

# **Law and the Global Health Crisis**

## **Overview for Session 5:**

### **The Role of Developing-Country Governments**

While we have not touched on the actions of governments in developing countries explicitly, our conversation in the past sessions have touched on several of these elements. In particular, we have focused on developing countries' policy choices concerning intellectual property regimes, generic drugs, and trade agreements. At issue are questions over the types of trade-offs governments are willing to endure in order to secure / forego generic alternatives to branded pharmaceuticals.

My intention this week is not for us to revisit this discussion, but rather consider some of the other ways in which developing countries may choose to deploy law to advance public health objectives, particularly for its most vulnerable citizens. Nevertheless, I realize that some of you may wish to discuss some of the earlier trade-related questions. To that end, I have prepared an Addendum that raises three trade policy questions that governments in developing countries confront, which in turn affect their population's access to medicines. We can refer to them as necessary, given your interests.

So far, our sessions have focused on legal constraints on developing country governments – imposed either formally or informally on account of factors within the domestic political economy – that impede the availability of affordable pharmaceuticals. Let us assume, for a moment, that such constraints disappear. This may be for a number of reasons including, but not limited to: (a) flexibility granted by treaty provisions for least developed countries (LDCs); (b) willingness to employ compulsory licensing; (c) donor assistance, (d) development of indigenous manufacturing capacity; (e) public-private partnerships, etc. A number of problems still remain:

#### **Health Insurance**

Most developing countries are not able to offer universal coverage to their population. Even among those that can afford it, many resist because economic policymakers believe that doing so will result in large social welfare expenditures that will forestall economic development. They tend to focus on improvements in primary health care delivery, but leave individuals to shoulder the costs associated with catastrophic risks (either through private savings or private insurance). The lack of a “success story” of a country that has rolled out a near-universal coverage scheme

while still navigating the “middle-income trap” leaves some economic policymakers to believe that there is a temporal trade-off associated with insuring the poor.

Consequently, many health care costs are shouldered privately and can place a heavy burden on the poor. Even those that have implemented expanded universal coverage schemes have encountered numerous problems, as we shall see with this week’s readings. Some questions to consider:

- Until a developing country reaches middle-income status, is universal coverage simply unattainable because governments lack fiscal and other resources?
- If so, how should governments structure partial insurance schemes? Who should get coverage? What types of medical ailments should be covered? How much should be reimbursed?
- Consider the equity/access trade-offs involved. How can this be minimized? Also, consider what is necessary to maintain political support for expanded coverage schemes among the wealthier, better-covered population segments.

### **Disparities in Health Delivery Systems**

Many countries face the problem of “two-tier” or “multi-tier” health care delivery systems, in which one segment of the population (often located in rural or urban poor communities) receives inferior service because of an inability to attract the necessary health care workers to serve this population. This problem is not unique to developing countries, but the disparities may be more acute and/or have a larger impact on outcomes.

Countries have tried to tackle this problem through incentives-based schemes (e.g., higher pay for working in certain areas), expanded training programs, and/or encouraging migration. Not all countries have the fiscal resources to offer such schemes. Moreover, financial incentives often times have to be substantial to overcome the reputational bias against working in such areas. Migration policies have their own equity concerns, as they may further increase shortages in the sourcing community as their medical professionals leave for better opportunities in wealthier regions/countries.

Please consider:

- What types of government policies/laws should developing countries enact to address intra-country disparities in health care delivery?
- Assuming that fiscal resources cannot be increased significantly, what types of factors should governments be taking into account in deciding whether to shift resources from pharmaceutical payment/reimbursement schemes to provider pay?

- What role should government regulation play in overseeing the performance of delivery systems? How can regulation serve to raise performance (instead of inducing or forcing exit) without added resources?

### **Price Regulation**

In many developing countries, even if an originator firm is willing to offer a discounted price for a given drug (through use of an inter-country or intra-country differential pricing strategy) or if the IP policies allow for provision of cheaper generic substitutes, consumers will pay a much higher price than the discounted price offered. Such concerns are not as acute in scenarios where the government is directly involved in supplying the drug (*e.g.*, through public clinics). But without a national health insurance scheme and with fragmented delivery systems with limited public coverage, distribution most often occurs through private channels in many developing countries. This creates ample opportunities for price mark-ups. This week's readings will highlight the various sources of price mark-ups. It also offers a discussion of the various strategies for regulating pharmaceutical prices.

