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Emily A. Mok

Georgetown University Law Center, eam223@law.georgetown.edu

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Emily A. Mok, DPhil candidate, MGA, MBE, is a Law Fellow at the O'Neill Institute for National and Global Health Law and Adjunct Professor of Law at Georgetown University Law Center, Washington, DC, USA.

Please address correspondence to the author at the O'Neill Institute for National and Global Health Law, 600 New Jersey Ave. NW, Fifth Floor, Hotung Building, Washington, DC 20001, email: eam223@law.georgetown.edu.

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INTERNATIONAL ASSISTANCE AND COOPERATION FOR ACCESS TO ESSENTIAL MEDICINES

Emily A. Mok

ABSTRACT

Access to essential medicines is a critical problem that plagues many developing countries. With a daunting number of domestic constraints — technologically, economically, and otherwise — developing countries are faced with a steep uphill battle to meet the human rights obligation of providing essential medicines immediately. To meet these challenges, the international human rights obligations of international assistance and cooperation can play a key role to help developing countries fulfill the need for access to essential medicines. This article seeks to highlight and expand upon the current understanding of international assistance and cooperation for access to essential medicines through a review of obligations identified in international human rights law and a synthesis of official guidance provided on the matter.

INTRODUCTION

The problem of access to medicines unduly 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 Southeast Asia bear a heavy burden in infectious diseases, where half of the deaths among this group are due to six treatable diseases — HIV/AIDS (14% of deaths), acute respiratory syndrome (11%), diarrheal diseases (11%), malaria (8%), measles (6%), and TB (2%).² Despite the existence of effective medicines, millions of people will continue to suffer and die needlessly from these and other life-threatening conditions because they cannot access the necessary treatments. It has been estimated that as many as two billion people (one-third of the world’s population) 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.²⁴ This includes the government option to use TRIPS "flexibilities," such as compulsory licensing and parallel importation, to address public health concerns.

Over the past decade, dramatic increases in access to first-line antiretroviral drugs for HIV/AIDS have been achieved; however, the general problem of access to medicines "for all" still persists.⁵ In the search for a solution, 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 that identifies access to medicines as a derivative of the right to health, outlines its component human rights obligations, considers its relationship with the competing interests of intellectual property rights, and analyzes its justiciability in domestic courts.⁶ There has been limited attention, however, to the extraterritorial obligations of developed countries on this issue. Hence, one might ask: What international assistance and cooperation obligations do developed countries hold in relation to access to medicines, and how should it affect their policies and practices on this issue? Developed countries have a critical role in access to medicines efforts; yet, their support and response to this issue has been weaker than needed and, in some cases, counterproductive in the policy measures taken.

This article seeks to develop the current understanding on international assistance and cooperation for access to medicines. It first determines the basis for international assistance and cooperation for access to medicines by reviewing the derivation of access to medicines in the right to health and official statements on international assistance and cooperation in international human rights law. The article then builds upon this knowledge to develop a set of standards to guide developed country actions and policies in domestic and international fora.

ACCESS TO MEDICINES AS A HUMAN RIGHT

In order to establish conceptual clarity on the international assistance and cooperation obligations of states, it is necessary to understand the scope of access to medicines entitlements under international

human rights law. The claim of "access to medicines" has been used by developing countries, activists, inter-governmental organizations, academics, and others in a variety of contexts, but their use of the phrase in relation to human rights does not always imply the same meaning. Quite often the phrase refers to treatment access for life-threatening diseases that affect critical public health needs, or such treatment access in cases of emergency, with a direct reference to the World Health Organization's definition of "essential medicines."⁷ In other instances, the phrase includes the category of "neglected diseases," that is, diseases for which a lack of attention has been paid toward research and development for appropriate treatments.⁸ There has also been increasing reference to treatments for the chronic diseases and conditions, such as pain management and cancer.⁹

