framework to address the issue of medicines for developing countries.⁸⁴¹

Kenya and Brazil championed this approach and introduced a WHA resolution proposal for a global framework for research and development at the WHO.⁸⁴² The

⁸⁴⁰ WHO, 'Frequently Asked Questions' WHO Commission on Intellectual Property Rights, Innovation and Public Health
<<http://www.who.int/intellectualproperty/documents/thereport/questions/en/index.html>> (10 July 2009); WHA 56.27

⁸⁴¹ M Khor, 'WHA establishes working group on IPRs and health R&D' *TWN Info Service on WTO and Trade Issues* (Geneva 29 May 2006).

idea stalled due to European Commission opposition, but the WHO member states settled on a revised resolution (WHA 59.24). The WHA Resolution 59.24 essentially gave WHO the mandate to establish the IGWG and develop a ‘global strategy and plan of action’ on public health, innovation, and intellectual property for consideration at the 61st World Health Assembly scheduled for May 2008.⁸⁴³ The Global Strategy and Plan of Action was to be ‘aim[ed] at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries ...’.⁸⁴⁴ In addition to the ‘innovation’ concerns, it addressed key ‘access’ issues. For example, WHA 59.24 ‘not[ed] that the [Doha Declaration] confirms that the Agreement does not and should not prevent Members from taking measures to protect public health’.⁸⁴⁵ It also mentioned that ‘[the Declaration] affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all’.⁸⁴⁶

The member state call for WHO to become involved in the area of intellectual property, however, has not been without controversy. For example, it has been observed that ‘some delegations felt that the management of intellectual property did not fall within WHO’s remit’.⁸⁴⁷ The disagreement over WHO’s involvement in

⁸⁴²WHO Board Wrestles With IP And Public Health Report, R&D Proposal’.

⁸⁴³ WHA 59.24

⁸⁴⁴ *ibid.*

⁸⁴⁵ *ibid.*

⁸⁴⁶ *ibid.*

trade-related matters was also voiced by certain governments with regard to WHA Resolution 59.26, which mandated the WHO to work on issues of international trade and health. This particular resolution so perturbed one country delegation that it caused them to walk out during the voting process; however, the resolution still passed under the WHA's consensus procedure. In any event, WHO's involvement in intellectual property related matters has been justified by the 'innovation and access' movement as necessary because it was widely felt among WHO member states that 'the intellectual property system was poorly understood in some parts of the world ... [and that] collaboration between health, trade and intellectual property officials ... would help to promote a better understanding of its implications for health'.⁸⁴⁸

The IGWG Process

The IGWG process entailed three sessions⁸⁴⁹ (occurring from 2006 through mid-2008), which focused on negotiation of two major items: the global strategy and the plan of action. The global strategy involved eight principal elements, which were prepared by the WHO after deliberations at the first IGWG session (held in December 2006) and during a set of regional consultations leading up to the second IGWG session (held in November 2007). These eight principal elements included:

⁸⁴⁷ WHO Regional Office for Europe, 'Background Document for the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property' (2007) <http://www.euro.who.int/document/pha/igwg_background.pdf>, p. 7. (The U.S. has commented that the WHO was trying 'to go beyond its technical expertise'. TIS Gerhardsen, 'US Advises Developing Country FTA Partners Not To Follow WHO IP Plan' *Intellectual Property Watch* (Online 11 December 2006).)

⁸⁴⁸ WHO Regional Office for Europe, p. 7.

⁸⁴⁹ The first session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property was held from 4 to 8 December 2006; the second session 5 to 10 November 2007; and the third session from 28 April to 3 May 2008. The third session of the IGWG, which was a week-long meeting before the May 2008 World Health Assembly, is often referred to as the '2nd resumed session' of the IGWG (as negotiations were left incomplete during the initial second session of the IGWG in November of 2007). The WHO Secretariat also undertook a series of intersession regional consultations with WHO Member States.

prioritizing research and development needs; promoting research and development; transfer of technology; building innovative capacity; management of intellectual property; improving delivery and access; ensuring sustainable financing mechanisms; establishing monitoring and reporting systems. The strategic elements, as exhibited by these topics, covered a broad range of issues related to the ‘innovation and access’ agenda. Hence, as a WHO country delegate has observed, the IGWG was ‘not mainly about [intellectual property], but also about [intellectual property]’.⁸⁵⁰ The WHO’s task of assembling the various elements for the global strategy was not easy. It has been observed that the ‘submissions to the ... consultation may be roughly divided into two groups: [t]hose who propose finding the solution to the issue within the current intellectual property system, and those who want an alternative system’.⁸⁵¹ This resulted in multiple ‘regionally-based’⁸⁵² versions of the draft global strategy text that had to be resolved into a single document during the negotiations. The plan of action, on the other hand, addressed the practical aspects of the strategy (i.e. specific actions, stakeholders, time frames, and progress indicators pertaining to each of the eight elements).

⁸⁵⁰ G Silberschmidt, ‘Public Health, Innovation and Intellectual Property Global strategy and Plan of Action (Presentation)’ (2008) Vice-Director, Swiss Federal Office of Public Health <www.cgdev.org/doc/ghprn/IGWG%20Process%20PATH.ppt> (18 Nov 2008).

⁸⁵¹ TI Gerhardsen, ‘Consultation On WHO IP Group Shows Polarised Debate; Challenge For Group’ *Intellectual Property Watch* (Online 16 November 2006)

⁸⁵² ‘It was agreed that the WHO regions would organize a series of consultation meetings with the Member States to provide further input to the global strategy and the plan of action. Meanwhile, the WHO Secretariat would work on a revised paper incorporating the additional inputs from the Member States, and that would be finalized in July 2007. The revised document could then be discussed by the regional committees before the second IGWG meeting in November 2007.’ WHO Europe, *Meeting on Public Health, Innovation and Intellectual Property - Input to the Global Debate from the Newly Independent States (report)* (WHO Regional Office for Europe, Health Technology and Pharmaceuticals Programme 2007), p. 1.

Within the WHO, the WHO Director General (DG) Dr. Margaret Chan quickly responded to the WHA Resolution 59.24's request 'to convene immediately the intergovernmental working group and to allocate the necessary resources to it'. A Secretariat for Public Health, Innovation and Intellectual Property was established to support the work of the IGWG. The WHO's Secretariat was rather understaffed to support the IGWG's requirements and, thus, heavily on cross-departmental support. This dependence on cross-developmental support can be problematic as many other WHO departments tend to be under similar staffing constraints themselves. As a result, some of the Secretariat's work was contracted to outside experts.

In addition to the Secretariat, the IGWG included a member state staffed 'bureau'. This bureau consisted of a chairman and five vice-chairmen.⁸⁵³ Also, in accordance with the WHA 59.24 mandate, the IGWG was to be supported by an independent expert group. DG Chan had to assure balanced representation within the group and, thus, selected representatives: two individuals from the Drugs for Neglected Diseases Initiative, two individuals from Médecins sans Frontières, one individual from the Biotechnology Industry Organization, two individuals from the OECD, one individual from the Bill & Melinda Gates Foundation, one individual from Sidley Austin LLP, and several experts from the other intergovernmental organizations (i.e. World Trade Organization, the World Intellectual Property Organization, and the Global Forum for Health Research).⁸⁵⁴ The list of aforementioned experts represents a roughly even split between those who represent

⁸⁵³ The bureau consisted of a Canadian, who was elected as the Chairman, and the following representatives served as vice-chairmen: individual from Netherlands, individual from Libyan Arab Jamahiriya, individual from Kenya, individual from Singapore, and individual from India. See WHO Regional Office for Europe.

⁸⁵⁴ *ibid.*

developing country and developed country interests. These experts were permitted to attend the IGWG sessions and ‘provide advice and expertise, as necessary, upon request of the Chairman, taking into account the need to avoid conflicts of interest’.⁸⁵⁵ Other individuals who were permitted to attend the IGWG sessions included NGOs with whom the WHO has established ‘official relations’ (as described in Chapter 3). These individuals are only permitted to attend the ‘open’ sessions, which do not include the drafting sessions where ‘closed’ member state negotiations are held, and are not permitted to speak during the sessions in their ‘observer’ capacity.⁸⁵⁶

The three week-long sessions of the IGWG revealed the WHO’s strengths and weaknesses in its ability to lead and serve as a forum on the matter of public health and intellectual property. The first session of the IGWG to develop the global strategy and plan of action was considered, by most accounts, unsatisfactory to member states and almost reduced to a diplomatic exercise due to the slow pace in negotiations and various impasses.⁸⁵⁷ While many of the problems in the first session could be attributed to strategic political wrangling and an attempt to delay

⁸⁵⁵ WHA 59.24, Paragraph 4(3).

⁸⁵⁶ With regard to the issue of NGO participation, Canada, the U.S. and Kenya made ‘interventions’ at the IGWG about the possibility of ‘fast-tracking’ NGOs into official relations with the WHO, so that they could attend the sessions. A fast-track accreditation process had been applied for an earlier Intergovernmental Working Group session on Tobacco Control and essentially entailed the designation of relations with the WHO ‘on an ad hoc basis’. The Secretariat responded that, according to official WHO procedures, a member state would ‘need to raise the [topic] of NGO accreditation at the [WHO’s next] Executive Board meeting’. The fast-tracking process was ultimately approved and applied for a number of NGOs before the second session was held. See T Balasubramaniam, ‘From Geneva: WHO Executive Board discusses Public Health, Innovation, and Intellectual Property (IGWG)’ *IP-Health List Website* (26 Jan 2007).

⁸⁵⁷ According to the Brazilian delegation, ‘[the session] did not bring hono[ur] to the WHO or to us. I’m not here to accuse anyone. The December meeting was ridiculous’. Kenya was similarly displeased with the first session’s progress and outcome and ‘request[ed] [that] WHO ... expedite the work of the Group’. The U.S. and E.U. similarly voiced their frustrations with the progress of the IGWG. See T Balasubramaniam, ‘From Geneva: Canada, United States, South Africa and Kenya raise issue of fast-tracking NGO accreditation’ *IP-Health Online* (8 Dec 2006).

proceedings, the WHO was the subject of criticism for its procedures in expert selection and NGO participation. DG Chan affirmed that the Secretariat would take the Member State comments into consideration and ‘pledg[ed] support for the IGWG ... as [she] [saw] how important it is for [the member states]’.⁸⁵⁸ In the period leading up to the second session of the IGWG, the WHO made sure to address the Member State concerns raised⁸⁵⁹ and shouldered the responsibility of preparing the draft texts for negotiations through a series of regional consultations and online submissions. The second session of the IGWG also proceeded with a slow start and the bureau decided to split the IGWG into two major drafting groups (and a later sub-group) in an attempt to accelerate the proceedings. (The two main drafting groups addressed different aspects of the global strategy and a third sub-group was formed to work on the plan of action.) This arrangement presented a participatory disadvantage for a number of developing countries, which will be discussed at the conclusion of this section. Due to the slow pace of the ongoing negotiations, the second session was suspended after a week’s time and it was determined that a third session (i.e. a ‘resumed second session’) would occur during the spring of 2008. The third session was timed to occur prior to the 61st World Health Assembly, so that the draft Global Strategy and Plan of Action could be presented to the assembly of WHO member states for passage. The WHO’s IGWG eventually concluded its deliberations on the draft strategy and plan of action on 3 May 2008 and sent the document to the WHA for consideration. The assembly passed the document as WHA Resolution 61.21, which was titled ‘Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property’.

⁸⁵⁸ Balasubramaniam, 'From Geneva: WHO Executive Board discusses Public Health, Innovation, and Intellectual Property (IGWG)'

⁸⁵⁹ As mentioned earlier, the WHO modified its procedures for expert selection and NGO participation.

WHA Resolution 61.21 is widely considered by developing countries and public health advocates as a milestone for access to medicines. In DG Chan's closing remarks at the 61st WHA, she stated that with the WHA resolution on IP and innovation 'public health leaps ahead in addressing two fundamental and long-standing needs: to improve access to existing interventions, and to include diseases of the poor in the drive to develop new products'.⁸⁶⁰ A lead negotiator for a developing country delegation commented that the resolution was 'the most important document since the Doha Declaration on Public Health'.⁸⁶¹ Various activist NGOs were similarly pleased with the IGWG outcome and the WHO's role in the process. According to the director of Knowledge Ecology International (KEI), he stated that the 'WHO [had] taken a big step forward to change the way we think about innovation and access to medicines'.⁸⁶² While the passage of the WHA 61.21 was highly significant in the sense that it was the first time the WHO was engaged as a forum for extensive deliberations on intellectual property and allowed the matter to be addressed from a public health perspective, the more practical details of its achievement for access to essential medicines remains uncertain (as explained in the next section).

⁸⁶⁰ W New, 'WHO Adopts 'Most Important Document Since Doha' On IP And Public Health ' *Intellectual Property Watch* (Online 29 May 2008).

