The Quality Conundrum:

Ensuring Access to Medicine in the Developing World

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Abstract

The availability of medicine is a keystone of public health and human development. Yet research on the issue of access to medicine in the developing world has underemphasized the role of states in providing regulation of this sector. A dearth of work on state systems ensuring quality and competition in pharmaceuticals has left us with few tools for conceiving, comparing and improving current systems. This paper reviews leading scholarship and subsequently offers a typology of state strength and capability in this sector. Building on the typology, the paper offers empirical evidence drawn from a survey of regulatory agencies in 22 countries in Latin America. The findings point to an abundance of new institutions, but an overall climate of weak state control; including lack of transparency, pervasive monopolistic behavior, and low or inexistent quality controls.

Keywords

Public health, pharmaceuticals, access to medicine, regulation

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Aim

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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 and human development.[2] Moreover, the cost of medicine has been shown to have a disproportionate impact on household income in developing countries, where disbursements on pharmaceuticals account for an average of 66% of household spending during serious illness. Perhaps not surprisingly, purchase of medicine is a frequent trigger of poverty (WHO 1988, 2005).

In a number of countries in the developing world, 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 patients and their families, well-documented economic sacrifices made to acquire medicine are rendered futile when the basic quality standards of available pharmaceuticals are not guaranteed. While the relationship between economic development and public health has long been a rich terrain for researchers, new scholarship emphasizes the important role of health for political stability.[4]

This paper reviews recent relevant regulatory literatures and subsequently offers 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 in Latin America to measure the level of state oversight strength in this sector. The paper

[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 multiple prisms of analysis can be used to understand material and non-material deprivation (Sen 1999). 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] Lit on health security.

suggests that over half the markets surveyed can be characterized as having weak state control; including lack of transparency, pervasive monopolistic behavior, and low or inexistent quality controls.[5] This work has important implications for current scholarly efforts to gauge "stateness" as well as for public health efforts to increase quality control systems in other developing regions.

Public policy concerning the management of pharmaceutical markets requires high levels of inter-governmental coordination, technical acumen, and political autonomy in the face of internal and external market actors. 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. Regulatory structures in industrialized countries illustrate the challenges of ensuring quality, timeliness within political institutions (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. This research offers a typology for analyzing how some states in the region have been able to rally those variables, while others have fallen short.[6]

The paper proceeds in the following structure: section two examines recent scholarship on regulation and its diffusion; section three overs a brief overview of emerging regulatory policies in Latin America; section four introduces a typology for measuring the strength of regulation and presents the data on "Stateness"; section five concludes offers pathways for future research and suggests how intergovernmental agencies and public health actors can help resolve the quality conundrum currently facing many developing states.

[5] Figures are drawn from a survey conducted in 2010 including 22 representatives from pharmacovigilence agencies in 18 Latin American countries.

[6] This paper leaves aside two important and expanding streams of research relating to access to medicine: the rigidity of intellectual property norms 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).

2. States, Structures and Pharmaceutical Regulation Policy

The notion that states, regulatory systems and organizations are in an iron cage of increasing bureaucratic convergence emerged in the seminal work of DiMaggio and Powell (1983) nearly a quarter of a century ago. Yet one of the central themes in state regulatory scholarship has remained how new patterns of policy emerge across different nation states and in particular, how they are transmitted from stronger to weaker states (Jordana and Levi-Faur 2005; Minogue and Cariño 2006; Bach and Newman 2010).[7] Focusing on the turn of the 21st century in Latin America, Jordana and Levi-Faur (2005) make a significant contribution through their tracing of the diffusion of regulatory apparatuses. They find a proliferation of autonomous regulatory authorities across myriad sectors and countries (expanding from 43 before 1979 to 138 by 2002). Instead of illustrating increased state capacity or strength, this trend, they suggest, represents a problematic shift in accountability, with political systems transforming through bureaucratic mechanisms, shifting from a "representative democracy to [an] indirect representative democracy." For Jordana and Levi-Faur, extension of regulatory domains reshapes the relationship between States and citizens: increased distance from the citizenry results 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)

In contrast to this approach, other recent scholars have examined state strength through models of regulatory policy diffusion in which policy convergence does not hinge on the citizen and their bureaucracy, but on the comparative strengths of market and state. In this stream, Bach and Newhman (2010) find that leading markets play a fundamental role in initiating cross-state regulatory change. They argue that the domestic regulatory capacity of "leading" markets has spillover effects across other

[7] Some notable scholarship in the Latin American region has analyzed how the establishment of modern regulatory systems where at their inception, intertwined with liberalization processes (Weyland 1993).

weaker countries. In this narrative, lead market players push an initial regulatory shift and states, regardless of their strength, or autonomy, or interconnectedness with the citizenry, are followers. These findings, though based on a survey of EU members, are consistent with recent narratives of pharmaceutical regulation in Latin America, Africa and developing Asia, where evidence points to local industry players as protagonists in processes of regulatory change in the pharmaceutical sector (Shadlen 2012).