The Universal Declaration of Human Rights (UDHR), adopted in 1948 by the UN, proclaims in Article 25.1 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*."¹⁰ The term "medical care" as used by the UDHR is understood to include medicines — such as drugs and vaccines.¹¹ Another key human rights source including access to medicines is the International Covenant on Economic, Social and Cultural Rights (ICESCR), which was adopted by the UN in 1966 and holds the status of 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."¹² Furthermore, in attaining the fulfillment of this right, the ICESCR's Article 12.2 specifies that States should take the necessary steps for "the prevention, treatment and control of epidemic, endemic, occupational and other diseases" and "the creation of conditions which would assure to all medical service and medical attention in the event of sickness."¹³

To assist states with their implementation of the ICESCR, the Committee on Economic, Social and Cultural Rights (CESCR) provides significant clarification on Article 12 through the CESCR's General Comment No. 14.¹⁴ For example, the CESCR has interpreted Article 12 to indicate 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.¹⁵ The World Health Organization (WHO) defines essential medicines as “those that satisfy the priority health care needs of the population.”¹⁶ To help guide countries in their selection and coverage of medicines under national policies, WHO develops a biennial “model list” of essential medicines.¹⁷ 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.”¹⁸ 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 regarded as essential medicines remains a national responsibility.”¹⁹

The distinction between essential medicines — which are a core obligation — and other medicines is important for the explication of state obligations. Brigit Toebes explains that core obligations must be guaranteed “immediately” and “under any circumstances.”²⁰ Given that such obligations are considered to “encompass the essence of the right,” it is critical to ensure its existence within a state or else the right would lose its significance.²¹ This contrasts with other non-core obligations of the right to health that are subject to “progressive realization,” which only require “deliberate, concrete and targeted” steps in an expeditious and effective manner.²² Such non-core obligations would include the other medicines that are not considered “essential” or have yet to exist. 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.”²³

The core obligation of access to essential medicines, however, can often 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) already cause a major strain on government resources, among other domestic economic and social concerns. In recognition of the disparate realities amongst the 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 technical” which enable developing countries to fulfil their core and other obligations.²⁴

This comment emphasizes that human rights duties are not limited to domestic borders, but also encompass those that fall outside state jurisdiction. If an industrialized nation were to disregard this, the nation could be considered to have “fail[ed] to fulfil its international legal obligations towards the right to health.”²⁵

The remainder of this paper focuses largely on the core obligation of access to essential medicines in order to explicate developed countries’ international assistance and cooperation duties. While it will touch upon the broader concept of access to medicines, in the interest of space, a detailed exploration of these various dimensions would require a separate study. The following section elaborates on how international assistance and cooperation obligations are defined under international human rights law.

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.²⁶

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 available resources.”²⁷ 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 “[t]he nature of states parties’ obligations.”²⁸ General Comment No. 3 explained that those who drafted the ICESCR intended that the statement, “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.”²⁹

Yet, in what manner should developed countries assist and cooperate? To address this question, the tripartite classification of obligations (that is, to respect, to protect, and to fulfill) has been used to elaborate on the developed country duty of international assistance and cooperation in greater detail.³⁰ The duty to respect, which 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.”³¹ 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.³² 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.”³³ 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 fulfill has been defined as the obligation of the state to take positive steps by facilitating, providing, and promoting human rights in other states.³⁴ 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 fulfill economic, social, and cultural rights” and when “measures taken to respect and protect are not sufficient.”³⁵

OBLIGATIONS OF INTERNATIONAL ASSISTANCE AND COOPERATION IN RELATION TO ACCESS TO MEDICINES

In light of the above summary, it is apparent that developed countries hold obligations of international assistance and cooperation for access to essential medicines. Yet, despite the allusions to these topics in international human rights law, there continues to be significant ambiguity around the specific international roles and responsibilities that should be met by states extraterritorially. 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, the UN Commission on Human Rights Resolution 2003/29, World Health Assembly Resolution WHA55.14, the UN Millennium Development Goals, Montreal Statement on Essential Medicines as a Human Right, WTO Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health, and the reports of the UN Special Rapporteur on the Right to Health.³⁶