⁸⁶¹ *ibid.*

⁸⁶² *ibid.*

The IGWG and Access to Essential Medicines

The IGWG process tackled an expansive agenda on innovation and intellectual property in relation to public health. While it was largely framed as a strategy to address the issue of the lack of innovation (i.e. research and development) for diseases that disproportionately affect developing countries, the IGWG was also highly concerned with the issue of intellectual property rights and access to existing essential medicines. This is evidenced by the IGWG's preoccupation with deliberating upon TRIPS (in terms of TRIPS flexibilities and TRIPS-plus provisions in FTAs), which was instigated by various developing countries. The ongoing concerns about TRIPS in relation to AEMs are reflected across Elements 4, 5 and 6 in the Global Strategy and Plan of Action.⁸⁶³ For example, the Global Strategy's Element 5 (i.e. on the application and management of intellectual property to contribute to innovation and promote public health) stresses the need to:

... strengthen capacity to manage and apply intellectual property in developing countries, including, in particular, the use to the full of the provisions in the TRIPS Agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public health.

In particular, this element promotes the 'adapt[ion] [of] national legislation in order to use to the full the flexibilities [in TRIPS] ...'. Element 5 also addressed the TRIPS-related issue of the WTO Doha Declaration 'Paragraph 6' system by encouraging states to 'tak[e] necessary measures in countries with manufacturing capacity to facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector ...'. In addition, it addressed the issue of 'TRIPS-plus' provisions by asking states to 'take

⁸⁶³ WHO, 'Global strategy and plan of action on public health, innovation and intellectual property (WHA 61.21)' (2008) World Health Organization <http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf> (24 May 2008), para. 35.

into account ... the impact of public health when considering adopting or implementing more extensive intellectual property protection than is required by the [TRIPS agreement] ...'. Furthermore, Element 5 cautions states entering into new trade agreements (e.g. bilateral and regional FTAs) to remember to take TRIPS flexibilities into account. In terms of dealing with the tensions between health and intellectual property, the element 'promote[s] [the] active and effective participation of health representatives in intellectual property-related negotiations' to account for health needs and asks states to 'strengthen education and training in the application and management of intellectual property, from a public health perspective'.

Element 6 (on Improving Delivery and Access) also details a number of supportive measures for AEM. For example, it endorses 'competition to improve [the] availability and affordability of health products consistent with public health policies and needs' and specifically mentions:

... support [for] the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a "regulatory exception" or "Bolar"-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement

The element also mentions 'the reduction or elimination of import tariffs' on medicines and endorses the consideration of differential pricing policies to promote access to medicines in developing countries.

Another positive development for AEM through the IGWG pertained to the 'transfer of technology' under Element 4. The transfer of technology was a provision

that was put into TRIPS as ‘part of the bargain in which they have agreed to protect intellectual property rights’.⁸⁶⁴ According to TRIPS Article 66.2:

Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.⁸⁶⁵

From the developing country and WHO Secretariat perspectives, technology transfer is an issue that has received far too little attention and insufficient follow through under the WTO. Element 4 of the Global Strategy directly addresses the issue of technology transfer by ‘promoting transfer of technology and the production of health products in developing countries’ through measures such as: investment, capacity building, technical support and identification of best practices.⁸⁶⁶ It also ‘support[s] improved collaboration and coordination of technology transfer for health products’ (with acknowledgement of the measure required by TRIPS Art. 66.2) as well as the exploration of potential ‘new mechanisms’ for technology transfer.⁸⁶⁷

It is also interesting to note that, during the IGWG deliberations, the human right to health was raised as an overarching principle for the Global Strategy and Plan of Action.⁸⁶⁸ As discussed earlier in this thesis, the right to health provides a critical basis of normative support for AEM. This suggestion proved to be contentious as one

⁸⁶⁴ WTO, ‘TRIPS Issues: Technology Transfer’.

⁸⁶⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) LT/UR/A-1C/IP/1, Art. 66.2.

⁸⁶⁶ WHO, ‘Global strategy and plan of action on public health, innovation and intellectual property (WHA 61.21)’, para 34 (4.1).

⁸⁶⁷ *ibid.*, para.34 (4.2) and para. 34 (4.3).

⁸⁶⁸ This idea was raised by the Brazilian delegation as part of the ‘Rio text’ (one of the regional drafts prepared for the IGWG’s 2nd session). The idea of applying ‘right to health’ language was supported by Egypt, Philippines, South Africa, and Norway. See WHO, ‘Report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property’ (2008) World Health Organization <http://apps.who.int/gb/ebwha/pdf_files/A61/A61_9-en.pdf> (19 May 2008), para. 17.

developed country did not want to be bound to human rights instruments (i.e. ICESCR) that it has not ratified. The IGWG ultimately reached a consensus on applying 'right to health' language from the WHO Constitution, but not the ICESCR. Hence, the following statement was accepted as a guiding principle: '[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'.⁸⁶⁹ Another major point of contention was a suggested principle stating that 'the right to health takes precedence over commercial interests'.⁸⁷⁰ Some developed countries objected to this language and suggested an alternative statement that 'the interests of trade and health should be appropriately balanced and coordinated'.⁸⁷¹ Due to a prolonged stalemate on this issue, the WHO Secretariat provided a suggestion from WHA 52.19, which states that '[p]ublic health interests are paramount in pharmaceutical and health policies'. These alternative suggestions were rejected by Kenya, which felt that they were 'not saying the same thing', and the text was left in brackets (signalling a lack of consensus). Ultimately, in the final draft text, there was a consensus to delete the suggested principle altogether for the purposes of moving the global strategy and plan of action forward to the WHA for considerations.

⁸⁶⁹ WHO, 'Global strategy and plan of action on public health, innovation and intellectual property (WHA 61.21)', para. 16.

⁸⁷⁰ WHO, 'Report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property', para. 18.

⁸⁷¹ *ibid*, para. 18.

IGWG's Governance Implications

Beyond the potential impact that the Global Strategy and Plan of Action could have on AEM, in relation to intellectual property and international trade, the IGWG process itself has triggered a few key governance implications that deserve attention. First, the IGWG process has significantly boosted the WHO's stature on matters of political and economic importance on the international agenda. Traditionally, public health has been considered a matter of 'low politics' for which most countries devote little attention and time. International trade, on the other hand, is a matter of high political importance. The linkage between health and trade through the IGWG at WHO has placed a spotlight on the institution, and questions have arisen as to whether the WHO is prepared to assume the new responsibilities imparted upon it. From the developed countries, there have been criticisms that the WHO is moving beyond its mandate and area of expertise. The developing countries, on the other hand, are generally enthusiastic about the WHO's new role on matters of innovation and intellectual property. The Brazilian delegation argues that the WHO is not going beyond its mandate; rather, WHO should do its own work based on its 'own mandate from its own decision-making body', with access to health as the main objective.⁸⁷² There have been concerns, however, about the WHO's resource capacity to sufficiently address its new responsibilities.⁸⁷³ India believes that the WHO needs to address this by building up its capacity to take on its new role with increased support from member states. From the WHO Secretariat perspective, it appears that the organization has been preparing itself for the new role. During the IGWG deliberations, an internal memo revealed that the WHO leadership (from within the

⁸⁷² Gerhardsen, 'US Advises Developing Country FTA Partners Not To Follow WHO IP Plan'.

⁸⁷³ As discussed earlier in this section, the Secretariat for Public Health, Innovation and Intellectual Property is staff constrained. In addition, the WHO budget places further constraints on its operations.

Director-General's office) was working on an 'institutional response' to the IGWG recommendations and expectations. The memo states that this response needed to 'represent a vision of WHO leadership' that would 'reassure countries that WHO can take the strategy forward' and that it would 'enhance the work of WHO as a whole' rather than specific parts of the organization. The vision plan was to be divided according to elements of the Global Strategy. While this sounds like a grand vision for WHO, its plan for Element 5 (on IP management) stated that WHO could lead on policy and technical guidance, monitoring and analysis, and strategic country support in training and enhancing capacity. Based on the discussion presented in Chapter 4 (on the role of WHO on trade matters), these functions appear quite similar to those that are already being performed. It is possible that the nature of WHO's 'guidance' and 'strategic support' could be more far reaching than that already offered. DG Chan has also indicated (at least organizationally) that she is dedicating greater attention to the Secretariat for Public Health, Innovation and Intellectual Property by moving the department into the Director-General's Office (DGO) and, thus, elevating its status.⁸⁷⁴

Another interesting implication of the IGWG was the emphasis on intergovernmental cooperation. While this is not the first time that institutional cooperation has been brought up at the WHO (as discussed in Chapter 4), the difference is that it is now accompanied by a detailed plan of action which divides

⁸⁷⁴ On 20 Nov. 2007, DG Chan sent an internal announcement to WHO staff reporting the following: '[i]n order to further strengthen the WHO secretariat support to, and follow up from, the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, I have asked ... [the director and associate director of the Department of Technical Cooperation for Essential Drugs and Traditional Medicine] to join Dr Elil Renganathan and his team. This new team for Public Health, Innovation and Intellectual Property will report to the Executive Director of the Office of the Director General'.

specific tasks by stakeholders (including WHO and WTO). This attempt at a less abstract notion of cooperation and collaboration through a detailed workplan could help lay the foundation for greater public health recognition at WTO. It also helps to establish a clearer division of labour between the organizations that would help to define the boundaries between mandates.

A final major implication of the IGWG is that the WHO has become part of a growing trend in the establishment of lawmaking regimes dealing with intellectual property rights.⁸⁷⁵ From the start, the IGWG was seen as an opportunity by some developing countries and activists to launch a push for the idea of an ‘R&D treaty’ (or similar legal framework) that would inevitably deal with the issue of intellectual property rights. Some developed countries were adamantly against such an idea at this stage, although tentative language about the idea has been included in the Global Strategy (i.e. it ‘encourage[s] further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty’).⁸⁷⁶ According to a WHO official, the countries are likely engaging in ‘forum shopping’ as they test the waters of various institutions for the most hospitable legislative arena to their agenda. (Similar developments, although not related to health *per se*, have been occurring in parallel at the World Intellectual Property Organization with the push by developing countries for a ‘development agenda’.) Since the completion of the IGWG at WHO, negotiations for a plurilateral treaty among several key developed countries has

⁸⁷⁵ Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking'.

⁸⁷⁶ WHO, 'Global strategy and plan of action on public health, innovation and intellectual property (WHA 61.21)', para. 30(2.3)(c).

appeared. This treaty, known as the Anti-Counterfeiting Trade Agreement (ACTA), assumes the form of what Daniel Drezner would consider a 'club' arrangement (as discussed in Chapter 2). Under the 'club' arrangement, powerful 'likeminded' countries can form a plurilateral agreement (without the use of any intergovernmental organization) and define their own set of constricting intellectual property terms (e.g. TRIPS-plus provisions). ACTA, at this time, has not completed negotiations. There are concerns by various activist NGOs that the terms defined by ACTA might set a new standard for intellectual property rights, which developing countries will be pressured into joining at a later point in time or via the terms of negotiated bilateral or regional FTAs. Hence, the public health progress achieved by IGWG might be short lived as developed countries move outside of the multilateral organizations to pursue stronger intellectual property terms.

Global Task Team on improving AIDS coordination among multilateral institutions and international donors (GTT)

Following from the discussion about UNAIDS in Chapter 4, this organization has tried to reassert its role of 'coordination' amongst the new and existing institutions involved in AIDS-related activities through the Global Task Team (GTT). In the mid 2000s, AIDS funding began to grow at a rapid pace but questions and concerns began to arise over the problem of aid effectiveness in the AIDS field. Many wondered why the increased financing of AIDS was not garnering greater and faster results and the international organizations began finger pointing and blaming others for faults. Ministries of health in developing countries, which are commonly understaffed, began to complain of the extensive burdens placed upon them by the multitude of donors in

terms of the varying grant proposals, monitoring and evaluation systems, and reporting requirements for the AIDS initiatives in their countries. Theoretically, UNAIDS was expected to bring coherence and coordination within the UN system on AIDS activities; however, fragmentation, overlap, and duplication was a prevalent problem across the system. This section details the formation of the Global Task Team and how the GTT could potentially strengthen the UNAIDS role in governing its cosponsors in a new operating environment for AIDS.