Research on the European regulatory state has long emphasized the inter-linkages between legal and regulatory systems and political institutions in which policy makers are embedded (Majone 1996). These works argue that the untangling of policy actors from the political process is a chimera at best and a weak point of analytical departure at worst. This view goes contrary to the belief, so popular during the liberalization period, that that policy making and policy delivery could be separated, the separation of these processes liberating "policy-makers to take a more strategic view of their role, and free[ing] policy deliverers to take a more entrepreneurial view of theirs (Moran 2001, 414)." Beyond analysis of individual players (or the debates about their autonomy) evidence indicates that if the relationship between the state regulatory apparatus is intertwined with local markets, roles in regulatory diffusion are far from static. According to Bach and Newhman, as regulatory systems converge, the process is accelerated by international regime building and cross-national coordination in which the states play a more active role.[8]

> "…The form of governance…shift[s] 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."

While multiple authors have observed increasing harmonization of regulatory systems, evidence of a process of convergence in the developing world is uneven. In contrast to the homogenizing view, regulation of pharmaceuticals remains notably fragmented across most developing states. In his analysis of the impact of globalization on what he calls "weak states", Moore (2011) disputes the notion of

[8] Institutional isomorphism was developed (DiMaggio and Powell 1983)

increasing transnational bureaucratic harmonization. Noting a biased focus on "homogenizing consequences," Moore points increasing state divergence as political elites in poor countries have "…more opportunities and incentives to enrich themselves, and correspondingly fewer reasons to build effective public institutions" (2011, 1758).

How regulatory institutions expand across developing states, how they are monitored and to what degree of quality they are able to provide are all fundamental questions for ensuring the delivery of public services. Yet, while we can rely on a wealth of research to debate how policies diffuse and who the main actors are in terms of their relationships with local markets, we have a weak grasp on what exactly a strong or weak regulatory framework in the pharmaceuticals sector might looks like. This gap contrasts quite strongly with more advanced research on a state's ability to regulate violence (XXX), trade (Fink and Reichenmiller 2006), and even compliance with intellectual property rules (Govaere and Ullrich 2007).[9]

Indeed, at the same time that scholars have focused numerous studies on the diffusion, or convergence of regulatory institutions (Vogel 1998; Permanand 2006), the fragility of regulation in pharmaceuticals in the developing world remains starkly apparent. A recent study found that only 23 of 55 least-developed countries publically funded their pharmaceutical regulatory agencies (Olsson et al. 2010). A significant proportion of state institutions dedicated to the control of pharmaceutical products are currently financed by external sources (for example, one third were funded by the Global Fund to fight AIDS, Tuberculosis and Malaria). These results are consistent with research that points to external actors as leading the demand for improvement of quality regulation and more profoundly, a lack of democratic control of health systems in developing countries. In these cases, democratic control is tenuous not because of the distance between the bureaucrats and the citizenry but because exogenous sources of funding with little transparency or accountability (forthcoming IO article by Conrad).[10] That international institutions are play such a central role in the finance of

[9] More here!

[10] Even in developed states, the relationship between politicians, regulators and the citizenry is a fraught one In the United States for example, politically imposed deadlines on quality review are found

regulatory agencies speaks to the weakness of these agencies as experienced in developing states.

Part of the problem for scholars and development practitioners is that while we can trace the expansion of regulatory agencies, we have a meager understanding of how national pharmaceutical quality agencies function and what concepts might guide us in analyzing their strengths and weaknesses. The last global survey conducted by the World Health Organization relating to pharmaceutical regulation was in 1999.[11] An abundance of measurements of state "strength" uniformly analyze public health through the metrics of infant or maternal mortality and life expectancy. These are important statistics, but they are outcomes of health systems. If the question is state strength, they reveal little about state inputs (MORRRRE). The following section analyzes relevant metrics and introduces a typology for understanding, gauging and comparing the strength of state regulatory oversight of the pharmaceutical sector.