Please consider:

- Of the various pricing strategies suggested, which do you find to be most attractive? Least attractive? Why?
- In particular, what do you make of the practice of reference pricing?
- Is the effectiveness of this dependent upon enforcement resources? What types of penalties should be placed on violators to deter violations?

### **Corruption / Perverse Incentives**

A pervasive problem in many developing countries is endemic corruption in the health care system. As this week's readings suggest, this problem certainly bedevils China and India, the two largest developing countries, but for different reasons. It also permeates aid-related schemes throughout the developing world. Corruption leads to the siphoning of resources intended for target populations, arbitrage undermining inter- and intra-country differential pricing schemes, higher prices for pharmaceutical products, etc.

A related problem concerns the fact that the structure of health care systems established in some developing countries may generate perverse incentives for some health care providers. For example, as we will see with China, there may be incentives to prescribe expensive branded pharmaceuticals, even when generic alternatives are available, because of how hospitals are

financed. Unlike instances with corruption, there is nothing illegal per se in the provider or official's actions, but it does serve to raise costs and limit access.

Please consider:

- How can law be deployed to fight against corruption? Assume that enforcement resources are limited, as they often are in developing countries. How ought laws be enacted and/or enforced to create the necessary deterrent effect?
- In the absence of large-scale changes to government financing policies, how can law be deployed to reduce / eliminate the structural elements of a health care system that generate perverse incentives? Or are such changes a necessary pre-requisite?

## **Addendum**

The following are a series of policy-choice questions made by developing country governments concerning trade / industrial policy that have been brought up either directly or indirectly in preceding sessions. This week's session will not focus on these issues in-depth, but you are welcome to raise these issues and have us revisit them as part of this week's discussion. For those who may not be as familiar with these topics, hyperlinks to background documents are provided below.

### **WTO Membership**

Governments must choose whether or not their countries wish to be part of the global trading system governed by the World Trade Organization (WTO).

The [TRIPS Agreement](#) is a core WTO agreement. While we may debate whether regulation of international IP should be part of the trade regime, the fact remains that the TRIPS Agreement was an integral part of the Uruguay Round bargain between developed and developing countries. The standard historical narrative is that developing countries, in order to secure greater market access and more stringent rules limiting the use of non-tariff barriers, agreed to higher standards for IP and services. A counter-narrative, raised by those more critical of the WTO regime overall, is that most developing countries (with the exception of large ones such as India and Brazil) were not involved in the Uruguay Round negotiations & were simply given terms to accept/reject.

The TRIPS Agreement requires countries to implement certain minimal IP standards. Of particular relevance for global health are provisions found in Part II, Sections 5 (Patents) and 7 (Protection of Undisclosed Information). The exact obligations differ depending on the economic level of the developing countries. Least developed countries (LDCs) were granted an [extension](#) to not protect pharmaceutical patents until 2016, with the possibility of further extension. With respect to other forms of intellectual property, LDCs have also been given various extensions, with the latest [agreement](#) providing them with certain flexibilities through June 2021, with the possibility of further extensions.

On a practical level, the biggest impact of the TRIPS Agreement has been on developing countries that are not LDCs, and in particular, in those with strong manufacturing capabilities for generic medicines.

There is no serious discussion within the WTO of amending the TRIPS Agreement, especially in light of the ongoing impasse in the Doha Round negotiations. Instead, the focus has been to

employ the TRIPS Council to provide extensions and/or clarifications on matters related to pharmaceuticals and public health. Thus, the WTO package remains a one-sized “take-it-or-leave-it” package, albeit with different versions of the deal available for different types of developing countries.

WTO membership provides most-favored-nation (MFN) status for one’s producers and access to dispute settlement regime to resolve trade disputes stemming from a highly elaborate set of rules. Most developing countries have decided that the overall gains from being a member of this system outweigh the costs of the TRIPS Agreement requirements and its negative impact on generic pharmaceuticals and public health expenditures (plus economic harm for other domestic industries competing with imports). Consequently, since the WTO’s inception in 1995, no original signatory has withdrawn and nearly 40 developing countries have acceded.

**Trade Question 1: Is this conventional wisdom correct? Should certain developing countries reconsider whether WTO membership serve their national interest?**

### **TRIPS Flexibilities**

The TRIPS Agreement, and in particular Article 31 (on compulsory licensing), provide all WTO members with flexibility to employ certain policies to advance public health interests, especially in times of national emergencies. These rights were reaffirmed in the [Doha Declaration on the TRIPS Agreement and Public Health](#) and the subsequent [WTO General Council Decision of 2003 on the Implementation of Paragraph Six of the Declaration](#).

