

The Quality Conundrum: Stateness, Health Equality and Pharmaceutical Markets in Latin America

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1. Introduction

Effective regulation of pharmaceutical markets is a core challenge to the provision of public health in the developing world (WHO 2011). How developing states establish and enforce standards for the production, registration and entry of effective medicines for public and private markets has an important impact on levels of national and sub-national health inequality.² Moreover, the cost of medicine has been shown to have a disproportionate impact on household income; across developing countries, disbursements on pharmaceuticals account for an average of 66% of household spending during illness. As a result, purchase of medicine is a frequent trigger of poverty (WHO 1988, 2005). In the Latin American region, the challenges of ensuring access to competitively priced medicine is compounded by problems regarding quality standards and their enforcement (World Health Organization 2002).³ For many patients and their families, economic sacrifices made to acquire medicine are rendered futile when basic quality standards are not guaranteed.

All nation states are not equal in their ability to manage levels of competition among the players in their pharmaceutical sector and ensure the quality of medicine in their markets. This paper builds on scholarship in public policy and regulatory literatures to offer a typology of state strength and capability in the pharmaceutical sector, focusing on competition policies and quality regulation. Building on this typology, the paper offers empirical evidence drawn from regulatory agencies in 22 countries to measure the level of state strength in this sector. The paper suggests that over half the markets in Latin America can be characterized as having weak state control; including lack of transparency, pervasive monopolistic behavior, and low or inexistent quality controls.⁴

Public policy concerning the management of pharmaceutical markets requires high levels of inter-governmental coordination, technical acumen, and political autonomy

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² The concept of “health inequality” has a long tradition in developed states (Drever and Whitehead 1997) and is not significantly correlated with overall inequality (Cotoyannis and Forster 1999). That is to say, consistent with the broader view of “poverty” established in the development literature (Sen 1999) multiple prisms of analysis can be used to understand material and non-material deprivation. One important example is health, where even in high-income countries, sharp divergences may exist in terms of access to medicine and overall care (the United States being a classic case).

³ In recent years, a set of protocols described as Good Pharmacovigilance Practice (GPP), has emerged. GPPs develop standards for the safety of medicine, including the collection, management, analysis and use of information.

⁴ The process of collection of data for this analysis is still ongoing. Current figures are drawn from a research project conducted in 2009. A more recent survey has been sent to 22 representatives from pharmacovigilance agencies in 18 Latin American countries.

in the face of internal and external market actors. Recent scholarship has identified the trade-offs in regulation of the pharmaceutical sector in industrialized countries (Carpenter et al. 2011). In Latin America, we have a solid understanding of how institutional models of regulation are diffused regionally (Jordana and Levi-Faur 2005; Weyland 1993), but not how they are sustained or enforced. Some states in the region have been able to rally those variables, while others have fallen short.⁵ Understanding how states control the production and distribution of medicine may help with a conceptualization of the development of regulatory capitalism in the global South. In what countries do we find effective state oversight? Under what conditions does state oversight emerge? Answers to these two questions will help in the formation of public policies.

The paper proceeds in the following structure: section two examines current debates on regulation and state capacity in Latin America; section three examines regulatory policies in the region; section four introduces a typology for measuring the strength of generics regulation and presents the data on “Stateness”; section five concludes and offers pathways for future research.

2. “Stateness” and Regulatory Capitalism

Across multiple disciplinary and methodological approaches, an abundant stream of research in the social sciences describes Latin American states as “weak” (O'Donnell 1993). Yet strikingly, despite significant scholarly work the state in the region, conceptual measurements of “stateness” remain scattered, under-conceptualized and difficult to test empirically (Giraudy and Luna 2011).⁶ Examples of recent work in this area focus on state’s legal legitimacy (Cárdenas 2010), capacity to penetrate subnational territories (Giraudy and Luna 2011) and ability to generate revenue (Besley and Persson 2008).⁷ This paper suggests that one important, under-examined measurement of modern state capacity is its ability to build and sustain institutions which ensure adequate regulation of private and public markets.⁸

Work on regulatory capitalism has centered on how systems are diffused (Jordana and Levi-Faur 2005; Minogue and Cariño 2006; Bach and Newman 2010), with a great deal of scholarship in Latin American intertwined with analysis of the liberalization process (Weyland 1993). Trends in regulation during the privatization period were grounded in the belief that that policy making and policy delivery could be separated, the separation of these processes liberating “policy-makers to take a more strategic

⁵ This paper leaves aside two important, vast, but often ideological streams of research on access to medicine; the role of intellectual property and the role of the State in the production of medicine. The debate about the role of the state in the production of medicine is an on-going one (Attridge and Preker 2005).