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.[12] 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

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to increase the number of products in quality (measured through three indicators, market withdrawls, safety warnings, and safety alerts) (Atkinson and Coleman 1989).

[11] This data is part of the World Health Organization Collaborating Center on Pharmaceutical Policy. A request has been made to the WHO for any updates on Level I and Level II Indicators and Methodology to Assess Country Pharmaceutical Situations for all available years. The request has been made to Department of Technical Cooperation for Essential Drugs and Traditional Medicine, World Health Organization, 1211 Geneva 27, Switzerland. A request has also been made to the PanAmerican Health Organization for similar data.

[12] Eli Villalabeitia, Chief of Cardiac Surgery, Hospital San Juan. As cited in "Escaso control de medicamentos (I): El riesgo que corren los pacientes de hospitals," 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.

tender systems are of such poor quality that they are deemed unusable.[13] In Colombia, the cost of generic medicines exceeds the average weighted price in Germany, by 20 times.[14] 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, despite increasing policy diffusion, 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 while significant numbers have not.

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 on the state in the region, conceptual measurements of "stateness" remain diffuse and difficult to test empirically (Giraudy and Luna 2011).[15] Examples of recent work in this area focus on states' legal legitimacy (Cárdenas 2010), capacity to penetrate subnational territories

[13] Interview with Farmanguinhos director Eduardo Costa, Rio de Janeiro. For more on the politics of pharmaceutical regulation in Brazil, see Sweet (2012).
[14] Generics prices are surprisingly divergent. Source…

[15] A new line of research has recently focused on the need to conceptualize "stateness" in Latin America, see the "Nucleo Mileneo Project" *official title*. RCP special issue coming forth.

(Giraudy and Luna 2011) and ability to generate revenue (Besley and Persson 2008).[16] 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.[17] This is particularly important for pharmaceutical regulation given the transversal importance of public health to economic development and political stability.

Before we can properly theorize or test for the sources of variation among regulatory systems, or embark on 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.[18] 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 reviews relevant metrics of pharmaceuticals and 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 puzzle 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 (Pal et al. 2011) which has continued in recent years.[19] 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 for the supply of affordable medicine in the developing world (Nolan 2001; Grace 2005). 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

[16] 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.
[17] By way of contrast with scattered work institutional strength, discussion of "state capacity" and the variables which may influence it has become once of the central themes in contemporary work on violence and conflict in foreign policy literatures (Kocher 2010).
[18] Goertz, concepts.
[19] The purchase of emblematic companies such as India's generic giant Ranbaxy by Japanese firm Daichi Sankyo reflects this trend.

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.

Pressures to harmonize national intellectual property rights norms to the standards set in the WTO have spurred important scholarship on the impact of intellectual property on access to medicine and the challenges of ensuring access to affordable medicine in the post-TRIPs context (Sweet and Das 2009; C. Akaleephan et al. 2009; Chakraborty and Singhvi 2009; D'Almeida et al. 2008; Grace 2004; Shaffer and Brenner 2009). One comprehensive survey of this impact has come from Cohen et al. (2007), which offers an index to analyzing 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 do data on 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 (Robinson, Meeks-old, Williams new) 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.[20] If market prices are artificially high, the benefit of pharmaceutical access gained through co-payments may be eliminated altogether. 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 are irrelevant. The average file-to-market time may only tell us that citizens enjoy speedy, laudable "access" to drugs with the medical

[20] Classic cases of pharmacy monopolies can be found in Chile and Brazil.

effectiveness of a placebo. By contrast, emphasis on state oversight of the sector allows for clearer insights into problems with the supply of medicine. While this metrics may not directly address the challenge 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.[21] 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 distinction between generics and patented originator products was inexistent in Latin America and most developing countries 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 bioequalivance 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 chose between three categories of products. On the heels of profound changes in the regulation of intellectual property, a number of countries introduced a product

[21] Exceptions include price controls or the state's ability to break patents through compulsory licenses.