A few governments have made use of these flexibilities. Please review the readings from Session 1 by [Professor Reichman](#) that provides an overview of the potential use of compulsory licensing as one such instrument. Examples of governments that have employed this tool, or threatened to do so, include Thailand, Brazil, Malaysia, Zambia, Zimbabwe, and Mozambique.

However, governments exercising this flexibility have faced consequences from both the private and public sectors. Pharmaceutical companies, faced with the threat of a compulsory license, have sometimes delayed or withheld introduction of new front-line drugs to a developing country with a demonstrated record of employing compulsory licensing. They will also choose not to invest in such countries. Governments of the affected branded pharmaceutical producer will protest, exerting pressure to prevent the further use of compulsory licensing. This pressure can take on an economic form, including the withdrawal of trade preferences and/or the withholding of future trade preferences, as Professor Wu has noted elsewhere. Such actions are legal under the WTO rules because these are unilateral preferences; hence, their withdrawal does not violate

MFN requirements. Moreover, the limits of the access-to-knowledge movement on changing the political economy dynamics in developed countries are evident in this instance. (Recall Professor Kapczynski's article from Session 3). Despite general public support for lower pharmaceutical prices and greater distributional equity, the American, European, or Japanese public has not cared to weigh in heavily against their governments' actions in instances when their multinational companies are directly hurt – as compared to other instances when general policy is concerned (e.g., Anti-Counterfeiting Trade Agreement, Paragraph Six issues).

Therefore, the decision by a government to exercise TRIPS flexibilities involve distributional trade-offs and inter-temporal trade-offs:

- To secure greater access to generic pharmaceuticals, is a government willing to trade off trade preferences in key developed countries for other export interests?
- How will doing so affect its longer-term competitiveness to attract investment/technology transfer in other sectors?
- Is the government willing to trade off access to the latest innovative products from pharmaceutical companies for its citizens? (Note: The top echelon of the population will simply go overseas for treatment, so this trade-off simply affects their cost. The middle and upper-middle class who cannot afford to do so, however, may be hurt more deeply.)

Obviously, the economic size and power of the developing country governments affect the leverage of that government in negotiations with pharmaceutical firms and trading partners.

**Trade Question 2: Should certain developing countries (with manufacturing capacity) be utilizing compulsory licensing and/or other TRIPS flexibilities to a greater extent than they have in the past to address their public health concerns?**

### **TRIPS+ Provisions of Plurilateral Trade Agreements with Advanced Economies**

With the stalemate in the WTO's Doha Round negotiations, most developed countries, for the moment at least, have given up on the possibility of radical reform of trade rules through multilateral negotiations. Instead, their focus has turned toward plurilateral trade agreements (PTAs). The highest-profile of these is the ongoing Trans-Pacific Partnership, but over 400 such agreements exist today.

Most of the high-standard PTAs negotiated by developed countries include intellectual property provisions beyond those required by the TRIPS Agreement. Known as TRIPS+ provisions, they include provisions such as additional requirements for protection of confidential data, subject matter patentability, etc. Within the US and EU, legislators are divided in their views about such provisions. We can discuss, if you would like, the political dynamics for why proponents tend to

prevail over opponents in the domestic political economy, but Session Six is devoted to the question of the obligations/duties of developed countries.

One can take a look through the [leaked IP chapter of the TPP](#) to discern the types of provisions being sought and the extent to which, even among developed countries, there is disagreement over the need to include such provisions. Not all preferential trade agreements include TRIPS+ provisions as extensive as those sought in the TPP, but the flip side is that these other PTAs may include less ambitious market access concessions that provide less economic gain for developing countries.

The economic benefits of concluding a PTA with a major advanced economy varies depending on a number of factors including, but not limited to, its relative position on global value chains, the existing competitiveness of certain export industries & the remaining trade barriers to those industries, the relative competitiveness of export industries as compared to its competitors, etc. Again, the decision of whether to negotiate a PTA involve distribution trade-offs across industries, population segments, time, etc.

Specific to public health, the impact will vary based on: (a) what types of social policies the government puts into place to redistribute economic gains to address economic harms, and (b) the medium- to long-term impact of the trade agreement on the well-being of various population segments.

**Trade Question 3: Are developing countries properly assessing the cost/benefits of negotiating a PTA with the US/EU/Japan properly? Are certain developing countries making the wrong calculus (to join or not to join)?**