⁶ A new line research has recently focused on the need to conceptualize “stateness.” the “Nucleo Mileneo Project” *official title* (Luna and Feldman 2011).

⁷ While providing an interesting measure of state reach, the expansion of electrical systems and roads are a classic example of a public good, are non-rivalrous, with low marginal cost. Major investment in these systems is weighted toward the initial investment. In contrast, the installation and maintenance of a system of regulation demands significant on-going technical vigilance, resources and political will.

⁸ In contrast, in foreign policy literatures, the notion of “state capacity” has become one of the central themes of contemporary work on violence and conflict (Kocher 2010).

view of their role, and free[ing] policy deliverers to take a more entrepreneurial view of theirs (Moran 2001, 414).” More recent work in the region however, has questioned the autonomy of policy making actors, in pharmaceuticals, showing that the strength of local pharmaceutical industry interests tend to shape policy in this sector (Shadlen, 2009). At the same time, research on the European regulatory state has emphasized the inter-linkages between legal systems and political institutions (Majone 1996) or are influenced by levels of regime stability (Reich, 1995).

One of the central themes of regulatory work has been how new patterns of policy have emerged. Jordana and Levi-Faur (2005) examine the diffusion of regulatory apparatuses, focusing on the emergence of regulatory systems in Latin America. They find a proliferation of autonomous regulatory authorities across myriad sectors and countries (from 43 before 1979 to 138 by 2002). This trend, they suggest, represents a potentially problematic shift in accountability, with political systems transforming through bureaucratic mechanisms from those of a “representative democracy to indirect representative democracy.” For Jordana and Levi-Faur, extension of regulatory domains has reshaped the relationship between States and citizens, in with increased distance from the citizenry resulting in diminished democratic control:

“A new layer of public policy specialization, regulatory in its orientation, is increasingly signifying a new approach to public policy whereby politicians delegate authority to regulators who in turn enjoy considerable autonomy in the formulation and administration of policies.” (Jordana and Levi-Faur 2005, 103)

Bach and Newhman (2010), examine regulatory trends across global pharmaceutical markets through the lens of political economy and develop a liberal functionalist argument hinging on historical institutionalism. They find that leading markets play a fundamental role in that their domestic regulatory capacity has spill-over effects, through a sequential development, in other markets. Increasing regulatory isomorphism however is accelerated by subsequent processes of international regime building and cross-national coordination.

“...The form of governance has shifted from occasional international spill-over of domestic rules to first deliberate extraterritorial imposition of domestic laws and subsequently to transgovernmental cooperation aimed at policy harmonization.”

These authors point to increasing harmonization of regulatory systems. In contrast to the homogenizing view, regulation of pharmaceuticals remains notably fragmented across in developing states.⁹ One indicator of the institutional strength of pharmaceutical vigilance is the finance of regulatory agencies. A recent study indicates that only 23 of 55 countries surveyed received budgets from national states (Olsson et al. 2010). In addition, a significant proportion of public institutions dedicated to the control of national pharmaceutical products are financed by external sources (for example, one third are financed by the Global Fund to fight AIDS,

⁹ Moore (2011, 1758) refutes the notion of increasing transnational bureaucratic harmonization. In contrary to what he calls a biased focus on “homogenizing consequences,” he points increasing state divergence and as political elites in poor countries have “...more opportunities and incentives to enrich themselves, and correspondingly fewer reasons to build effective public institutions.”

Tuberculosis and Malaria). This finding is consistent with research that points to external actors as leading the demand for improvement of quality regulation (Pal et al. 2011) and more profoundly, a lack of democratic control of health systems in developing countries (new article).¹⁰ That international institutions are playing such a central role in the finance of regulatory agencies speaks to the weakness experienced in developing states. Ensuring the safety and efficacy of medicines is one of the primary roles of the state in public health. It is a regulation of a market, but one which has also hinged on the capacity of the state to introduce a category of generic medicines.

