The Quality Conundrum

States, Health Equality and Pharmaceutical Markets in Latin America

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Outline

Introduction

Access to medicine: How do we measure quality and competition? What does the literature say? What is the role of these points for public health?

Data, definitions, methodology: Quality and Competition
Introduction of the typologies. How do we measure our sub-levels? What channels are important for pharmaceutical access?

Results
Comparative outcomes across 22 Latin American countries.

Conclusions
What do the results mean? What implications do they have for policy analysis and theory building?

Introduction

- Access to medicine is a core issue in public health policy and appears increasingly in PP literatures (WHO 2006, 2008, 2001; PAHO 2009).

- Yet, current research focusing on access to medicine has overlooked a key factor in public health systems: is *quality* medicine available in a given pharmaceutical market? (Cohen et al. 2007, Olsson et al. 2010, Pal et al. 2010, Carpenter et al. 2011)

- In addition, current measurements of *competition* have not been appropriate for developing countries. (supply-side vs demand side/Vogel 1998, Premanand 2002, CEPAL 2008)

- Anecdotal evidence indicates that low standards of pharmaceutical quality and competition can be found in the region. Scant research has shown the variance in pharmaceutical institutions or sough to explain these differences (Ugalde 2007, Shadlen 2009).

Introduction

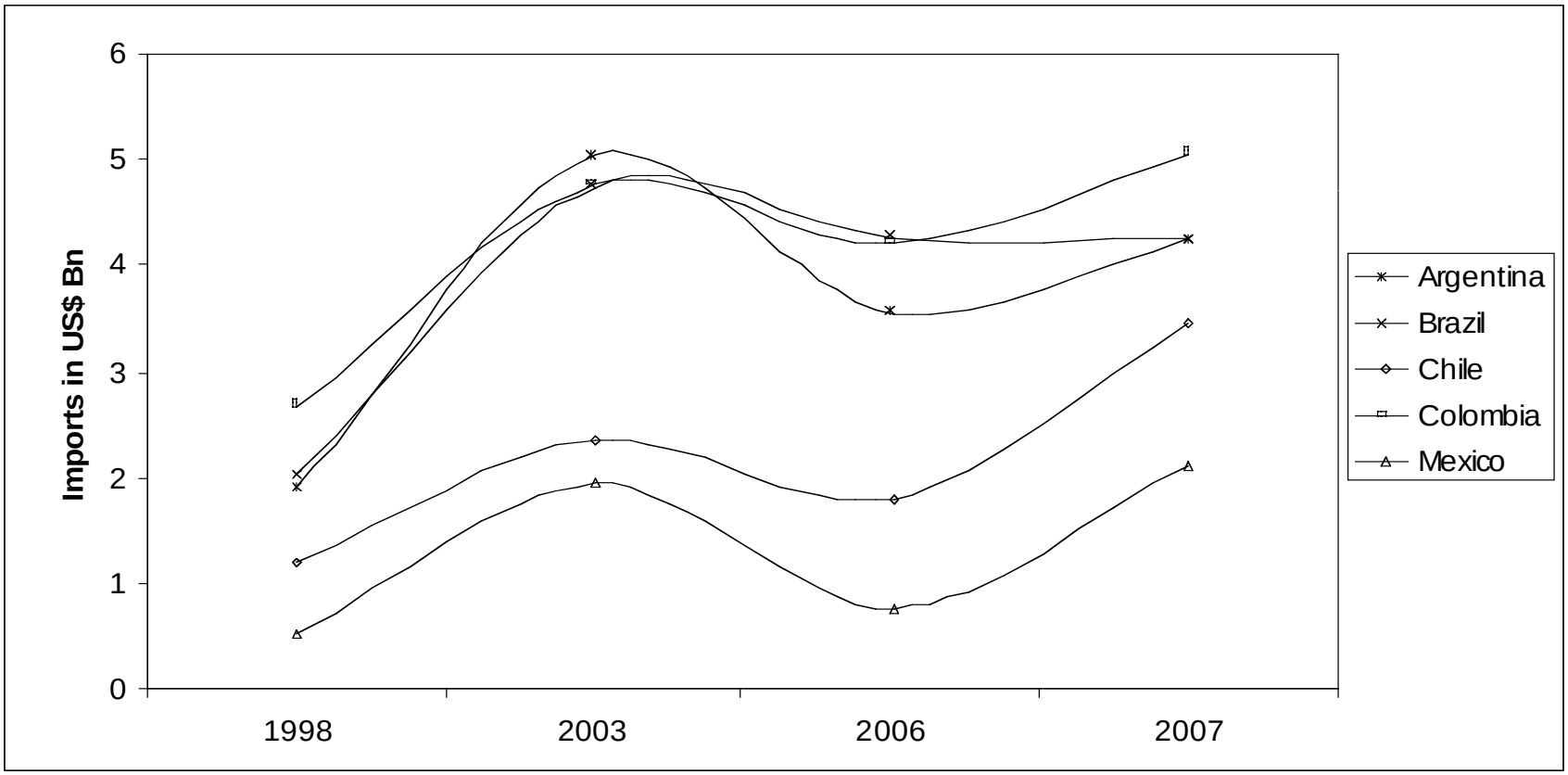
- This paper offers a typology for analysing levels of quality and competition across Latin American pharmaceutical markets, focusing on the regulation of generic medicines.