The Establishment of the Global Task Team

Renewed international consideration into the issue of organizational coordination on HIV/AIDS began in 2005 with the formation of the Global Task Team (GTT), which was facilitated by UNAIDS. The GTT arose after a series of international declarations⁸⁷⁷ (from 2003 to 2005) on the need for ‘harmonization and alignment’⁸⁷⁸ in development assistance and a UNAIDS campaign to promote ‘the Three Ones’ principles. The Three Ones, which were coined by UNAIDS, are a set of guiding principles for the coordination of donor assistance in recipient countries and the promotion of greater developing country ownership of AIDS initiatives with the aim to achieve greater aid effectiveness and programme sustainability. The principles stand for the need to establish (1) one national AIDS action framework (i.e. strategy)

⁸⁷⁷ OECD Development Assistance Committee, ‘Rome Declaration on Harmonisation’ (Statement from Development Assistance Committee, Rome, Italy 25 February 2003) <<http://www.sti.ch/pdfs/swap327.pdf>>; Paris Declaration on Aid Effectiveness, March 2005 <<http://www.oecd.org/dataoecd/11/41/34428351.pdf>>; UN, Monterrey Consensus, 2002 <<http://www.un.org/esa/ffd/monterrey/MonterreyConsensus.pdf>>; OECD DAC, Paris Declaration and the Accra Agenda for Action <http://www.oecd.org/document/18/0,2340,en_2649_3236398_35401554_1_1_1_1,00.html>

⁸⁷⁸ The concepts of ‘harmonization and alignment’ refer to the emerging consensus in the development community that aid effectiveness depends on the ‘harmonization of donor practices’ and their ‘alignment with national development priorities’. See UN, ‘UN Reform: Harmonization & Alignment to Achieve the Millennium Development Goals.’ New York, 2005., p. 3. <http://www.searo.who.int/LinkFiles/Strategic_Alliance_and_Partnerships_5f_UNDP_UN_Reform.pdf>

to coordinate the work of country donors, (2) one national AIDS coordinating authority, and (3) one national monitoring and evaluation system within each recipient country. While the Three Ones clearly emphasized the criticality of international alignment through particular national mechanisms, it remained uncertain as to how the principles would overcome the prevailing UN organizational troubles of turf battles, budget shortfalls, and other issues at the global level. Essentially, the harmonization of the UN agencies needs to occur both globally and nationally and the principles would falter without an overarching coordination mechanism to facilitate a cooperative working relationship between the numerous organizations as a complement to developing country plans for AIDS initiatives.⁸⁷⁹ At the Consultation on Harmonization of International AIDS Funding in April 2004,⁸⁸⁰ participants endorsed the Three Ones and specifically called upon UNAIDS ‘to act as mediator and facilitator in efforts to realize these principles’.⁸⁸¹

In an effort to mobilize international action pertaining to the principles, UNAIDS co-hosted a meeting on 9 March 2005 in London (along with the U.K., the U.S., and France) called ‘Making the Money Work: the “Three Ones” in Action’. The meeting gathered various stakeholders (i.e. representatives of donor and recipient governments, international organizations, and civil society) to discuss the next steps in implementing the Three Ones. A key issue in the discussions was the need for

⁸⁷⁹ 'Improving Coherence Among Multilateral Institutions and International Donors to Develop and Support Effective AIDS Programmes'; UN, 'The Global Task Team: A Model for Reform of Operational Activities for Development' (2005) <<http://www.un.org/esa/documents/GTT-Send%20Ctte%20rev.pdf>> (9 November 2005).

⁸⁸⁰ The Consultation on Harmonization of International AIDS Funding was a meeting co-hosted by UNAIDS and the U.S. and U.K. governments in Washington, DC. It convened a group of representatives from donor and recipient governments, international organizations, and civil society.

⁸⁸¹ WHO SEARO, 'WHO Harmonization and Alignment: The UN role' (2006) <http://www.searo.who.int/EN/Section1257/Section1259_11221.htm> (2 May 2006).

improved coordination amongst the various multilateral institutions and donors working on HIV/AIDS assistance.⁸⁸² It was determined that a ‘non-bureaucratic coordinating instrument at the global level’ was needed to:

... ensure that the major funders and providers of technical expertise ... [were making progress on] : (i) common decisions; (ii) exchanging information; (iii) cooperating and avoiding duplication; (iv) providing appropriate and coordinated country level support; and (v) learning common lessons in each of the “Three Ones” areas.⁸⁸³

Despite an ongoing atmosphere of UNAIDS distrust and hostility from some of the UN agencies, the participants settled on the establishment of a UNAIDS-led and supported Global Task Team to make recommendations on the key issues raised at the London meeting.

The Global Task Team structure and meetings

The Global Task Team (GTT) was formed in April 2005, under the co-chairmanship of a UNAIDS official (Michel Sidibe, who is now the UNAIDS Executive Director) and Swedish AIDS ambassador (Lennarth Hjelmaker), and comprised of 18 high-level institutional leaders from across the UNAIDS cosponsors (including WHO, World Bank, UNDP, UNICEF, and UNDG), donor and recipient countries, the Global Fund, and civil society.⁸⁸⁴ The GTT was directed to recommend options, which would be presented for endorsement by the governing bodies of UNAIDS and its UN cosponsors as well as the Global Fund,⁸⁸⁵ on how ‘to improve the performance of the

⁸⁸² UNAIDS, 'The Global Response to AIDS: 'Making the Money Work' The Three Ones in Action'

⁸⁸³ 'Improving Coherence Among Multilateral Institutions and International Donors to Develop and Support Effective AIDS Programmes'

⁸⁸⁴ UNAIDS, 'The Global Task Team on Improving Coordination Among Multilateral Institutions and International Donors: Terms of Reference' (2008) UNAIDS <http://www.unaids.org/Unaidresources/images/GTT/GTT_TOR_15Apr05.pdf> (8 April 2008).

international architecture supporting country-led national programmes to scale up the AIDS response'.⁸⁸⁶ Given the deadline of the UNAIDS Program Coordinating Body meeting in June 2005, the GTT was only given an 80 day timeframe to reach its recommendations. After that point, the GTT was to disband.

To inform and advise the GTT, three Working Groups were formed around the major international support areas of: (1) programming and financing; (2) technical support; and (3) monitoring and evaluation. The working groups were charged with the identification of the main challenges in global support to developing countries by analyzing: 'the existing players and their relationships, including existing coordination mechanisms'; 'differences in preferred modes of operation with recipient governments'; 'duplications, gaps, bottlenecks and barriers to harmonization'; and 'the comparative advantages of UN system agencies, major fundraising mechanisms and major funding institutions'.⁸⁸⁷ In addition, they were to suggest actions that would address these challenges. Membership of the Working Groups included those 'resource persons with insights in and concrete experiences with coordination and alignment at country or inter-agency level' from the UN agencies and developed and developing country governments along with representatives from civil society. Each Working Group was co-chaired by a multilateral institution and member state.⁸⁸⁸

⁸⁸⁵ In particular, the GTT's recommendations would be used 'to inform the replenishment process of the Global Fund, and will be presented for endorsement to the governing bodies of UNAIDS and its Cosponsors, the Global Fund, the World Bank, regional lending institutions, civil society networks, and other relevant multilateral institutions'. See UN, 'The Global Task Team: A Model for Reform of Operational Activities for Development'

⁸⁸⁶ UNAIDS, 'Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors'

⁸⁸⁷ *ibid.*

The three Working Groups met twice each to discuss the priority challenges and develop recommendations for the GTT in their respective areas. The Working Group recommendations were then taken forward to the GTT, which met twice between late May and early June to reach a consensus on the recommendations, and a final report of the recommendations was released on 15 June 2005. The recommendations were then presented to the UNAIDS PCB and the governing bodies of the UNAIDS cosponsors for approval. The UNAIDS secretariat was mandated with the facilitation and monitoring of the implementation process.

GTT Final Report Recommendations

To achieve a more effective multilateral response through reform, the GTT recommends that several steps be taken.⁸⁸⁹ First, the GTT calls for the establishment of a joint UN team on AIDS that is to be tasked with ‘develop[ing] a unified UN country support programme on AIDS within the national planning framework’. This joint team, which would be facilitated by UNAIDS and connected to ‘global-level problem-solving mechanisms’, is intended to provide national stakeholders with ‘a common entry point’ to the UN system’s AIDS-related services and support.⁸⁹⁰

Second, the GTT recommends the creation of a joint problem-solving team comprised of the UN system institutions (including WHO, UNICEF, UNFPA, UNDP, World Bank, UNAIDS Secretariat) and the Global Fund. This team is intended to

⁸⁸⁸ *ibid.*

⁸⁸⁹ UNAIDS, ‘Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors – Final Report’

⁸⁹⁰ *ibid.*

meet on a regular basis in order to support developing countries in addressing any implementation bottlenecks and to identify country lessons and best practices for dissemination.⁸⁹¹

Third, the GTT directs the UNAIDS cosponsors and the Global Fund to establish a more functional and clear division of labour that is based upon the ‘comparative advantages and complementarities’ of the different institutions. Under the leadership of UNAIDS, the UN institutions are to develop the division of labour for technical support to developing countries and to present this division to the UNAIDS PCB.⁸⁹² It is interesting to note that this approach helped to ‘introduced the concept of “lead agency” into the [UN] system’, which is believed to have helped in defining roles in the HIV/AIDS response.⁸⁹³

Fourth, to achieve improved accountability and oversight, the GTT recommended that UNAIDS ‘assist national AIDS coordinating authorities to lead participatory reviews of performance of multilateral institutions, international partners, and national stakeholders’ in accordance with OECD/DAC standards and criteria for alignment and harmonization. The GTT specifically suggested that performance be measured through a ‘scorecard-style accountability tool’. This tool was developed into what is now known as the Country Harmonization and Alignment Tool under the leadership of UNAIDS.⁸⁹⁴

⁸⁹¹ *ibid.*

⁸⁹² *ibid.*

⁸⁹³ Nemes and others, p. 27.

⁸⁹⁴ UNAIDS, 'Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors – Final Report'

The recommendations also address the involvement of the Global Fund. The GTT recommended that the World Bank and Global Fund find ways to better align institutional financing with countries' cycles and AIDS action plans. It also called upon these institutions to participate in and adopt national joint annual reviews as their primary evaluation method. Furthermore, the GTT recommends that UNAIDS, the Global Fund, and the World Bank support countries in addressing the issues related to the relationship between the national AIDS coordinating authority and the Global Fund's Country Coordinating Mechanism and to jointly report on progress to the UNAIDS PCB. The GTT also calls for an institutional shift from project to programme financing that is based off of national AIDS action frameworks and a greater 'commit[ment] to harmonizing and better coordinating [institutional] programming, financing, and reporting'. Specifically, the GTT asks the World Bank and Global Fund to engage in a pilot effort to adopt joint financial management and procurement assessments, joint supply management policies and procedures, and joint programmatic and financial reporting.⁸⁹⁵

Implementing the GTT Recommendations - New Governance Mechanisms and Structures for International Institutional Coordination on AIDS

One of the new governance structures to arise from the GTT recommendations was the creation of the Global Problem-Solving Implementation Support Team (GIST). The team was initially comprised of the UNAIDS secretariat, WHO, the World Bank, the Global Fund, UNDP, UNICEF, and UNFPA, but was expanded in 2006 to include

⁸⁹⁵ *ibid.*

states (such as the U.S. PEPFAR programme) and NGOs (e.g. the International Council of AIDS Service Organisations and the International HIV/AIDS Alliance). The GIST, which is supported by the UNAIDS secretariat, functions as a global forum for members to meet at regular periods (i.e. 3-4 times a year) to identify implementation issues, share and discuss lessons and other information, and respond collaboratively to technical support concerns.⁸⁹⁶ While originally conceptualized to address implementation issues at the country level,⁸⁹⁷ an independent evaluation found that the GIST 'add[s] the most value when it responds to systemic problems at the regional or global level' as it 'creates space for interagency dialogue and coordination that does not otherwise exist'.⁸⁹⁸ For example, through global collaboration, the GIST has created a set of principles for technical support for users and providers as well as global-level database for technical support planning and coordination called CoATS. One solution that GIST has helped to address was the substantial technical assistance dependency (as mentioned in Chapter 4) of the Global Fund upon WHO and the need to finance WHO for this work.⁸⁹⁹

Another mechanism that arose from the GTT recommendations was the Country Harmonization and Alignment Tool (CHAT). In response to the GTT's recommendation for UNAIDS to develop a 'scorecard-style accountability tool', UNAIDS and the World Bank collaborated to create the CHAT. The tool serves to assist the national coordinating authority in measuring and assessing partner

⁸⁹⁶ UNAIDS, 'Terms of Reference: The Global Implementation Support Team (GIST)' (2008) <http://data.unaids.org/pub/BaseDocument/2008/200801_gist_tors_en.pdf>

⁸⁹⁷ UNAIDS, 'The Global Implementation Support Team' (2008) UNAIDS <<http://www.unaids.org/en/CountryResponses/TechnicalSupport/gist.asp>>

⁸⁹⁸ UNAIDS, 'Terms of Reference: The Global Implementation Support Team (GIST)'.

⁸⁹⁹ Nemes and others, p. 26-27.

compliance with the “Three Ones” Principles including ‘the degree of harmonization and alignment among international partners’ at the country level.⁹⁰⁰ It is intended that this tool can help pinpoint blockages, establish greater transparency, and hold partners accountable through advocacy and dialogue. The CHAT is an innovative contribution to international coordination as one of the first mechanisms created to monitor donors’ ‘adherence ... to their global commitments to harmonise and align’ on HIV/AIDS.⁹⁰¹

A third mechanism recommended by the GTT is the division of labour amongst the UNAIDS cosponsors. As noted earlier, the division of labour aims to leverage the comparative advantages of each UNAIDS cosponsor in order to deliver the most effective and efficient technical assistance to countries. In addition, the division of labour was intended to allow the cosponsors specialize in certain areas of support and more obviously differentiate themselves in their HIV/AIDS activities.⁹⁰² This approach involves assignment of the UNAIDS secretariat and its cosponsors as either the Lead Organization or Main Partner under three thematic categories of technical support: (1) strategic planning, governance and financial management; (2) scaling up interventions; and (3) monitoring and evaluation, strategic information, knowledge sharing and accountability. The Lead Organization holds the primary responsibility in ‘coordinating the provision and/or facilitation of ... technical support

⁹⁰⁰ UNAIDS, 'Country Harmonization and Alignment Tool' (2007) UNAIDS <http://data.unaids.org/pub/Report/2007/jc1321_chat_en.pdf> (June 2007).

⁹⁰¹ D Whyms, S Jensen and I Huijts, 'Setting standards for harmonisation' (2007) 370 (9602) *The Lancet* 1826, p. 1826.

⁹⁰² UNAIDS, 'UNAIDS Technical Support Division of Labour' (2005) UNAIDS <http://data.unaids.org/una-docs/JC1146-Division_of_Labour.pdf> (August 2005).