3. The Quality/Competition Conundrum: A Typology

In Chile, the chief cardiac surgeon of a leading public hospital refuses to operate without a name-brand blood thinner. She has lost too many patients on the operating table with ineffective generic versions.¹¹ In Mexico, the consumption of lower-cost generic medicines decreases after legislation designed to increase access to medicine is implemented. In Brazil, a leading public laboratory loses 30 percent of its procurement budget because generic active ingredients acquired through international tender systems are of such poor quality that they are deemed unusable. In Colombia, the cost of generic medicines exceeds the average weighted price in Germany, by 20 times.¹² In Panama, lower-priced generic pharmaceutical products take on average, 3-5 years longer to achieve regulatory approval for market entry upon the expiration of a patent, in some cases, effectively extending monopoly rights to patent holders for a half a decade.

Throughout the Latin American region, multiple examples illustrate tenuous state control of public and private pharmaceutical markets, a dearth of competition, and scant quality controls for medicine. In light of this regulatory diversity, how can we adequately measure and compare state oversight of the pharmaceutical sector? This paper argues that two dimensions underlie state institutional capacity to regulate the pharmaceutical goods 1) the ability to provide and enforce adequate levels of competition and 2) the capacity to ensure medical efficacy or quality. Across both dimensions, the picture in Latin America is decidedly heterogeneous. Nevertheless, over the last decade, the majority of states in the region have pushed to strengthen domestic institutions, most notably through the creation of independent agencies to regulate introduction of medicines. Even still, the results are varied; some states have strengthened pharmacological systems, implemented quality registration, enforced new norms and promoted competition. Others have not.

¹⁰ Even in developed states, the relationship between politicians, regulators and the citizenry is a fraught one (Atkinson and Coleman 1989). In the United States for example, politically imposed deadlines on quality review are found to increase the number of products in quality (measured through three indicators, market withdrawals, safety warnings, and safety alerts) (Carpenter et al. 2011).

¹¹ Eli Villalabeitia, Chief of Cardiac Surgery, Hospital San Juan. As cited in “Escaso control de medicamentos (I): El riesgo que corren los pacientes de hospitales,” Fransica Skoknic, Centro de Investigacion Periodistica, <http://ciperchile.cl/2008/10/17/escaso-control-de-medicamentos-i-el-riesgo-que-corren-los-pacientes-de-hospitales/>, as accessed, December 2, 2011.

¹² Generics prices are surprisingly divergent. Source...

Before we can properly theorize about why outcomes among states in the region are diverge so markedly, or provide public policy analysis as to how weaker systems may be strengthened to the benefit of public health, we need to come to a common understanding of what effective state management of the pharmaceutical sector looks like. Measuring state oversight of pharmaceutical markets is a complex undertaking because of the multiple channels in both supply of pharmaceutical goods and their demand in public and private settings. This section introduces a typology for gauging state control of the pharmaceutical markets through two dimensions, competition and quality.

States in the developing and industrialized world today face a conundrum in crafting policies which influence levels of competition and quality in national markets: A strong tendency toward consolidation in the global pharmaceutical supply chain brought on a “frenzy” of mergers and acquisitions activities in the 1990s (Nolan 2001) which has continued in recent years. The purchase of emblematic companies such as India’s generic giant Ranbaxy by Japanese firm Daichi Sankyo reflects this trend. More than 65% of world active pharmaceutical ingredient production is now based in one of two countries, India or China. Fewer global suppliers have increased competitive pressure, especially in the supply of affordable medicine in the developing world (Sweet and Das 2009).

At the same time that production is increasingly streamlined and concentrated in a handful of countries and companies, the rules defining the ownership rights of pharmaceutical goods have been consolidated through the creation of global intellectual property rights rules in the WTO. The pathways of production and rules governing them are now largely global.

While there is scattered scholarship on state pharmaceutical regulation (Vogel 1998; Permanand 2006)XXX, measurements of access to medicine are many (XXX). A particularly important work is that of Cohen et al. (2007), which offers an index to analyze access through eight sub-dimensions: marketing approvals, coverage, cost sharing, conditions of reimbursement, speed from marketing approval to reimbursement, extent to which beneficiaries control choice of their drug benefit, and evenness of the availability of drugs to the population. These metrics cover some important indicators. Marketing approvals show us how fast products may take to reach a market. Coverage of pharmaceuticals as a part of public and private insurance plans gives insight into how costs are managed as does insights into systems which regulate consumer choice. Evenness of availability may help us come to term with the breadth and depth of health inequality.