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

*To respect access to essential medicines in other countries, and to prevent others (that is, third parties) from violating this right*³⁷

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 medicines.³⁸ 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.³⁹ 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 licenses and the freedom to determine the grounds upon which such licenses are granted.”⁴⁰ 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.”⁴¹ Hence, industrialized nations should refrain from interfering in developing country activities to apply compulsory licensing or parallel importation for access to essential medicines. Historically, the US has placed countries that attempt to exercise compulsory licensing on the US Trade Representative Watch List, known as the Special 301. This practice would effectively pressure US trading partners, especially developing countries, into acting in accordance with US preferences in order to gain or maintain a favorable trading position with the US. Furthermore, industrialized nations should prevent others (for example, pharmaceutical companies) from interfering in such activities as well.

*To facilitate access to essential medicines in other countries, whenever possible, and to provide the necessary aid in times of emergency*⁴²

In recognition of the limitations of developing countries’ abilities “to fulfill” their core obligations (for example, access to essential medicines) to their populations, it follows that an associated international assistance and cooperation duty calls upon industrialized nations “to support to fulfill” access in those countries. Furthermore, in situations of emergency, it is emphasized that developed countries have a responsibility to contribute to “the maximum of [their] capacities.”⁴³ 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.”⁴⁴ Though General Comment No. 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.”⁴⁵

*To ensure that access to essential medicines is granted due attention in international agreements and to consider the development of further legal instruments*⁴⁶

Industrialized nations are urged “to develop and implement national strategies,” including legal measures, that “safeguard or promote” access to essential medicines.⁴⁷ Though many States have acceded to numerous international agreements recognizing obligations to assist and cooperate in the provision of access to medicines, such agreements are often not ratified at the national level and, in consequence, are ignored and often relegated to rhetoric. This is a standard that requires greater attention and evaluation.

*To ensure that no international agreement or policy adversely impacts upon access to essential medicines*⁴⁸

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 in another state as a tool of political or economic pressure – such as embargoes, political or theological ideology, or other similar measures.⁴⁹ This has been an issue for a number of developed countries and their tendency for corporate protectionism through the creation of “TRIPS-plus” provisions (that is, measures that go beyond what is required by TRIPS) in bilateral and regional trade agreements with developing countries.

*To ensure (by way of membership) that the actions of international organizations take due account of access to essential medicines*⁵⁰

International organizations, such as the World Health Organization, the World Trade Organization, and the World Bank, play critical roles in setting policy and handling international agreements that can influence access to 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 of intellectual property rights (that is, Agreement on Trade-Related Aspects of Intellectual Property

Rights) have a significant impact on developing countries' access to medicines. Member states have worked to ensure that TRIPS address the issue of access to medicines through a subsequent clarifying statement known as the Declaration on the TRIPS agreement and public health.

*To provide an environment that facilitates the fulfillment of responsibilities in access to essential medicines by other actors*⁵¹

Though states possess primary accountability for the right to health, the General Comment also emphasizes that “all members of society” possess certain “responsibilities towards the realization of the right to health.”⁵² In the case of access to essential medicines, other societal actors involved include inter-governmental and nongovernmental organizations, health professionals, civil society organizations, and private industry. The CESCR notes that in order for these actors to fulfill their responsibilities, states have an obligation to “provide an environment which facilitates the discharge of these responsibilities.”⁵³ For example, the US 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.

CONCLUSION

This article seeks to highlight and clarify the international assistance and cooperation obligations of developed countries in relation to access to essential medicines. While developing countries hold the “primary obligation” for ensuring access to essential medicines within their jurisdiction, there are times when they might not have the necessary resources available to support such an effort.⁵⁴ This dilemma has prompted attention into the international obligations of states to support access to essential medicines. While international obligations in human rights indicate that there is a duty to fulfill (for example, through foreign aid), there are also duties to respect and protect the realization of access to essential medicines in other states.