[in its specified thematic category]'.⁹⁰³ This not only involves a strong leadership and brokering role in relation to its Main Partners and national stakeholders, but also a liaison role to the UNAIDS, the UN Theme Groups and Joint Teams (as discussed later), and the GIST. While the Main Partners simply function as other actors within a thematic technical support area, their relationship with the Lead Organization is not based on a hierarchy and they must be consulted by the Lead Organization when requests for support are made to the UN. This is to ensure that the appropriate providers and financing has been jointly deliberated and selected.⁹⁰⁴

It is interesting to note, however, that UNAIDS efforts to push for a division of labour amongst its cosponsors is not an entirely new concept.⁹⁰⁵ UNAIDS had tried in earlier unsuccessful attempts to encourage a division of labour, but its lack of authority over its cosponsors caused its efforts to fall short of success. For example, one of UNAIDS' main coordinating mechanisms over its cosponsors is the Unified Budget and Workplan; however, the fact that it 'only covers a fraction of the AIDS-related expenditures of some of the Cosponsors ... lessen[ed] its effectiveness in this regard'.⁹⁰⁶ Several factors, however, have enabled the division of labour to occur in 2005 amongst the UNAIDS cosponsors. One factor was the advance of UN reform, which requires the UN agencies to look for solutions to 'deliver as one'. The other factors can be attributed to extreme changes in the AIDS environment since UNAIDS inception in 1996. For example, the agencies had become clearer about what they

⁹⁰³ *ibid.*, p. 6.

⁹⁰⁴ *ibid.*

⁹⁰⁵ *ibid.*

⁹⁰⁶ UNAIDS, 'Global Task Team on Improving AIDS Coordination Among Multilateral Institutions and International Donors – Final Report' (2005) UNAIDS (14 June 2005) <http://data.unaids.org/Publications/IRC-pub06/JC1125-GlobalTaskTeamReport_en.pdf>, p. 14.

were capable of doing based upon working experience. There were also significantly greater resources available from the donors for HIV/AIDS, but they ‘made clear ... that increased financing is contingent upon the UN system [to] improve[e] its ability to plan and coordinate [technical assistance]’.⁹⁰⁷

Finally, the Joint UN Team on AIDS is a central structure that was developed based upon the GTT recommendations to help bring coherence and coordination to UN agency actions at the country-level. The Joint Team, which operates within each country receiving UN assistance on AIDS, serves to coordinate UN technical activities based upon the Division of Labour and allow team members to ‘reach consensus’ on internal issues before working with external stakeholders (i.e. national and international partners).⁹⁰⁸ As the Division of Labour is intended to be adaptable to each country, the roles of the UN agencies on the Joint Team might differ from country to country depending on agency presence. The Joint UN Team aims to provide each country with a single point of entry to the UN system for technical assistance.⁹⁰⁹ Also, in keeping with the ‘Three Ones’ principles, the team operates based on country requests for support as the UN seeks to establish a ‘demand-driven process’ rather than UN and donor dictated technical assistance.⁹¹⁰

⁹⁰⁷ UNAIDS, 'UNAIDS Technical Support Division of Labour'

⁹⁰⁸ UNAIDS, 'Second Guidance Paper - Joint UN programmes and teams on AIDS: Practical guidelines on implementing effective and sustainable joint teams and programmes of support.' (2007) UNAIDS <http://data.unaids.org/pub/Manual/2008/jc1512_second_guidance_paper_en.pdf> (November 2007).

⁹⁰⁹ *ibid.*

⁹¹⁰ *ibid.*

The Joint Team is comprised of all UN technical staff working on AIDS at the country level and operates under the chairmanship of the UNAIDS Country Coordinator (UCC), who is in regular communications with other country-level UN agency bodies (i.e. UN Resident Coordinator, UN Country Team, and UN Theme Group on HIV/AIDS). The UCC acts on behalf of UNAIDS at the country-level by ‘provid[ing] policy and technical advice as well as advocat[ing] for and mobiliz[ing] effective action on HIV/AIDS by cosponsors and agencies’ as well as representing the Joint Team to non-UN entities.⁹¹¹ Given the existence of the established UN Theme Group on HIV/AIDS, which also holds a coordinating role amongst the UN agencies on HIV/AIDS at the country-level, UNAIDS has since clarified that the Theme Group (which is comprised of heads of agencies) should hold a policy and strategic oversight role while the Joint Team plays on a technical implementation role.⁹¹² Hence, this helps the different teams focus on their respective areas and respond more quickly to any issues that might arise.

GTT’s Governance Implications

The operating environment in the fight against HIV/AIDS has changed dramatically since 1996 when UNAIDS was launched. With new technical knowledge and approaches, new financing, and new actors, it would appear that we should be closer to ending the HIV/AIDS crisis in 2010; however, the battle rages on. UNAIDS was a revolutionary institution created specifically to address the HIV/AIDS emergency and to change the way the UN system was working on issue. Through UNAIDS’

⁹¹¹ UNDP, ‘Proposed Working Mechanisms for Joint UN Teams on AIDS at Country Level’ (2006) UNDP <http://data.unaids.org/pub/Manual/2007/jc1325_jointu_teams_en.pdf> (19 May 2006), p. 5.

⁹¹² *ibid.*, p. 3.

struggles to achieve coordination amongst its cosponsors, the GTT has emerged as a revamped approach to how UNAIDS would conduct its business going forward – in targeting coordination at two levels – internationally and nationally. In attempting to understand the influence that the GTT has had on UNAIDS governance, it helps to consider coordination at these two levels.

At the international level, the GTT's recommendation for a division of labour has helped UNAIDS to more clearly establish how its cosponsors should work together. By designating the Lead Organization and Main Partners across the different areas of technical support, it aims to eliminate the murky lines of responsibility that have plagued the UN agencies over the years. Hence, UNAIDS can begin the process of relieving the UN system of the institutional tensions (e.g. turf battles and infighting) and addressing the inefficiencies that had arisen over the years in the UN's HIV/AIDS operations.

At the national level, in keeping with the growing international and multilateral appreciation for country ownership, the GTT's recommendation for a Joint UN Team at country-level provides the operational opportunity for the UN agencies to coordinate. With the UNAIDS Country Coordinator as the Joint Team facilitator and the directive for the Joint Teams to adapt the division of labour, the UNAIDS influence is further reinforced amongst its cosponsors and the defined role of each agency is solidified through action. The GTT innovations of the CHAT (as a monitoring and evaluation mechanism) and the GIST (as a regular forum) help to maintain the UNAIDS leadership and cosponsor relations that have formed as a result of the GTT recommendations.

With the promising new approach to AIDS governance offered by the GTT, it still remains to be seen if UNAIDS can achieve and maintain the level of coordination sought. The division of labour, while operational in some countries, has not been consistently implemented and accepted. (In addition, the division of labour has been criticized for focusing too much on country-level tasks and coordination as opposed to the larger, underlying problems at the global level.)⁹¹³ Another challenge pertains to the financing of GTT implementation and the budget shortfalls that have been experienced in recent years (though funds have been recovered through other sources). A final, critical issue relates to the challenge of coordinating with donors beyond the UN system. The GTT involved a number of donor countries during its planning process, but it ultimately only addresses the UN agencies. With the massive funds of donor programmes, such as PEPFAR and DFID, a true international coordinated effort will depend on harmonization with these entities also.

The UN Committee on Economic, Social and Cultural Rights (CESCR)

While the emerging governance approaches hold some promise for improved international assistance and cooperation, it still remains highly uncertain if these new structures will succeed in their objectives and make a significant impact on AEM.

This section now turns to the potential role of international human rights in the

⁹¹³ UNAIDS, 'Second Independent Evaluation of UNAIDS' (2009) UNAIDS <http://data.unaids.org/pub/BaseDocument/2009/sie_final_report_annex_9_en.pdf> , p. 21; Nemes and others, p. 28.

governance of this issue. As established in Chapter 1 (Introduction), AEM is a core obligation of the ICESCR's right to health (Article 12). This places the issue of IAC implementation for AEM firmly within the realm of the Committee on Economic, Social and Cultural Rights (CESCR), which is the 'principal body concerned with the [ICESCR]' and a subsidiary of the UN Economic and Social Council (ECOSOC).⁹¹⁴

The Committee on Economic, Social and Cultural Rights (CESCR) was established by ECOSOC in 1985 and meets twice a year for three to four week periods in Geneva.⁹¹⁵ It is comprised of 18 independent experts⁹¹⁶ who are charged with monitoring state compliance with the ICESCR and facilitating its implementation.⁹¹⁷ According to Philip Alston⁹¹⁸ and his colleagues, the CESCR has three objectives: (1) '[to] develop the normative content of the rights recognized in the Covenant'; (2) '[to] act as a catalyst to state action in developing national mechanisms for establishing accountability, and providing means of vindication to

⁹¹⁴ HJ Steiner, P Alston and R Goodman, *International Human Rights in Context* (3rd edn, Oxford University Press, Oxford 2008), p. 277; WHO, 'International Covenant on Economic, Social and Cultural Rights' World Health Organization (Health and Human Rights) <http://www.who.int/hhr/Economic_social_cultural.pdf> (8 Feb 2010), p. 3.

⁹¹⁵ ECOSOC Res 1985/17 (28 May 1985) UN Doc E/RES/1985/17; Office of the High Commissioner for Human Rights, 'Fact Sheet No.16 (Rev.1), The Committee on Economic, Social and Cultural Rights' UN Office of the High Commissioner for Human Rights <<http://www.ohchr.org/Documents/Publications/FactSheet16rev.1en.pdf>> (10 June 2010). (According to the Office of the High Commissioner for Human Rights, the CESCR is 'a subsidiary organ of ECOSOC and derives its authority from that body'.)

⁹¹⁶ CESCR members are 'experts with recognized competence in the field of human rights' and 'serve in their personal capacity, not as representatives of Governments'; in addition, the 'principles of equitable geographic distribution and representation of different social and legal systems guide the selection process'. *ibid.*

⁹¹⁷ 'Subsidiary Bodies of the ECOSOC' <<http://www.un.org/ecosoc/about/subsidiary.shtml>> (20 Jan 2007); ECOSOC, 'General comment 1. (General Comments) Reporting by States parties (1989) E/1989/22', para. 1; 'International Covenant on Economic, Social and Cultural Rights (adopted on 16 December 1966, entered into force 3 January 1976)', art 16.

⁹¹⁸ Professor Philip Alston served as chairman of the UN CESCR from 1990-1998. He is currently a Professor of Law at New York University.

aggrieved individuals and groups'; and (3) '[to] hold states accountable at the international level through the examination of reports'.⁹¹⁹ This translates into several functional tasks for the CESCR, which include: issuing 'general comments';⁹²⁰ holding 'days of general discussion';⁹²¹ and requesting state reports (i.e. initial and periodic reports) for review and providing 'concluding observations' based on them.⁹²² Another potentially powerful function of the CESCR arises from the recent adoption of the Optional Protocol to the ICESCR (UN General Assembly Resolution A/RES/63/117), which grants the CESCR 'competence to receive and consider [individual] communications' (i.e. complaints).⁹²³

As indicated by this set of functions, the CESCR possesses various powers to influence states. It also has methods, as described later in this section, to involve and

⁹¹⁹ Steiner, Alston and Goodman, *International Human Rights in Context*, p. 277.

⁹²⁰ General comments are interpretations of the provisions of the ICESCR. They serve to 'assist and promote' state implementation; 'suggest improvements in reporting'; and 'stimulate the activities of [states], international organizations and United Nations specialized agencies'. WHO, 'International Covenant on Economic, Social and Cultural Rights', p. 4. (In addition to General Comment No. 14 [on the right to health], other general comments issued by the CESCR include: the right to adequate housing; persons with disabilities; the right to adequate food; and the right to water. See Office of the High Commissioner for Human Rights, 'Committee on Economic, Social and Cultural Rights - General Comments' Office of the United Nations High Commissioner for Human Rights <<http://www2.ohchr.org/english/bodies/cescr/comments.htm>> (10 July 2010).)

⁹²¹ 'Days of general discussion' are held during the CESCR sessions in Geneva and provide the committee with the opportunity to understand and discuss 'a particular right or ... a particular aspect of the [ICESCR]' through input from a range of interested experts (e.g. civil society, UN special rapporteurs, UN specialized agencies, and academia). See ECOSOC, 'Revised General Guidelines Regarding the Form and Contents of Reports to be Submitted by States Parties under Articles 16 and 17 of the International Covenant on Economic, Social and Cultural Rights.' (1991) E/C.12/1991/1', para. 48.; Office of the High Commissioner for Human Rights, 'Fact Sheet No.16 (Rev.1), The Committee on Economic, Social and Cultural Rights'; Steiner, Alston and Goodman, *International Human Rights in Context*, p. 277.

⁹²² Articles 16 and 17 of ICESCR mandate the CESCR to request reports from state parties.

⁹²³ UN General Assembly, 'Optional Protocol to the International Covenant on Economic, Social and Cultural Rights' (2008) Resolution A/RES/63/117 <<http://www2.ohchr.org/english/bodies/cescr/docs/A-RES-63-117.pdf>> (10 Dec 2008); Office of the High Commissioner for Human Rights, 'Committee on Economic, Social and Cultural Rights: Monitoring the economic, social and cultural rights' UN Office of the High Commissioner for Human Rights <<http://www2.ohchr.org/english/bodies/cescr/>> (10 April 2010).

coordinate UN specialized agencies (such as the WHO and World Bank) on matters pertaining to the ICESCR. Proceeding with the establishment of IAC for AEM, which is derived from the CESCR's General Comments No. 14 and No. 3,⁹²⁴ this section directs its attention to the CESCR's powers in inducing state implementation and addressing state violations, specifically, the CESCR's mechanisms of periodic reporting and complaints procedures.