Yet, a key problem with these “sub-dimensions” and with others attempting to measure access to medicine (XXXX) is that they overlook both the competitiveness of markets and the quality of the medicine which they are analyzing. This is particularly important in developing states. If for example, a market is dominated by a handful of pharmacies or distribution chains, which control the bulk of the market, indicators regarding the level of “cost sharing” and “cost coverage and reimbursement” may have diminished importance.¹³ If market prices are artificially high, the benefit of pharmaceutical access gained through co-payments may be

¹³ Classic cases of pharmacy monopolies can be found in Chile and Brazil.

neutralized. Moreover, if the medical effectiveness of medicine available in a market is not ensured, then measurements of the speed which a product enters the market become irrelevant. The average file-to-market time may only tell us that citizens enjoy speedy, laudable “access” to drugs with the medical effectiveness of a placebo. By contrast, emphasis on state capacity allows for clearer insights into problems with the supply of medicine. This does not address the problem of access, but examining the underlying institutions which frame the pharmaceutical market is a fundamental step toward public policies aimed at equitable access.

The Competition Conundrum: Generics

Pharmaceutical markets with intellectual property rights systems are by definition highly monopolistic. The classic term “patent bargain,” describes the agreement between states and innovators in which states grant innovators ownership rights through patents, with the goal of spurring incentives to innovate. During the period for which medicines are under patent, their owners may determine the price of their products, without a competing supplier.¹⁴ The primary mechanism through which to introduce competition into the pharmaceutical market is the introduction of generics products. Generics products are copies of the originator product, which should have the same active ingredients as the original product.

The line between generics and patented originator products was inexistent in Latin America until the mid-nineties; until that time most of the countries in the region did not have patents for pharmaceutical products, which were considered public goods. Instead, local pharmaceutical companies were permitted to copy innovator products, offering a category of goods called “*similares*.” The bioequivalence of these products was not guaranteed by the state. Consumers therefore chose between unregulated pharmaceutical products for which trust was established by a brand name, and those original products, frequently at a price that was significantly higher.

With the end of the Uruguay Round negotiations and the introduction of patent regimes in Latin American markets, consumers in the region could now choose between three categories of products. On the heels of profound changes in the regulation of intellectual property, a number of countries introduced a product category of “generics,” which required bioequivalency.¹⁵ Brazil, the most aggressive country in the region, installed generics also with the vision that *similares*, would be phased out completely, leaving only two product categories, patented originals and quality guaranteed generics. Other countries have introduced generics, with the vision that they will exist simultaneously with *similares* products, with consumers determining which product to use.

Precisely because generics are not protected by ownership rights, they tend to be lower-priced and highly competitive. The logical expectation therefore would be that their penetration would be higher in the developing world, where resources for expenditure on health goods are more constrained. That is not the case; resulting in a

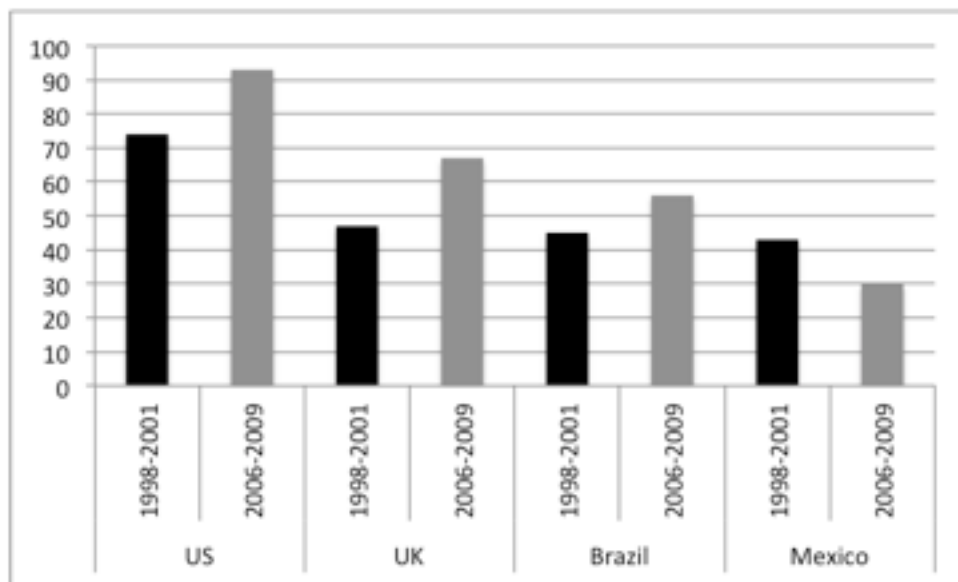
¹⁴ Exceptions include price controls or the state’s ability to break patents through compulsory licenses.