It is undoubtedly the case that international assistance and cooperation standards for access to essential medicines exist, but the wide array of authoritative documentation from which they had to be drawn could make it difficult for states to take notice and

acknowledge such standards. A review of these various aforementioned documents revealed an array of scattered agreements and declarations that pertain to state obligations, but also a general consistency in the expectations for international assistance and cooperation that are addressed most comprehensively by General Comment No. 14. Despite the general consistency in the international expectations of states, as illustrated in the synthesized set of international standards, the scattered nature of these standards amongst the various documents can allow states to conveniently “miss” or disregard certain obligations. Hence, for the purposes of implementation, it would be best to present a single, coherent set of standards from which states can report on or be criticized against and to promote comprehensive implementation by states.

The array of authoritative guidance indicates a deliberate movement by the international order to crystallize the elusive access to medicines obligations of developed countries. The acceptance of these international standards, however, still faces significant challenges due to its heavy basis on socioeconomic rights. As Paul Hunt has noted, “[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.”⁵⁵ In addition, other conflicting or competing foreign policy concerns (for example, international trade and development) may be granted special preference over access to medicines because of their impact on national economic or security interests.

To some degree, it would appear that developed countries are supporting access to medicines in other countries through their growing involvement in global health programs providing treatment. Such programs include multilateral initiatives (for example, the Global Fund) and bilateral programs (for example, the UK Department for International Development [DFID] and PEPFAR). Recent history has shown, however, that developed countries still need to remain cognizant of their international assistance and cooperation obligations to respect, protect, and fulfill human rights when partaking in international organizations and in adopting multilateral, regional, or bilateral agreements. For example, the selective activities of bilateral global health programs have sometimes shown a preference for recipient countries that provide a national security interest. In addi-

tion, bilateral programs have not always upheld non-discrimination principles by neglecting vulnerable populations requiring treatment, such as sex workers and men who have sex with men. States need to also develop ways to incorporate their international human rights commitments into their domestic and foreign policy strategies. This would allow states to account for international human rights interests in all government sectors and is especially important for access to medicines. For example, the UK recently launched a government policy strategy known as “Health is Global,” which aims to take the health of people beyond its borders into account.⁵⁶

Developed countries also need to find ways of regulating and incentivizing the pharmaceutical industry to pay greater attention to the medicines that are needed by developing countries. In terms of existing medicines, the participation of corporations in drug donation and discount programs are a critical factor in alleviating the problem of medicines affordability in developing countries. Neglected diseases, however, will require the developed countries to implement incentive schemes that would attract the pharmaceutical industry to invest their R&D resources for new or improved medicines. The current approaches have been weaker than needed, and states can do much to establish the enabling environment that would encourage industry participation in access to medicines.

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44. *Ibid.*
45. World Trade Organization (see note 4), para. 5(c).
46. Committee on Economic, Social and Cultural Rights (see note 13), para. 39; World Health Organization (see note 36); UN Commission on Human Rights (see note 42).
47. UN Commission on Human Rights (see note 42).
48. Paul Hunt, UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, The Right to Health and the Reduction of Maternal Mortality, UN Doc. A/61/338 (2006). Available at <http://www2.ohchr.org/english/issues/health/right/annual.htm>; UN Committee on Economic, Social and Cultural Rights (see note 11), para. 39; UN Commission on Human Rights (see note 42).
49. UN Committee on Economic, Social and Cultural Rights (see note 11), para. 41.
50. *Ibid.*, para. 39; UN Commission on Human Rights (see note 42).
51. UN Committee on Economic, Social and Cultural Rights (see note 11), para. 42.
52. *Ibid.*
53. *Ibid.*
54. Hunt and Khosla (see note 6).
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