Periodic Reporting

ICESCR states are expected to submit a periodic report⁹²⁵ to the CESCR detailing their progress on the treaty's implementation.⁹²⁶ These periodic reports, according to General Comment No. 1, serve the following objectives:⁹²⁷

- (1) to ensure that a comprehensive review is undertaken with respect to national legislation, administrative rules and procedures,
- (2) to ensure that the State party monitors the actual situation on a regular basis,
- (3) to enable to Government to demonstrate that policy-making has been undertaken as needed for compliance with the Covenant,
- (4) to facilitate public scrutiny,
- (5) to evaluate the extent to which progress has been made,
- (6) to enable the State party to develop a better understanding of the problems,
- (7) to facilitate the exchange of information among States parties and to develop a better understanding of the common problems faced.

⁹²⁴ As discussed in Chapter 1 (Introduction), IAC for AEM is a set of norms that were derived from General Comment No. 3 (on the Nature of State Parties Obligations) and General Comment No. 14 (on the Right to Health).

⁹²⁵ The reporting frequency has been revised since the drafting of the ICESCR. According to the revision, the first report must be submitted to the CESCR after two years of the ICESCR's ratification. Subsequent reports to the CESCR are expected every five years thereafter. See Office of the High Commissioner for Human Rights, 'Committee on Economic, Social and Cultural Rights: Monitoring the economic, social and cultural rights' .

⁹²⁶ Toebe, p. 93-94.

⁹²⁷ *ibid*, p. 94; ECOSOC, 'General comment 1. (General Comments) Reporting by States parties (1989) E/1989/22', para 2-9.

The CESCR's reporting processes, as indicated by these objectives, encourages a regular practice of state self-assessment and public information exchange. In terms of formal assessment, the CESCR holds periodic sessions to discuss submitted reports with state representatives and issue its 'concerns and recommendations to the [state] in the form of "concluding observations"' .⁹²⁸

Prior to March 2009, the CESCR applied a set of 'revised guidelines' (adopted in 1991) as the standard format for state report submissions.⁹²⁹ Under these guidelines, in reference to Article 12 of the ICESCR, the CESCR specified a particular set of measures and questions to guide states in their reporting on the right to health. The questions are predominantly concerned with the realization of the right domestically (or within a state's territories). For example, the CESCR reporting measures and questions requested the following information:

Infants immunized against diphtheria, pertussis, tetanus, measles, poliomyelitis and tuberculosis ...⁹³⁰

Proportion of the population having access to trained personnel for the treatment of common diseases and injuries, with regular supply of 20 essential drugs, within one hour's walk or travel.⁹³¹

Please describe the measures taken by your Government to prevent, treat and control epidemic, endemic, occupational and other diseases.⁹³²

⁹²⁸ Office of the High Commissioner for Human Rights, 'Committee on Economic, Social and Cultural Rights: Monitoring the economic, social and cultural rights'.

⁹²⁹ ECOSOC, 'Revised General Guidelines Regarding the Form and Contents of Reports to be Submitted by States Parties under Articles 16 and 17 of the International Covenant on Economic, Social and Cultural Rights.' (1991) E/C.12/1991/1'.

⁹³⁰ *ibid.*, para. 4(d).

⁹³¹ *ibid.*, para. 4(f).

⁹³² *ibid.*, para. 5(g).

As illustrated above, all of these reporting questions ask for details pertaining to implementation by the Government domestically. There were two questions, however, that the CESCR used to track the duty of IAC. In relation to the right to health, the question asked was: '[p]lease describe the role of international assistance in the full realization of the right enshrined in article 12'.⁹³³ The guidelines also posed a general question pertaining to ICESCR Article 2, which asked:

If your State participates in development cooperation, is any effort made to ensure that it is used, on a priority basis, to promote the realization of economic, social and cultural rights?⁹³⁴

To understand how the developed countries of concern in this thesis have handled the CESCR's reporting mechanism, it helps to consider the submitted reports of the UK. Based on a review of the U.K.'s reports submitted to the CESCR (as of August 2007),⁹³⁵ the state has historically given little attention to the role of IAC for AEM (or, more generally, IAC for the right to health) in its submissions. The CESCR, however, has raised concerns about the matter of AEM for HIV/AIDS in the UK's Overseas Territories. According to the CESCR's concluding observations in 2002:⁹³⁶

The Committee is concerned about the high incidence of HIV/AIDS in some of the State party's Caribbean territories. It is particularly concerned about the number of HIV/AIDS cases in the Turks and Caicos Islands and St. Vincent and the Grenadines, and the lack of availability of, and access to, anti-retroviral medication for migrant workers and AIDS orphans.⁹³⁷

⁹³³ *ibid.*, para. 5(g).

⁹³⁴ *ibid.*, Annex Art 2, para.3.

⁹³⁵ The next periodic report from the UK is due on 30 June 2014, which follows five years after the CESCR's 2009 examination of the UK's latest (2007) report.

⁹³⁶ ECOSOC, 'Report on the Twenty-Eighth and Twenty-Ninth Sessions (Supplement No. 2)' (2003) UN Doc E/2003/22.

⁹³⁷ *ibid.*, para. 224.

In the context of HIV/AIDS, the Committee urges the State party to ensure the availability of, and equal access to, anti-retroviral medication for all individuals in Overseas Dependent Territories.⁹³⁸

In response to these concerns about AEM for HIV/AIDS, the UK clarified that the Overseas Territories 'are responsible for managing their own health budgets and National AIDS programme budgets' and, hence, the UK government was not involved in the direct provision of ARVs to the region. The CESCR's enquiry, however, has helped to focus the UK's attention on the problem and 'self-assess' its efforts in the region. In its 2007 accounting of government's efforts in the Overseas Territories, the UK noted that: '[it] facilitated contact between the Caribbean [Overseas Territories] and the Clinton Foundation HIV/AIDS Initiative for the acquisition of anti-retroviral medication at lower cost'; three Overseas Territory countries (i.e. Anguilla, the British Virgin Islands, and Montserrat) are able to procure ARVs at a 'reduced cost' through the Organisation of Eastern Caribbean States (OECS) Pharmaceutical Procurement Service; and support was provided to the region's national AIDS programmes through the 'Caribbean Epidemiology Centre'.⁹³⁹ The UK also indicated that it was completing the design of a new regional HIV/AIDS program that would 'support the [Overseas Territories] own national plans and maximize support from other donors such as the European Commission'.⁹⁴⁰

⁹³⁸ *ibid.*, para. 243.

⁹³⁹ ECOSOC, 'Fifth Periodic Reports Submitted by States Parties under Articles 16 and 17 of the Covenant: United Kingdom of Great Britain and Northern Ireland' (31 January 2008) UN Doc E/C.12/GBR/5, para. 173 and 174.

⁹⁴⁰ *ibid.*, para. 174.

Considering the timing of the UK's 2002 report and its response to the CESCR in the following periodic report (i.e. 2007), it is important to note that much has occurred in terms of global HIV/AIDS activity between those years.⁹⁴¹

This may have prompted the UK to respond, more specifically and directly, on the matter of IAC in relation to health (and related matters) in its 2007 report to the CESCR. For example, in the 2007 report, there is a section dedicated to 'the role of international cooperation in the implementation of the Covenant'. The state reports the following UK activities in the promotion of the right to health:

On the containment and progressive elimination of the spread of HIV/AIDS, the UK prioritises the rights and needs of women, young people and children affected by AIDS. The UK is the second largest bilateral donor to combating AIDS (after the United States) and committed £1.5 billion over the period 2005-2008 of which around 10% will be spent on programmes for children affected by AIDS. The UK also made AIDS a centrepiece of its 2005 presidencies of the G8 and the European Union, and supported a number of specific programmes, including: harm reduction programmes (including needle exchange) in Russia, a Bangladesh-based outreach programme to empower prostitutes and their children to access basic services, an HIV/AIDS programme in Ghana to establish legal and policy frameworks to protect the rights of vulnerable groups living with HIV/AIDS.⁹⁴²

It is interesting to note that the UK also reported on the matter of 'corporate social responsibility' and government's efforts to promote this in international activity by domestic companies. In particular, the UK reported:

The Government is working closely with businesses and international organisations to promote "Corporate Social Responsibility" aimed at providing a framework to help businesses act more responsibly, in terms of human rights protection, in the countries where they operate. ... [This includes] the UN Global Compact (a set of ten principles for businesses covering labour rights, environmental protection and anti-corruption), the

⁹⁴¹ A flurry of donor and international organizational activity has occurred on the issue of HIV/AIDS as described in Chapters 4 and 5.

⁹⁴² ECOSOC, 'Fifth Periodic Reports Submitted by States Parties under Articles 16 and 17 of the Covenant: United Kingdom of Great Britain and Northern Ireland', para. 67.

Organisation for Economic Co-operation and Development (OECD)
Guidelines for Multinational Enterprises ...⁹⁴³

Such activity is supportive of the IAC for AEM norms (set out in Chapter 1) pertaining to the state role in developing an enabling environment for non-state actors to help to achieve the realization of AEM. While these state reports provide some promising results in directing developed countries towards the implementation of IAC for AEM, the state reporting guidelines to the CESCR were recently revised again in 2008. The changes to the reporting guidelines are stated to be for the purposes of ‘harmonizing’ the various reports submitted, so that ‘each treaty body and State party [can] obtain a complete picture of the implementation of the relevant treaties, set within the wider context of the State’s international human rights obligations ...’⁹⁴⁴

The new reporting process consists of two parts: the common core document and the treaty-specific document (e.g. the ICESCR-specific report). According to the new ICESCR report guidelines, there is no longer a question asking states to ‘describe the role of international assistance in the full realization of the right enshrined in article 12’ (as requested in the 1992 version). Instead, in relation to IAC for AEM, it appears that such information is to be gleaned from state responses to a general question on Article 2:

Indicate the impact of international economic and technical assistance and co-operation, whether received or provided by the State party, on the full realization of each of the Covenant rights in the State party or, as the case may be, in other countries, especially developing countries.⁹⁴⁵

This question addresses the full range of ICESCR rights. With regard to Article 12 reporting, there is now a question directed at AEM specifically whereby states are

⁹⁴³ *ibid.*, para. 70.

⁹⁴⁴ UNGA, ‘Compilation of Guidelines on the Form and Content of Reports to be Submitted by States Parties to the International Human Rights Treaties’ (2009) UN Doc HRI/GEN/2/Rev.6.

⁹⁴⁵ *ibid.*, Article 2 (para. 9).

asked to report ‘on the measures taken ... [t]o ensure affordable access to essential drugs, as defined by the WHO, including anti-retroviral medicines and medicines for chronic diseases’.⁹⁴⁶ It is not certain, however, if states will report on this in relation to IAC (either in response to this question or the question posed for Article 2). It is possible that developed countries, such as the UK, will interpret this question in terms of access to essential drugs domestically – rather than internationally.

At the conclusion of these sessions, the CESCR produces a Concluding Observations report, which determines the extent of government compliance with the ICESCR’s provisions and identifies any ‘factors and difficulties affecting the ... fulfilment of the obligations’.⁹⁴⁷ The Concluding Observations may also provide compliance suggestions in the form of ‘specific legislative, policy and other ... recommendations such that economic, social and cultural rights are more effectively secured’.⁹⁴⁸ The observations are not considered punishing, but rather to ‘develop a constructive dialogue with States parties’ on ICESCR implementation matters.⁹⁴⁹

Despite the intentions of the CESCR reporting and monitoring process, it still possesses certain shortcomings in holding states accountable to their obligations under the ICESCR. One issue is the CESCR’s serious backlog in conducting country reviews. This backlog can be attributed to the common problem of late country report

⁹⁴⁶ *ibid.*, para. 57(f).

⁹⁴⁷ S Gruskin and D Tarantola, ‘Health and Human Rights’ in R Detels and others (eds) *The Oxford Textbook of Public Health* (Oxford 2002).; Steiner, Alston and Goodman, *International Human Rights in Context*, p. 277.

⁹⁴⁸ Office of the High Commissioner for Human Rights, ‘Fact Sheet No.16 (Rev.1), The Committee on Economic, Social and Cultural Rights’.

⁹⁴⁹ *ibid.*

submissions and the limited number of country reports the CESCR can review each year due to insufficient meeting time.⁹⁵⁰ It has been observed that it can take as long as four years after submission before a country report is discussed by the CESCR and, as a result, the report's information is often out of date at that point.⁹⁵¹ (The new harmonized reporting guidelines for the ICESCR, as well as other international human rights treaties, are intended to help improve state reporting for timeliness and efficiency; however, it was recently adopted in 2009 and its impact remains to be seen.)⁹⁵² A second issue with the CESCR process is the generally poor compliance by states with their reporting obligations, which they many view as a 'diplomatic chore'.⁹⁵³ This attitude has led to the common reporting problems of incomplete, overdue, or poor quality reports as well as non-submissions.⁹⁵⁴ It has also been noted that state reports 'often do not seem to reflect reality', which can be attributed to the fact that states do not want to 'wash their dirty linen in public' and may want to 'circumvent difficult questions' from the CESCR.⁹⁵⁵ Thirdly, a fundamental problem of the CESCR process is that reporting and monitoring is only required for states that have ratified the ICESCR.⁹⁵⁶ As a result, the CESCR is not able to monitor the

⁹⁵⁰Gruskin and Tarantola, p. 317.