¹⁵ The wave of generics regulation also struck Europe around the mid-nineties. Spain for example introduced its generics law in 1996.

interesting puzzle in public policy. How is it that cheaper pharmaceutical products are less utilized in poorer markets?

A comparative examination of generic consumption in four countries highlights the discrepancy between use and utility. Figure 1 shows the patterns in generic pharmaceutical consumption for the United States, United Kingdom, Mexico and Brazil. In Mexico, during the period 1998-2001, generics accounted for 48% of sales by volume. Consumption of generics decreased to 30% in the next period for which data is available, from 2006-2009. This decrease is particularly notable because in the interim period, the Mexican government established a generics policy with the aim of expanding access to medicine. In contrast, in the United States, in the period 1998-2001, generics accounted for 89% of the market by volume, a figure which reached 92% in the period from 2006-2009. How is it that in Mexico, where the amount of resources available to allocate toward spending on pharmaceuticals is significantly lower than in the United States are generics consumed at such a smaller rate?

Figure 1: Generic Share of Volume in Two Years Following Market Entry



Source: Adapted by author from Danzon and Furukawa, 2011.

The dynamics illustrated in Figure 1 are not isolated to these specific countries. Throughout the Latin American region, generics consumption is low, with the exception of Brazil which has a dynamic bioequivalent generic sector. The factors which lead to levels of generics consumption rest in the states ability to create and regulate markets for affordable and quality products. Table 1 presents the indicators used to gauge the state's ability to promote competition in the pharmaceutical sector through generics. The typology is comprised of three sub-sections: product standards, institutions regarding the registration of generics products; and the systems in place for the distribution of generics products and the perceptions of those products in the marketplace.

Table 1: Typology of Competition

Product Standards

1. Do generics exist?
2. Is clinical data available to generics producers?
3. Do standards include bioequivalency?
4. Do they include biodisponibility?

Registration Institutions

5. Number of laboratories to do the testing.
6. Must testing be realized in-country.
7. Comparative cost of in-country testing.

Distribution Systems and Perceptions

8. Are doctors mandated to prescribe generics?
9. Are pharmacists mandated to offer generic alternatives?
10. Are generics marketed only with generic name?
11. Per cent of population which trust generics.
12. Per cent of population with access to medicine
13. Are generics covered by public health systems?

This typology is helpful in understanding why some countries experience low levels of generic penetration. An examination of product standards indicates how robust the rules for generic products are. The sub-category of registration institutions lends insight into the domestic technical ability to fulfill commonly stipulated regulatory regulations. For example, in Chile, where bioequivalence is not yet a necessary requirement for product entry, the cost of laboratory work to prove pharmacological effectiveness is 50 thousand dollars, while in Argentina it is 65 thousand and in Brazil, where local regulatory agency ANVISA requires companies to test generic products within-country, the cost is US\$ 90 thousand. By way of contrast, the cost in the US is about 300,000. In addition to cost, the typology reveals one of the central limitations to stronger generics regulation, a lack of technical capacity. In the case of Chile, only two laboratories are equipped to perform bioequivalency tests and under optimal circumstances, could provide services for 15 percent of the market.¹⁶ This is an institutional constraint which makes more complex the test of implementing and enforcing standards aimed to promote market competition. The third prong of the typology focuses on the elements affecting the competition of a pharmaceutical market, by examining the rules governing their prescription, sale, reimbursement and levels of trust enjoyed by the population.¹⁷ The focus of the competition typology is to unravel the levels of competition along the delivery of the product to the consumer.