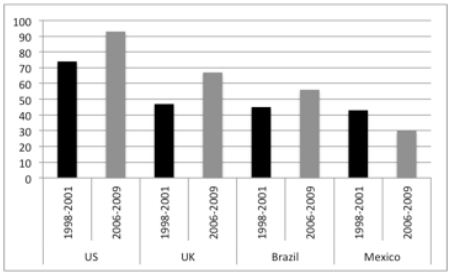
category of "generics." which required bioequivalency.[22] Brazil, the most aggressive country in the region, installed generics also with the vision that *similares,* would be phased out completely, leaving only two product categories, patented originals and quality guaranteed generics. Other countries 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 an 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 that in the United States are generics consumed at such a smaller rate?

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

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



Source: Adapted by author from data available in 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 comparatively low, with the exception of Brazil which has a dynamic bioequivalent generic sector. This paper asserts that 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 contributes to an understanding of 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 approximately 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.[23] 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.[24] 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

[23] 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.
[24] See appendix 1 for a table exhibiting specific legislation on prescription, marketing packages and reimbursement of generics products.

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.

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 safely 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: Outcomes in Quality and Competition

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 aim of this 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

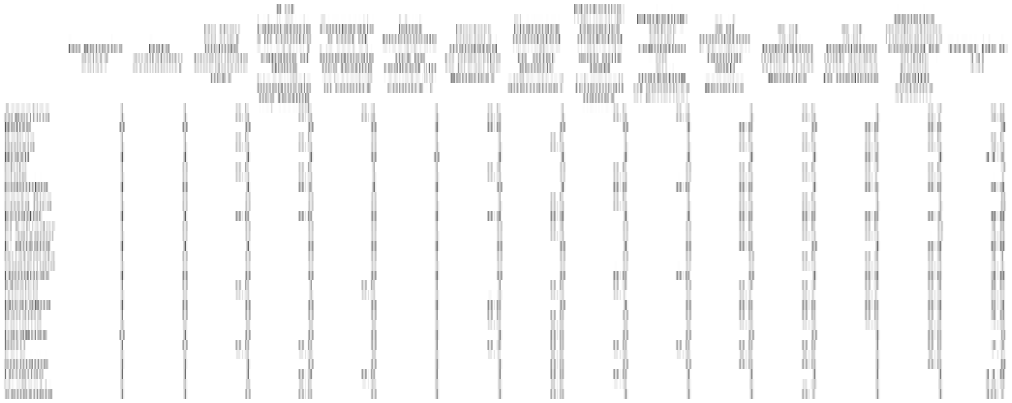
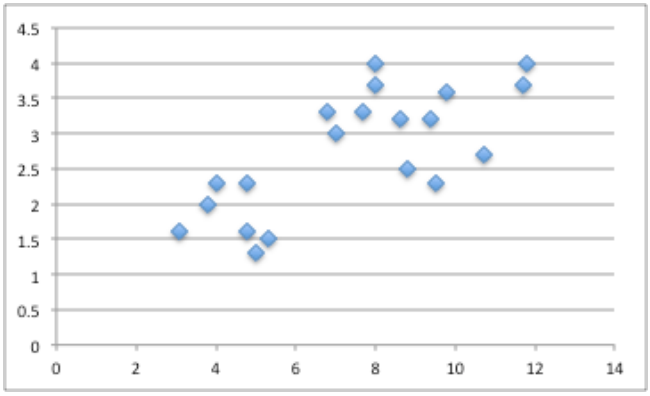


Table 5 presents the results on regulation of quality standards in the region.

Table 5: Preliminary Results in Quality and Institutional Capacity

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 and in other developing regions 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. Those who cannot, will risk the effectiveness of the medicine they purchase in acquiring poorly regulated generics. Uneven state capacity to regulate the pharmaceutical sector increases health discrimination and limits 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 makes a first step toward fill an analytical gap in reform literatures while contributing to public policy research on access to medicine in the region. A quality conundrum faces contemporary developing states. Inability to provide proper regulation of pharmaceutical has resulted in consumers in poorer countries purchasing more expensive medicine. 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 b refused if INN abser 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 "simila 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 Hygyine Institute	Law 2000-12, Regulation 59 (2000), Law 152, Decree 1076	Mandatory	Optional	Substitution at patient' option
El Salvador	CSSP	Health Code 55 (1988)	No	n/a	
Guatemala	MSPAS	Agreement 712 (1999)	No	n/a	
Honduras	Health 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 Heath	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 Hygyine Institute	Law 37,006 (2000)	Mandatory	Optional	

Source: Author

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