⁹⁵¹ Toebes, p. 99; ECOSOC, 'Effective Functioning of Human Rights Mechanisms: Treaty Bodies' (2000) Commission on Human Rights (56th Session, Item 18(a) of the provisional agenda, E/CN.4/2000/98) <<http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G00/102/73/PDF/G0010273.pdf?OpenElement>> (20 Jan 2000), para. 60.

⁹⁵² UNGA, 'Compilation of Guidelines on the Form and Content of Reports to be Submitted by States Parties to the International Human Rights Treaties'.

⁹⁵³Toebes, p. 98.

⁹⁵⁴ *ibid.*, p. 98; Office of the High Commissioner for Human Rights, 'Fact Sheet No.16 (Rev.1), The Committee on Economic, Social and Cultural Rights'.

⁹⁵⁵ Toebes., p. 98.

⁹⁵⁶ Gruskin and Tarantola.

activities of countries and address its concerns in relation to their activities in relation to IAC for AEM.

The Optional Protocol

On 10 December 2008, the UN General Assembly adopted a resolution establishing an Optional Protocol to the ICESCR. This Optional Protocol, which is considered operationally similar to the complaints mechanisms for the other UN human rights treaties, endows the CESCR with a quasi-judicial adjudication role.⁹⁵⁷ Essentially, the optional protocol provides: an individual or group communications procedure;⁹⁵⁸ an inter-state communications procedure;⁹⁵⁹ and an inquiry procedure.⁹⁶⁰ (These functions can only be carried out by the CESCR if the state from which the complaint originates is a party to the Optional Protocol as well as the state at which the complaint is targeted.⁹⁶¹ This also assumes that both states are parties to the ICESCR.) The communications procedure permits the CESCR to receive complaints against a state in relation to the ICESCR. In the case of individuals or groups, who are within the jurisdiction of a state party, they can file a complaint 'claiming to be victims of a violation of any of the economic, social and cultural rights set forth in the

⁹⁵⁷ Office of the High Commissioner for Human Rights, 'Fact Sheet No.7/Rev.1, Complaints Procedure' UN Office of the High Commissioner for Human Rights <<http://www.ohchr.org/Documents/Publications/FactSheet7Rev.1en.pdf>> (10 June 2009).

⁹⁵⁸ UN General Assembly, Art. 1-9.

⁹⁵⁹ *ibid.*, Art. 10.

⁹⁶⁰ *ibid.*, Art. 11.

⁹⁶¹ See ESCR-Net, 'Resource Page on the Optional Protocol to the ICESCR' ESCR-Net <http://www.escr-net.org/resources/resources_show.htm?doc_id=431553> (10 July 2010). (Also, the Optional Protocol will only enter into force after ten states have ratified or acceded to the agreement.)

Covenant'.⁹⁶² Under the inter-state communications procedure a state party to the protocol can send communications to the CESCR that another state party 'is not fulfilling its obligations under the Covenant'.⁹⁶³ Under the protocol's inquiry procedure, '[i]f the [CESCR] receives reliable information indicating grave or systematic violations' of the ICESCR, the CESCR can invite the state party 'to cooperate in the examination of the information concerned' and 'designate one or more of its members to conduct an inquiry'.⁹⁶⁴

There is an optimistic expectation that the Optional Protocol will 'enable those suffering from violations ... to seek remedies and to hold those responsible to account for their actions' and provide a 'promising tool for all victims ... to speak out and be heard'.⁹⁶⁵ It has also been expressed that this addition to the ICESCR could allow 'the human rights community to assist States in taking concrete steps to realize the rights of all and to reach out to the most marginalized and disadvantaged' and help to dispel the belief of a 'hierarchy between human rights' (i.e. the varying importance granted to civil and political rights as opposed to economic, social and cultural rights by some countries).⁹⁶⁶ This is related to the fact that many other human rights treaties, such as the International Covenant on Civil and Political Rights, already possess a complaints mechanism.

⁹⁶² UN General Assembly, Art. 2

⁹⁶³ *ibid*, Art. 10.

⁹⁶⁴ *ibid*, Art. 11.

⁹⁶⁵ Office of the High Commissioner for Human Rights, "'Economic, social and cultural rights: legal entitlements rather than charity'" say UN Human Rights Experts' (2008) UN Office of the High Commissioner for Human Rights (press release) <<http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=9216&LangID=E>> (10 Dec 2008)

⁹⁶⁶ *ibid*.

Various academics, however, have voiced concerns about the new Optional Protocol to the ICESCR. One concern pertains to the whether the CESCR is the appropriate body to assume an adjudicative role. Given its already full workload and the problem of backlogs with state reports, there is a fear that the CESCR's assumption of this additional responsibility could 'potentially undermine [its] ability to perform ... existing functions'.⁹⁶⁷ A second concern is that the protocol's approach leads to 'overarching legal positivism' and the furtherance of the belief that 'judicial or quasi-judicial processes intrinsically produce better, more insightful policy choices than, their legislative counterparts'.⁹⁶⁸ Critics of the Optional Protocol argue that no single approach to economic, social and cultural rights can be imposed upon all governments; rather, national governments should be given 'a substantial measure of discretion in dealing with their disparate domestic situations'.⁹⁶⁹ Another concern is that '[p]roviding quasi-judicial international monitoring, such as the production of views under communication procedures ... under the Optional Protocol to the ICESCR, does not provide the real answer'.⁹⁷⁰ Instead, it is argued that the right needs 'to be given teeth' through 'adequate legal or other remedies provided at [the] national level'.⁹⁷¹ It has even been suggested that the Optional Protocol's efforts to bind states through international adjudication could actually backfire by 'causing

⁹⁶⁷ MJ Dennis and DP Stewart, 'Justiciability of Economic, Social, and Cultural Rights: Should There Be an International Complaints Mechanism to Adjudicate the Rights to Food, Water, Housing, and Health?' (2004) 98 (3) *American Journal of International Law* 462, p. 466.

⁹⁶⁸ *ibid.*, p. 466.

⁹⁶⁹ *ibid.*, p. 467; L Helfer, 'Overlegalizing Human Rights: International Relations Theory and the Commonwealth Caribbean Backlash against Human Rights Regimes' (2002) 102 *Columbia Law Review* 1832.

⁹⁷⁰ E Riedel, 'The Human Right to Health: Conceptual Foundations' in A Clapham and M Robinson (eds) *Realizing the Right to Health* (Swiss Human Rights Book, 2009), p. 34.

⁹⁷¹ *ibid.*, p. 34.

states to deemphasize [the ICESCR] and further undermin[e] [its] stature and acceptability'.⁹⁷² As an alternative, some international legal scholars suggest that developing 'voluntary obedience' and acceptance as opposed to 'compelling compliance' could be more effective in achieving 'norm internalization' (as discussed in Chapter 2).⁹⁷³ Beth Simmons holds a different opinion of the Optional Protocol from these critics. She argues that the Optional Protocol would actually encourage norm internalization and that the concerns about judicialization by the CDESCR are superfluous. Simmons considers the Optional Protocol would not actually transform the CDESCR into 'a judicial or litigatory mechanism in a strict sense' and that the CDESCR's quasi-judicial procedures and powers lack legal force.⁹⁷⁴

Coordination with the UN agencies and other bodies

UN specialized agencies (such as WHO) and other UN bodies (e.g. UNAIDS) have an important complimentary role to play in the CDESCR's work. For example, while the CDESCR is charged with addressing state implementation of the right to health (in terms of offering interpretations, monitoring progress, and addressing violations), the WHO possesses the related normative role of defining state actions on particular

⁹⁷² Dennis and Stewart, p. 467.

⁹⁷³ *ibid*, p. 467.; Koh.

⁹⁷⁴ Beth Simmons draws several comparisons between the CDESCR and a court. She finds that the following differences: the CDESCR is 'empowered to receive and consider "communications," not charges'; it can request that the state 'take interim measures, [but] ... not injunctions'; its communications are 'transmitted "confidentially" to the State party and discussed in "closed meetings," in contrast to public accusations and proceedings in a trial setting'; states respond 'with "clarifying" statements, not a dense brief'; the Optional Protocol process encourages the amicable settlement of complaints – 'not explicitly to find guilt or to punish an offender'; the CDESCR transmits 'views' and 'recommendations', not verdicts; and violating states are 'not fined or imprisoned' but obliged to 'give due consideration to the views of the committee' and 'provide a written response within six months'. B Simmons, 'Should States Ratify Protocol? Process and Consequences of the Optional Protocol of the ICESCR' (2009) 27 (1) *Nordic Journal of Human Rights* 64.

health issues.⁹⁷⁵ This results in a significant overlap⁹⁷⁶ in their functions and there are several implications based on this relationship. The CESCR's General Comment No. 14 was drafted, according to a committee member, to address right to health obligations that are deemed 'absolutely essential', but also 'formulated as broadly as possible in order to take account of future developments'.⁹⁷⁷ Hence, state implementation of such high-level guidance is likely to be further shaped and influenced by the WHO due to its legislating, policy-making and technical assistance functions.⁹⁷⁸

In addition to providing input to the CESCR's general comments and 'days of general discussion', the UN agencies and other bodies could provide valuable assistance to the CESCR during the state reporting and complaints procedures. The CESCR's work in the examination of state reports involves a series of steps, which include: pre-sessional working group meetings, dialogue with state representatives about the report, and the drafting of concluding observations.⁹⁷⁹ The CESCR's

⁹⁷⁵ ECOSOC, 'Summary Record of the 10th Meeting : Portugal' (2000) ECOSOC Committee on Economic, Social and Cultural Rights (22nd Session) <http://www.bayefsky.com/summary/portugal_cescr_e_c.12_2000_sr.102000.php> (1 May 2000), para. 29 and 32. (See also Chapter 3 – the International Institution for Health. The WHO's normative functions were described and discussed in that chapter.)

⁹⁷⁶ Based on the institutional interaction framework discussed in Chapters 2 and 4, the relationship between the WHO and the CESCR could be characterized as 'embedded'. The WHO is constitutionally mandated to uphold the 'right to health', which is embedded within the broader UN institution for human rights (which includes the CESCR).

⁹⁷⁷ ECOSOC, 'Summary Record of the 10th Meeting : Portugal', para. 32. (Another CESCR member commented that the General Comment had to be of 'a general and legal nature'. ECOSOC, 'Summary Record of the 10th Meeting : Portugal', para. 38.)

⁹⁷⁸ A former Deputy UN High Commissioner for Human Rights (Bertrand Ramcharan) has commented that 'WHO's engagement with human rights presents an opportunity to get practical and meaningful about the right to health'. See WHO, 'Second Informal Consultation on Health and Human Rights: Towards a WHO Health and Human Rights Strategy' (2000) World Health Organization <<http://www.who.int/hhr/Second%20Informal%20Consultation%20on%20Health%20and%20Human%20Rights.pdf>> (4 April 2000), p. 3.

working methods note that '[r]epresentatives of relevant specialized agencies and other international bodies may also be invited to contribute at any stage of the dialogue [with states]'.⁹⁸⁰ While this stage of involvement would allow for critical input for UN agencies and other bodies, UNAIDS has actually pressed for earlier involvement during the pre-sessional working group meetings. UNAIDS believes that this would allow for '[a]dditional information [to] be presented in oral or written form on States parties' reports, thereby enhancing the focus on specific areas of concern'.⁹⁸¹ There may even be value in involving UN agencies and other bodies during the concluding observations stage, so that these organizations can help to highlight how state ICESCR obligations pertain to state activities under their respective institutions. In terms of the optional protocol, there is also a potential role for the UN agencies and other bodies. When an individual or group files a complaint with the CESC, the complaint might be related to the policies, laws or programmes of another UN body. Hence, UN agency participation could be critical in such cases to offer expert advice or clarification or address potential conflicts⁹⁸² in its policies.

It has been argued that coordination between the CESC and the UN agencies and other bodies needs to be strengthened. In the past, the WHO's engagement with the CESC has been criticized for being weak and uncoordinated whereby its

⁹⁷⁹ ECOSOC, 'Report on the Twenty-Fifth, Twenty-Sixth and Twenty-Seventh Sessions (Supplement No. 2), E/2002/22' (2002) ECOSOC Committee on Economic, Social and Cultural Rights <[http://www.unhcr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa0238025668700518ca4/70c0860d23495a54c1256be50045d8ac/\\$FILE/G0240953.pdf](http://www.unhcr.ch/Huridocda/Huridoca.nsf/e06a5300f90fa0238025668700518ca4/70c0860d23495a54c1256be50045d8ac/$FILE/G0240953.pdf)> (2002), para. 29-39.

⁹⁸⁰ *ibid.*, para. 36.

⁹⁸¹ ECOSOC, 'Effective Functioning of Human Rights Mechanisms: Treaty Bodies' ., para. 47.