The Quality Conundrum: A Typology

States have at their disposal a number of policies that can promote competition in the pharmaceutical sector, including rapid registration processes, the availability of clinical data for generic firms, and mandated prescriptions at the physician or pharmacist level. Each of these policies however, depend on a base-level guarantee of the quality of the generic product. If generic medicines do not enjoy the credibility that they deliver the same pharmacological effectiveness as innovator products, doctors and consumers will opt for the brand-name product. Quality regulation is fundamental to ensuring competition.

¹⁶ According to Hector Larenas, in a study undertaken by the IF, the cost would be 2 million dollars to make such a laboratory and the country needs 8 more centers.

¹⁷ See appendix 1 for a table exhibiting specific legislation on prescription, marketing packages and reimbursement of generics products.

Table 2 presents the typology for a state’s institutional capacity to ensure quality generic products. The two subgroups consist of types which measure the level of a state’s institutional infrastructure and the degree to which this institution functions, both by perception and by delivery of safety notifications to its public.

Table 2: Typology of Quality and Institutional Capacity

Quality Infrastructure

1. Does a regulatory agency exist?
2. What is the budget per capita?
3. Number of enforcement agents per capita?

Quality Enforcement

4. Perception of quality by population
5. # of safety alerts per year, per capita

The combined dimensions allow us to hypothesize about the outcomes for pharmaceutical markets. Figure 2 explores the results of weak or strong institutional capacity across quality or competition.

Figure 2: Theoretical Outcomes in Quality and Competition

		Quality	
		Strong	Weak
Competition	Strong	Multiple industry players, with low-cost generics widely available and widely consumed.	Multiple providers of low-priced generic options, but a lower penetration of generic products because doctors and consumers do not trust their efficacy.
	Weak	Limited market players, slow entry of generic products but high consumption of those generic goods.	Limited market players and low level of generics due to a lack of trust in their efficacy.

We can expect that markets with high levels of competition and ensured quality will have a number of market suppliers, bringing the costs down and broadening the access to pharmaceutical goods. In contrast, markets with lower levels of competition will have fewer players, more limited levels of public trust, and less consumption of generic pharmaceutical products.

4. Measuring State Capacity

The goal of this last section is to empirically examine the results of the survey on competition and quality regulation in the region. The previous decade in Latin America has witnessed a surge in the expansion of independent regulatory institutions monitoring the entry and definition of generics pharmaceutical products. And yet, despite this institutional expansion, regulation of pharmaceutical markets remains weak. Table 3 focuses on the results in five major markets, Argentina, Brazil, Chile, Mexico and Peru.

Table 3: Examples of State Regulatory Roles in Delivery of Medicine

Channel	State Regulatory Role (SRR)	Ar	Br	Ch	Mx	Pr
Production	Clinical trials data available	×	✓	×	×	×
	Application of GMS Standards	✓	✓	✓	✓	✓
	Import standards	×	×	×	×	×
Certification	Bioequivalency	×	✓	×	✓	×
	Biodisponibility	×	✓	×	×	×
Distribution	Doctors mandated to prescribe generics?	×	✓	✓	×	×
	Pharmacies mandated to offer generics?	×	✓	×	×	×
	Customers aware of generics?	×	✓	✓	✓	✓
	Customers trusting of generics?	×	✓	×	✓	×

Elaborated by author

Table 4 presents the findings of the survey institutions in the region.