⁹⁸² The UN agencies have to come to recognize that 'human rights violations' could even be 'committed by themselves' and, hence, they are paying greater attention to the human rights impact of their work. See WHO, 'Second Informal Consultation on Health and Human Rights: Towards a WHO Health and Human Rights Strategy' , p. 8.

involvement was limited to the submission of a few reports to the CESCR and to the provision of oral advice on some health-related issues at CESCR meetings.⁹⁸³

Officially, WHO is invited to submit information on a country and attend state report discussion meetings.⁹⁸⁴ The information submitted typically includes ‘statistical information and other data collected as part of [an agency’s] routine work’, but it has been noted that agencies are also providing best practice guidelines to assist CESCR in its assessment of state compliance.⁹⁸⁵ However, given the intricate relationship between the CESCR and WHO over state implementation (as described earlier), it seems that both have a vested interest in working together more closely to help states achieve their mutual objectives on health.⁹⁸⁶ Also, since the CESCR is unable to address states that have not ratified the ICESCR, the WHO possesses the critical ability to influence member states that fall beyond the CESCR’s domain.⁹⁸⁷ The

⁹⁸³ Toebes, p. 100. See also Gruskin and Tarantola. (‘It is also interesting to note the “historically ambivalent” attitude of the WHO towards human rights. It is probably because of the conservatism of the public health tradition, the suspicion that most health care workers have of lawyers, and a degree of caution and skepticism that is the residue of a professional attraction to a different and more paternalistic principle, sometimes described by the phrase “Nanny knows best.”’). See M Kirby, ‘The Right to Health Fifty Years on: Still Skeptical?’ (1999) 4 (1) *Health and Human Rights: An International Journal* 7, p. 21.)

⁹⁸⁴ Toebes, p. 94.

⁹⁸⁵ Gruskin and Tarantola, p. 317.

⁹⁸⁶ On the subject of treaty body (e.g. CESCR) coordination with UN specialized agencies and other bodies, New Zealand considered this ‘to be entirely appropriate where different bodies were working towards the same objective, namely the promotion and protection of human rights as established by international law’. It also commented that ‘[m]echanisms for regular dialogue, both among treaty bodies and between them and other United Nations bodies, needed to be developed and sustained’. Cuba, on the other hand, expressed concern about ‘the possibility that the so-called “rights-based approach” might change the priorities of the agencies, funds and programmes to the detriment of the long-term structural needs of developing countries. ... [as] new demands would be placed upon Governments of countries from the South without any guarantee that additional financial resources would be mobilized for international efforts for their development needs ...’. See ECOSOC, ‘Effective Functioning of Human Rights Mechanisms: Treaty Bodies’, para. 43-46.

⁹⁸⁷ It is also worth noting that the UN Special Rapporteur for the Right to Health has the ability to monitor and report on states that have not ratified the ICESCR. The three main objectives in the Special Rapporteur’s mandate include: ‘rais[ing] the profile of health as a fundamental human right’; ‘increas[ing] the jurisprudential understanding of the right to health’; and ‘identif[y]ing good practices on how the right to health has been respected, protected and fulfilled’. See also WHO, ‘Human Rights

WHO appears to increasingly recognize the importance of human rights in its work⁹⁸⁸ and seems to be making some progress on this front with strategies and techniques to develop a rights-based approach into the institution.⁹⁸⁹ An interesting complementary role to the CESCR that the WHO envisions for itself is to assist states with the inputs and outputs to the CESCR process. For example, the WHO has commented on the UN Human Rights Treaty Bodies that it can ‘assist States Parties in ensuring that their reports are up-to-date, accurate and comprehensive in relation to health’ as well as ‘[use] [its] country presence, [to] support action to catalyze, facilitate, and support the implementation of treaty bodies’ concluding observations by governments’.⁹⁹⁰

Conclusion

This chapter presented two new international efforts (i.e. the IGWG and the GTT) to change the prevailing system of governance over AEM. It also suggested a potentially greater role for the under-recognized UN CESCR in dealing with the matter of IAC for AEM. At present, the WHO finds itself in the epicentre of an array of institutional interactions over the matter of AEM. In one set of interactions,

Day: Advancing the Dialogue on Health & Human Rights' (2002) World Health Organization <http://www.who.int/hhr/information/en/Human_Rights_Day2002report.pdf> (10 Dec 2002), p. 6.

⁹⁸⁸ At a meeting in 2000, the then-WHO Executive Director (David Nabarro) stated that ‘[h]uman rights are at the center of how we should be working at WHO’. See WHO, ‘Second Informal Consultation on Health and Human Rights: Towards a WHO Health and Human Rights Strategy’, p. 2.

⁹⁸⁹ See generally WHO Health and Human Rights. <http://www.who.int/hhr/en/>; WHO, ‘WHO Consultations on Health and Human Rights’ World Health Organization (Health and Human Rights) <<http://www.who.int/hhr/information/consultations/en/index.html>> (10 June 2008). (The WHO also holds training sessions on ‘health and human rights’ for its staff at the WHO headquarters. The session provides a basic primer on issues of human rights in relation to health and is conducted by the ETH Health and Human Rights team.)

⁹⁹⁰ WHO, ‘Cooperation of Human Rights Treaty Bodies with United Nations Departments, Specialized Agencies, Funds, Programmes and Non- Governmental Organizations (Fifteenth Meeting of Chairpersons of the United Nations Human Rights Treaty Bodies)’ (2003) World Health Organization <<http://www.who.int/hhr/information/en/15thChairpersonsMtg%282003%29final1.pdf>> (27 June 2003).

namely international health and trade, the WHO has dealt with intellectual property tensions confronting its member states over access to medicines. In another set of interactions, specifically health and development in the context of HIV/AIDS, the WHO has found itself struggling to keep in step with the array of external changes that have occurred since it was divested of its 'star' Global AIDS programme almost two decades ago. (Likewise, UNAIDS has found itself in a similar position as new actors have entered the realm of HIV/AIDS initiatives armed with the financial power that it lacks.) Finally, in a third set of interactions relating to health and human rights, the WHO's role in asserting AEM as a core obligation of the right to health has been weak and its relationship with the CESCR appears limited. Hence, one might ask what opportunities these three structures provide for the WHO.

In the case of the IGWG and the resultant Global Strategy and Plan of Action, the WHO could attain a much more prominent role on matters of intellectual property that it previously did not possess. The IGWG process, in a sense, served as a 'testing grounds' by developing countries as they pushed their agenda of 'access and innovation' at the WHO. While the IGWG has been considered an effort to shift some intellectual property matters (e.g. medicines) to WHO, it is probably too early to tell if this is the case. The implementation of the Global Strategy and Plan of Action remains slow and the WHO's role has yet to be dramatically altered by the resolution. Based on observations of the IGWG process, it appears that the WHO is working to prove to states that it can assume leadership over the issue. The WHO's internal efforts (through reorganization and strategy development) indicate an organizational pro-active effort to appear capable and ready to address the issues of intellectual property and innovation. The recent developments by developed countries in the

development of the ACTA, however, could provide a serious challenge to the roles of the WTO and WHO. At present, a shroud of secrecy surrounds much of the ACTA negotiations among developed countries, so it is uncertain what its precise terms are. There is concern that the ACTA will incorporate TRIPS-plus measures; hence, limiting AEM.

The GTT does not appear to have a significant impact on the WHO's role in the governance of HIV/AIDS amongst international and multilateral donors; however, it could have a major impact on UNAIDS. As discussed, UNAIDS has struggled in its coordination role amongst the various UN agencies and the later entry of the Global Fund. Its lack of financial power made it difficult to dictate and direct policy. The GTT recognizes these challenges and makes the effort to align the various UN agencies into a cooperative relationship through a division of labour to facilitate operations.

The UN's CESCR and WHO appear to hold complimentary roles in the promotion of AEM. As mentioned earlier in Chapter 3, the WHO has developed an array of AEM-related resolutions, but has not exercise its monitoring and reporting powers in relation to such recommendations. This can lead to inconsistent or weak compliance with WHO guidance. This chapter reviewed the CESCR's established periodic state reporting mechanism, which can direct questions at developed countries on the matter of IAC for AEM. In addition, the potential added enforcement power of its ICESCR Optional Protocol could add to the power of this process and the CESCR's authority in addressing ICESCR implementation matters, in general. The

limitation of the Optional Protocol process is that it depends upon states being a party to the ICESCR (which the US is not) as well as the Optional Protocol.

Chapter 7: CONCLUSION

A substantial body of literature asserts that access to essential medicines (AEM) is a core component of the right to health by drawing upon an array of authoritative guidance. Given developing countries' inability to meet this core component for an array of priority health problems (such as HIV/AIDS), there have been recent efforts to establish the associated international assistance and cooperation (IAC) duty for AEM. IAC for AEM, as established in Chapter 1 (Introduction), does not only encompass the financing or donation of essential medicines (i.e. the duty to 'fulfil'). IAC also entails the duties to 'respect' and 'protect' AEM in other countries. For example, respect would entail avoiding measures that obstruct the realization of AEM in other countries. Protection requires states to account for AEM when engaging in international relations (e.g. treaty negotiations and participation in international organizations). It also obligates states to prevent non-state actors (e.g. corporations) within their jurisdiction from the interference of AEM in other countries. This thesis builds upon the recent body of research, which includes the struggles in the domestic implementation of AEM within developing countries and the establishment of IAC for AEM norms, in order to address the next critical phase of IAC for AEM implementation by developed countries.

Despite developing countries' severe resource constraints and their need for AEM (as discussed in Chapter 1), the implementation of IAC for AEM by developed countries has been weak and inconsistent. Hence, the research aim of this thesis was to understand how industrialized states could

be influenced to implement IAC for AEM standards with a view to the improvement of international governance over this issue. This entailed three sub-questions: (1) what is the current international order governing access to essential medicines, (2) what are the processes and mechanisms that the international order has used to influence developed countries and how have the countries responded, and (3) is there an alternative model to the current governance structure that could lead to improved implementation of international assistance and cooperation by developed countries. As discussed in Chapter 2 (Theoretical Framework), it is important to recall that the international order's methods of influence can assume three primary forms: enforcement (i.e. formal penalties and sanctions), monitoring and reporting, and socialization.⁹⁹¹ Socialization is a broad concept that primarily relies upon informal mechanisms and processes, which include material inducement (e.g. material rewards and punishments to coerce or entice), moral-consciousness raising (e.g. the use of dialogue in the form of argumentation, persuasion, and shaming), and acculturation (which depends on self-imposed or social pressures to motivate behavioural change).

To address the first sub-question on the current international order, the thesis sets out to analyze the key international institutions involved in the governance of AEM. Institutions, as discussed in Chapter 2 (Theoretical Framework), play a central role in facilitating the implementation of international standards. They provide a framework for rule generation and

⁹⁹¹ These three forms do not mutually exclude each other and, in practice, they often happen in combination.

keeping society in alignment with them.⁹⁹² The WHO, which is the main international institution for health, was analyzed in Chapter 3 based on Oran Young's three institutional components (i.e. the substantive, procedural, and compliance components). The WHO carries out a range of functions related to AEM, such as the development of a 'model list' of essential medicines, and has generated a number of soft law resolutions pertaining to AEM. The WHO has also developed a set of prominent programmes targeted at improving AEM, which include the WHO Prequalification programme and the '3 by 5' initiative. Though the WHO possesses 'hard law' powers (i.e. treaties and regulations), it has rarely formed such laws. In addition, while the WHO possesses the power to invoke state reporting for resolutions, it prefers not to do so. The WHO is designated as the UN agency for international health, but there have been growing concerns about its apparent lack of power. Its ability to issue hard law is member driven and lack of budgetary control (due to limited funds in its general budget) prevents the WHO from exercising greater organizational autonomy, such as setting policy and programme directions. WHO leadership can have a major impact on the direction and activities of the organization, as seen during the term of DG Brundtland, but it is not certain if the current DG will have the same impact.

The governance of AEM also involves the WHO interactions with the international institutions for trade (i.e. WTO) and institutions for development (the World Bank, UNAIDS, and the Global Fund). In Chapter 4 (on the

⁹⁹² North, p. 3-4; Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking', p. 11.

analysis of institutional interactions), these two sets of interactions were characterized and studied for their implications and management potential. The WHO's interactions with the WTO can be primarily characterized as one of 'overlap' in terms of its norms. With the establishment of the TRIPS agreement under the WTO, the new international intellectual property rules were seen to clash with the AEM standards upheld by the WHO. Though this concern led to the eventual establishment of the WTO Doha Declaration on the TRIPS agreement and Public Health, the WHO had begun to broaden its mandate to address the issues of trade and intellectual property rights through a series of WHA resolutions. It was interesting to observe that the WHO relied heavily upon the processes of socialization, due to a lack of enforcement powers (in contrast to the WTO's dispute settlement mechanism), in order to influence its member states. These processes can assume the forms of policy guidance and legal interpretations (of intellectual property law), technical assistance (endorsing the use of TRIPS flexibilities), and training sessions (which include 'diplomatic' negotiations and policy coherence sessions). As indicated, these WHO functions are not necessarily value neutral and provide WHO with a means through which AEM norms can be recognized and protected.

The institutional interactions between the WHO and the World Bank (also covered in Chapter 4) can be characterized as 'parallel' in the sense that their objectives are not necessarily conflicting (i.e. they both aimed to fight HIV/AIDS) and some of their functions (e.g. the HIV/AIDS programme design and technical assistance) were similar. In terms of AEM, the World

Bank also relied on the processes of socialization. It set out policy guides and research publications endorsing the use of generics (either in procurement or manufacturing). It also had a pharmaceuticals group that performed economic analyses of the medicines and built in generic medicines policies into its loans and grants. As noted in the World Bank discussion, this may or may not have had an influence in lowering market prices, but it helped to establish a new standard among international assistance agencies in procurement and financing for the cost-effective utilization of generic medicines. Another interesting observation, in the institutional interactions between health and development, was the growing concern about HIV/AIDS programme redundancies, gaps, turf battles, lack of coordination, and other inefficiencies. The unforeseen implication was the establishment of two new HIV/AIDS institutions, UNAIDS and the Global Fund, which occurred in succession due (in large part) to developed country concerns about the inefficiencies seen in the UN system. The entry of the new institutions, however, did not necessarily make things more clear and organized due to ongoing bureaucratic struggles between the institutions. The institutional interactions between health and development eventually transformed into a state of 'complexity' with a combination of both parallels and overlaps running across the HIV/AIDS programme landscape.

While it is understood from the previous institutional discussion that the international order could apply a combination of socialization, enforcement, and monitoring and reporting to induce state behaviour towards greater IAC for AEM, it is not clear how states respond to these processes and

mechanisms. Thus, to address the other half of the second sub-question posed earlier, a case study of the UK was performed to study the national implementation of IAC for AEM. Given that the state does not immediately recognize IAC for AEM (via ratification and adoption of this standard in domestic law), it was determined that a modified version of the 'spiral model' would be helpful in understanding how socialization may influence states towards acceptance of IAC for AEM. (The phases of this modified spiral model include: (1) denial, (2) tactical concessions, (3) prescriptive status, and (4) rule-consistent behaviour.) The U.K. case study revealed two diverging paths of progression in terms of: (1) trade and health and (2) health and development. In terms of international trade, there was an initially similar pattern of IAC for AEM denial by the U.K. (as part of the E.C.), but it has since progressed into the early stages of prescriptive status with the passage of laws giving greater recognition to TRIPS flexibilities for developing countries. In terms of health and development, the U.K. did not exactly deny IAC for AEM initially; however, it appears to have started with an array of tactical concessions (e.g. evading the topic of compulsory licensing and promoting the less threatening options to intellectual property) before its current state of explicitly recognizing IAC for AEM in its comprehensive global health strategy. In contrast to some other developed countries, the U.K. is moving towards bringing greater coherence (and consistency) between its international health and trade policies. This is very likely influenced by efforts within the international order (namely WHO) in promoting greater policy coherence in state foreign policies between health and trade.

The international order governing AEM has not remained static. The various institutions and states have come to recognize the conflicts, overlaps, and redundancies prevalent across the system, and there have been efforts to address these issues on two fronts – (1) the coordination of health and intellectual property and (2) the coordination of health and development assistance on HIV/AIDS (as discussed in Chapter 6). On the health and intellectual property front, an Intergovernmental Working Group (IGWG) was formed at WHO to develop a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. As the talks covered a range of matters pertaining to TRIPS and the Doha Declaration (as well as the possibility of new mechanisms for future innovations), the IGWG could be perceived as an effort by developing countries to shift the governance of intellectual property (in terms of health) to the WHO. A resolution was passed affirming TRIPS flexibilities, cautioning states on TRIPS-plus provisions, directing the WHO director-general to consider an array of intellectual property-related tasks, and forging additional cooperation with the WTO; however, it remains to be seen whether the WHO is up for the task of governing this issue. As mentioned in Chapter 3 (on the International Institution for Health), the WHO faces an array of internal challenges (including resource constraints) in the governance of health issues. The WHO director-general's apparent commitment to the issue, however, could be a strong indicator of organizational change. The multilateral governance of intellectual property (by either WHO or WTO), however, faces an emerging challenge in the form of a plurilateral treaty amongst a group of developed countries called the Anti-Counterfeiting Trade Agreement. There is a

possibility that developed countries will use this governing structure to enforce stronger intellectual property standards than TRIPS and will pressure developing countries into joining the treaty at a later point in time.

On the matter of changes in the governance of health and development assistance on HIV/AIDS (covered in Chapter 6), a Global Task Team (GTT) was formed to address the lack of coordination between international and multilateral donors on HIV/AIDS. UNAIDS, which led and facilitated the GTT process, had been struggling with the coordination of its UN 'partner' agencies on HIV/AIDS since its formation in 1996. The GTT provided an opportunity for UNAIDS to define a 'division of labour' that played upon the strengths of each UN agency and attempted to reduce the overlaps and conflicts in roles. This had an interesting impact on the WHO, World Bank, and Global Fund as it set out different leadership roles for each agency (e.g. the WHO would lead on technical assistance, the World Bank would lead on monitoring and evaluation, and the Global Fund would focus on financing harmonization with the UN efforts). Yet, the GTT does not necessarily eliminate agency roles on other functions as the division of labour details that these agencies can play secondary (or supporting) roles in other areas. The question remains, however, as to whether this division of labour will effectively eliminate the past turf battles that plagued the governance system on HIV/AIDS. As each agency has built up a vested interest in their respective functions and programmes on HIV/AIDS over the past decade, it is hard to see them easily relenting to the direction of UNAIDS as underlying lingering tensions still exist. In addition, the GTT seeks to coordinate at the

country level. This raises the concern about whether country level coordination will sufficiently address the institutional tensions between the organizations. Furthermore, the GTT does not directly address the role of PEPFAR, which is the single largest donor on HIV/AIDS today. This leaves concerns about the actual effectiveness of donor coordination efforts when the largest player in the field is not part of the strategy.

Chapter 6 also addressed the potential role of the UN Committee on Economic, Social and Cultural Rights (CESCR) in the governance of IAC for AEM. The CESCR is the human rights body charged with monitoring the implementation of economic, social and cultural rights (including the right to health and, thus, the core component of AEM). The CESCR has a range of useful mechanisms at its disposal, including general comments, days of general discussion, the monitoring of state reporting, and the new Optional Protocol (which provides an individual and group complaint mechanism, inter-state communications, and an inquiries procedure). It appears that the WHO's ability to influence states would benefit greatly by forging closer links with the CESCR to leverage its implementation compliance mechanisms. For example, as discussed in Chapter 3, the WHO lacks the capacity and resources to monitor state compliance with its body of resolutions. Hence, its state reporting mechanism has rarely been applied. The WHO could potentially work with the CESCR to address state issues and have them bring relevant WHA resolutions to the attention of states in the CESCR's concluding observations in order to improve implementation (particularly for IAC for AEM). Another mechanism that may prove useful in influencing states on

IAC for AEM is the Optional Protocol. It appears that the inter-state communications and inquiries procedure would be particularly useful in this regard as it would allow state parties to raise concerns about IAC for AEM implementation with other states as well as permit the CESCR to engage in an inquiry into this issue. These are powers that the WHO and UNAIDS do not possess and could help induce developed states to recognize and consistently apply in their international affairs.

While the findings of this research indicate some hope for greater implementation of IAC for AEM by developed countries, the general problem of access to medicines remains a highly complex issue. As defined at the introduction to this thesis (Chapter 1), it was determined that the scope of this research would only focus on access to essential medicines. Hence, this analysis has only covered existing medicines. The broader issue of access to medicines also concerns the problem of the lack of research and development for the discovery of new medicines to treat a significant group of ‘neglected diseases’ (i.e. diseases that disproportionately affect poor populations and, thus, does not create a viable market). This is an urgent area of research for the topic of international assistance and cooperation in access to medicines that should be addressed in the future. Also, my research was strictly concerned with state implementation of IAC for AEM, but there is also a range of non-state actors (e.g. corporations and philanthropic organizations) that possess social responsibilities in addressing AEM. This is another area of research that needs to be better understood through future investigation in terms of how these actors are meeting developing country needs.

APPENDICES

Table of Select World Health Organization Resolutions pertaining to 'Access to Essential Medicines'

Year	Document Index	WHA Resolution Title
2008	WHA 61.21	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
2007	WHA 60.30	Public health, innovation and intellectual property
2007	WHA 60.18	Malaria, including proposal for establishment of World Malaria Day
2006	WHA 59.26	International trade and health
2006	WHA 59.24	Public health, innovation essential health research and intellectual property rights: towards a global strategy and plan of action
2004	WHA 57.14	Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS
2003	WHA 56.30	Global health-sector strategy for HIV/AIDS
2003	WHA 56.27	Intellectual property rights, innovation and public health
2002	WHA 55.14	Ensuring accessibility of essential medicines
2002	WHA 55.12	Contribution of WHO to the follow-up of the United Nations General Assembly special session on HIV/AIDS
2001	WHA 54.14	WHO medicines strategy
2001	WHA 54.13	Strengthening health systems in developing countries
2001	WHA 54.11	WHO medicines strategy
2001	WHA 54.10	Scaling up the response to HIV/AIDS
2000	WHA 53.14	HIV/AIDS: confronting the epidemic
1999	WHA 52.19	Revised drug strategy
1997	WHA 50.20	The quality of biological products moving in international commerce
1996	WHA 49.14	Revised drug strategy

WHA Resolutions mandating WHO's involvement on AEM and/or Trade-related Matters

WHA Resolution	Title
<p>WHA 49.14 (Adopted in 1996)</p>	<p>Revised Drug Strategy</p> <p>Requests the Director-General: ' to report on the impact of the work of the WTO with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate'</p>
<p>WHA 52.19 (Adopted in 1999)</p>	<p>Revised Drug Strategy</p> <p>Requests Director-General to: ' ... to support Member States in their efforts to develop and implement policies and programmes that achieve the objectives of the revised drug strategy, including the development of tools, guidelines and methodology for evaluation and monitoring';</p> <p>' ... to cooperate with Member States, at their request, and with international organizations in monitoring and analyzing the pharmaceutical and public health implications of relevant international agreements, including trade agreements, so that Member States can effectively assess and subsequently develop pharmaceutical and health policies and regulatory measures that address their concerns and priorities, and are able to maximize the positive and mitigate the negative impact of those agreements'</p>
<p>WHA 53.14 (Adopted in 2000)</p>	<p>HIV/AIDS: Confronting the Epidemic</p> <p>Requests the Director-General: to continue strengthening the involvement of WHO, as a cosponsor of UNAIDS, in the United Nations system-wide response to HIV/AIDS, including at country-level.</p>
<p>WHA 56.27 (Adopted in 2003)</p>	<p>Intellectual Property Rights, Innovation and Public Health</p> <p>This resolution calls upon WHO to establish a body to study intellectual property rights and their impact upon public health.</p>
<p>WHA 57.14 (Adopted in 2004)</p>	<p>Scaling up Treatment and Care within a Coordinated and Comprehensive Response to HIV/AIDS</p> <p>Urges member states to pursue policies promoting</p>

	affordability and availability of relevant medicines as a matter of priority.
WHA 59.24 (Adopted in 2006)	<p>Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action</p> <p>Requests the Director-General:</p> <p>‘... to invite, as observers at the sessions of the intergovernmental working group, representatives of non-Member States, of liberation movements referred to in resolution WHA27.37, of organizations of the United Nations system, of intergovernmental organizations with which WHO has established effective relations, and of nongovernmental organizations in official relations with WHO, who shall attend the sessions of the working group in accordance with the relevant Rules of Procedure and resolutions of the Health Assembly’.</p>
WHA 59.26 (Adopted in 2006)	<p>International trade and health</p> <p>Requests the Director-General:</p> <p>‘... to provide support to Member States, at their request and in collaboration with the competent international organizations, in their efforts to frame coherent policies to address the relationship between trade and health’;</p> <p>‘... to respond to Member States’ requests for support of their efforts to build the capacity to understand the implications of international trade and trade agreements for health and to address relevant issues through policies and legislation that take advantage of the potential opportunities, and address the potential challenges, that trade and trade agreements may have for health’;</p> <p>‘... to continue collaborating with the competent international organizations in order to support policy coherence between trade and health sectors at regional and global levels, including generating and sharing evidence on the relationship between trade and health’</p>
WHA 60.30 (Adopted in 2007)	<p>Public health, innovation and intellectual property</p> <p>Requests the Director-General:</p> <p>‘... to provide as appropriate, upon request, in collaboration with other competent</p>

	<p>international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products,⁹⁹³ and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments’.</p>
<p>WHA 61.21 (Adopted in 2008)</p>	<p>Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property</p> <p>Requests the Director-General ‘in implementing the global strategy and agreed parts of the plan of action without prejudice to the existing mandates’:</p> <p>‘ ... to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action’.</p>

⁹⁹³ A footnote was included on point within WHA 60.30: ‘[t]he WTO General Council in its Decision of 30 August 2003 on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health decided that “pharmaceutical product” means any patented product, or products manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included’.

Official WTO Text

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
 - a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
 - b. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
 - c. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
 - d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

SOURCE: World Trade Organization. WT/MIN(01)/DEC/2 (20 November 2001)
http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.doc

Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

Decision of the General Council of 30 August 2003

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization (“the WTO Agreement”);

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

(a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; (1)

(b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification (2) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members (3) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) “exporting Member” means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes

of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:

- (i) specifies the names and expected quantities of the product(s) needed (5);
- (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
- (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

- (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
- (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
- (iii) before shipment begins, the licensee shall post on a website (7) the following information:
 - the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

SOURCE: World Trade Organization. WT/L/540 and Corr.1 (1 September 2003)
http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

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