Table 4: Preliminary Results in Competition and Institutional Capacity

COMPETITION: GENERICS

	Do generics exist?	Data availability	Do they include bioequivalency?	# of Laboratories in country capable of doing bioequivalency testing	Comparative cost of bioequivalency testing in country	Must bioequivalency be realized "in country"?	Doctors mandated to prescribe generics?	Pharmacy mandated to offer generic alternative?	Marketing: Generics marketed with only ISSN (chemical name)?	Marketing: Other regulation on marketing of generics?	% of population familiar with generics	% of population which trust generics	% of population with access to medicine	Generics medications covered by public health system?	TOTAL (de 0-14)
Argentina	1	1	0.5	0.5	0.3	1	0.5	1	0.5	0.3	1	0.5	1	0.7	9.8
Belize	0	0	0	0	0	1	0.5	0	0	1	0.5	0	0.5	0.5	4
Bolivia	1	1	0.5	0.5	0	1	1	0.5	1	1	0.5	0.5	0.5	0.5	9.5
Brazil	1	1	1	1	0	0	1	1	1	1	1	1	0.7	1	11.7
Chile	1	0	0.5	0.5	1	1	0.3	0	0.5	0	0.5	0.5	0.7	0.5	7
Colombia	1	0	1	0.7	1	1	0	1	0.5	0.5	0.5	1	0.7	0.5	9.4
Costa Rica	1	0	0	0	0	1	1	0.5	0.5	1	0.5	0.5	1	1	8
Ecuador	1	1	0.5	0.5	0	1	0.3	0.3	1	1	0.5	0.5	0.5	0.7	8.8
El Salvador	1	0	0	0	0	1	0	0.3	0	0	0.5	0.5	0.5	0	3.8
F. Guyana	1	1	1	0	0	1	0	0	1	0	0.5	0	1	0.3	6.8
Guatemala	1	0	0	0	0	1	0	0	0	0	0	0.5	0.3	0.3	3.1
Honduras	1	0	0	0	0	1	0	0	0.5	0.5	0	1	0.3	0.5	4.8
Mexico	1	0	0.5	1	0.5	1	1	0.5	0.7	0	0.7	0.7	0.7	0.3	8.6
Nicaragua	1	0	0	0	0	1	0.5	0	1	0	0.5	0.5	0.5	0.3	5.3
Panama	1	0	0	0	0	1	0.5	0.5	0	0	0.5	0.5	0.5	0.3	4.8
Paraguay	0	1	0	0	0	1	1	0.5	0	0	0	0	1	0.5	5
Peru	1	0	0.5	0.5	0	1	0.7	0.5	0.5	0.5	0.5	0.5	1	0.5	7.7
Suriname	1	1	1	0	0	1	1	0.5	0	0	0.5	0.5	1	0.5	8
Uruguay	1	1	1	0.3	0.5	1	1	0.5	0.5	1	1	1	1	1	11.8
Venezuela	1	1	0	0.5	0	1	1	0.5	1	1	1	0.7	1	1	10.7

**1=Highly competitive; .7=Moderately competitive; .5=relatively competitive; .3 slightly competitive; 0=not competitive

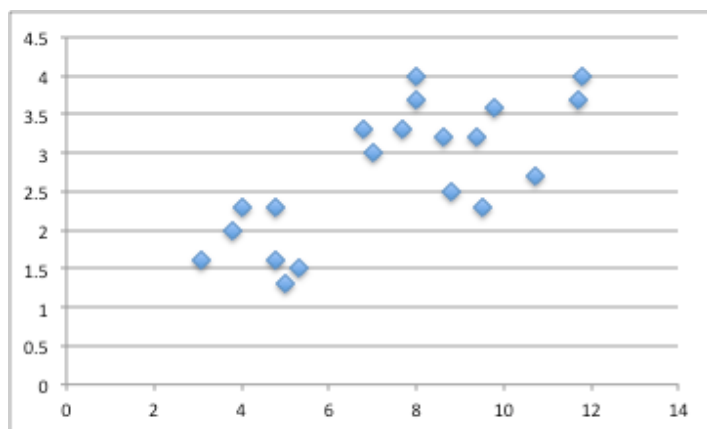
Table 5 presents the results on regulation of quality standards in the region.

Table 5: Preliminary Results in Quality and Institutional Capacity

	Does a regulatory agency exist	Budget/population	# of agents per population	Perception of quality by population	# safety alerts per year	TOTAL (0-5)
Argentina	1	1	0.3	1	0.3	3.6
Belize	1	0.5	0.3	0.5	0	2.3
Bolivia	1	0.3	0.3	0.7	0	2.3
Brazil	1	1	0.7	1	0	3.7
Chile	1	0.7	0.5	0.5	0.3	3
Colombia	1	0.7	1	0.5	0	3.2
Costa Rica	1	1	0.7	1	0	3.7
Ecuador	1	0.5	0.5	0.5	0	2.5
El Salvador	1	0	0.3	0.7	0	2
F. Guyana	1	1	1	0	0.3	3.3
Guatemala	1	0	0.3	0.3	0	1.6
Honduras	1	0	0.3	0.3	0	1.6
Mexico	1	0.7	0.5	0.7	0.3	3.2
Nicaragua	1	0	0	0.5	0	1.5
Panama	1	0.5	0.3	0.5	0	2.3
Paraguay	1	0.3	0	0	0	1.3
Peru	1	1	0.5	0.5	0.3	3.3
Suriname	1	1	1	1	0	4
Uruguay	1	1	1	1	0	4
Venezuela	1	0.7	0	1	0	2.7

In synthesizing the cumulative results in Table 4 and Table 5, Figure 3 illustrates the results.

Figure 3: Index on State Capacity in the Pharmaceutical Sector



5. Conclusions

The availability of competitively priced, effective medicine is one of the keystones of public health (WHO) and depends directly on the ability of the state to regulate the pharmaceutical sector. The delivery of public health goods has transversal effects on economic growth, education and productivity. Nevertheless, the complexity of pharmaceutical regulation demands on-going and transversal coordination of state units. Building an understanding of how some developing states are able to manage regulation of medicine and how others fail is key to informing policy in this area. A first step in this direction is to constructing an understanding of the oversight of pharmaceutical markets.

Weak state institutional capacity to regulate the pharmaceutical sector generates the medical equivalent of enclosed communities. In recent decades, many societies in Latin America have experienced increasing a physical segregation along social economic lines. When security is not effectively provided by the state, citizens procure it privately, enclosing themselves in “gated communities” (Caldeira 2001). A parallel segregation has the potential to emerge in the delivery of medicine. Those who can pay for medicine which is guaranteed by private companies will do so, at a significantly higher cost. Uneven state capacity to regulate the pharmaceutical sector increases health discrimination by limiting competition.

Debates in health systems research have identified the central role of quality regulation in the provision of effective health systems but scant research has identified how institutional design may influence models of quality regulation. This paper to fill an analytical gap in reform literatures while contributing to public policy research on access to medicine in the region. Why do states with higher economic levels have lower levels of generics penetration? The paper has provided a typology for analyzing institutional capacity in Latin America, which spans the process of production, registration, delivery of medicine and illustrates how access to medicine is weakened when states fail to regulate pharmaceutical markets.

APPENDIX 1: Institutions and Standards

Countries	Market regulator	Key pharmaceutical legislation	INN-only prescribing	Generic substitution	Special conditions
Argentina	ANMAT	Law 25,649 (2002) Decree 150 (1992)	Brand Name optional	Optional	Reimbursement may be refused if INN absent from script
Bolivia	Ministry of Health	Basic Health Law (1996)	Mandatory in public sector	Optional	
Brazil	ANVISA	Law 9787 (1995)	Mandatory in public sector	Optional	Substitution with "similar" drug prohibited
Chile	ISP	Decree 1,876 (1995)	Mandatory in public sector	Optional	Pharmacist's/patient discretion
Colombia	INVIMA	Decree 2092 (1986), Decree 677 (1995), Decree 2200 (2002)	Brand Name option in public sector	Optional	
Costa Rica	DRC	General Health Law (1973), Decree 28466-S (2000)	Mandatory in public sector	Optional	Brand names prohibited
Ecuador	National Hygiene Institute	Law 2000-12, Regulation 59 (2000), Law 152, Decree 1076	Mandatory	Optional	Substitution at patient's option
El Salvador	CSSP	Health Code 55 (1988)	No	n/a	
Guatemala	MSPAS	Agreement 712 (1999)	No	n/a	
Honduras	Secretariat	Health Code 65 (1991)	No	n/a	
Mexico	COFEPRIS	General Health Law (1998), SSA Regulation 177 (1998)	Brand Name optional in public sector	No	
Nicaragua	DARMA	Law 292 (2002)	Mandatory in public sector	Optional	
Panama	DFD	Law 1 (2001)	No	n/a	
Paraguay	Ministry of Health	Law 1, 630 (2000)	Mandatory in public sector	n/a	
Peru	DIGEMID	Law 26,842 (1997), Decree 20 (2001)	Brand Name optional in public sector	Optional	
Uruguay	Ministry of Health	Law 15,443 (1983), Decree 315/002 (2002)	Brand Name optional	Optional	
Venezuela	National Hygiene Institute	Law 37,006 (2000)	Mandatory	Optional	

Source: Author

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