- Subsequently, the study presents preliminary results from 22 states to gauge the depth of pharmaceutical regulation across Latin America.

- The aim of measuring regulation across these two dimensions is a fundamental first step toward understanding a) what variables are necessary to enable effective regulatory systems and b) why some states are able to rally these variables and others not.

The Conundrum: States, Inequality and Access

- Although generic medicines provide an alternative to higher priced on-patent, "originator" medicines, generic penetration in the region is comparatively low. With the introduction of the patent system, three product categories remain. On patent, "similares" and generics. The trend is toward importation of higher-priced medicines.



Source, UN Comtrade Data, 2010

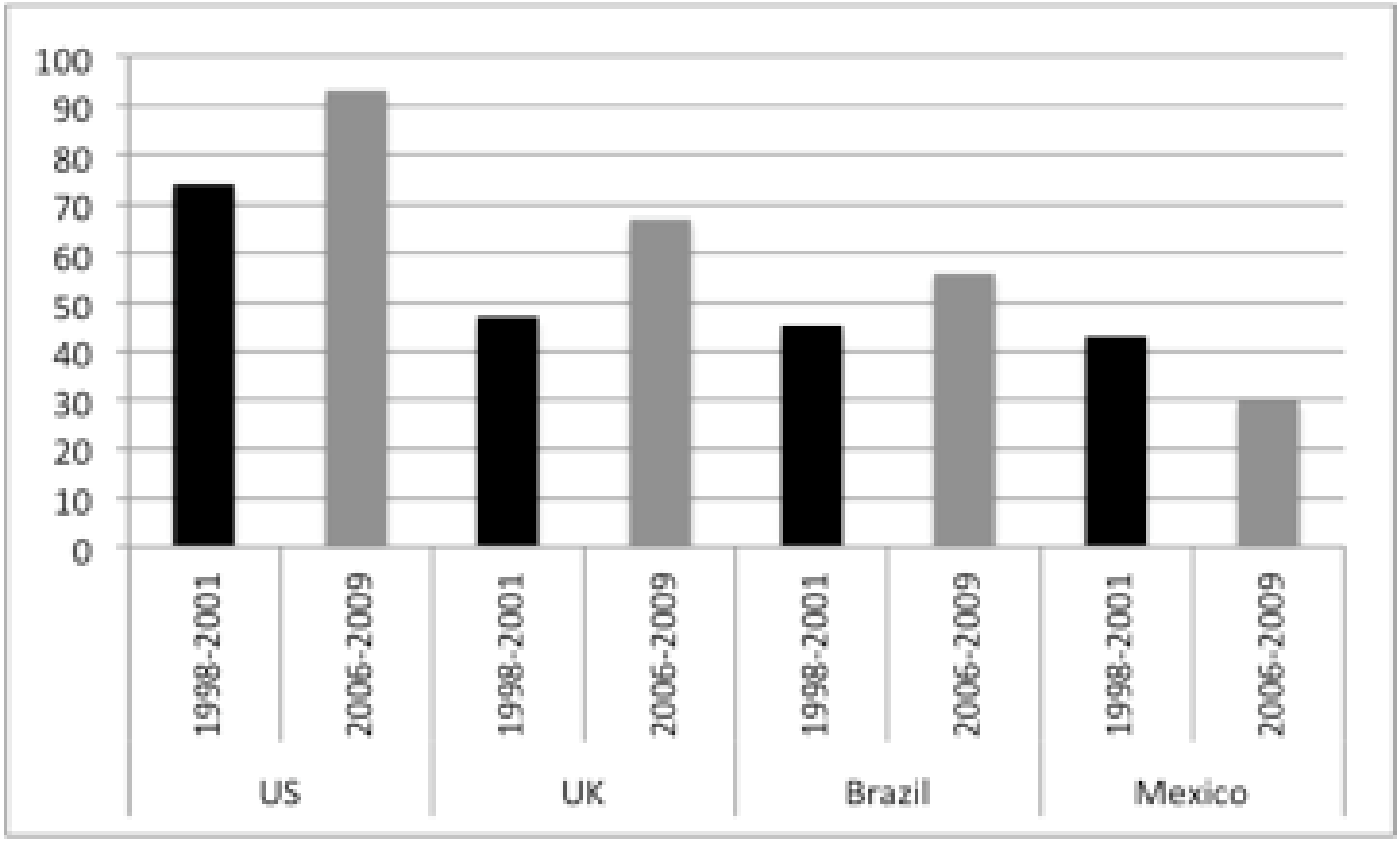
The Conundrum: States, Inequality and Access

- On-going legal battles regarding the implementation of intellectual property rights in the region also impact the manner in which generics are regulated and perceived.

	Strategies	Examples	Cases	Country
1	*Evergreening*	> spurious patents		Chile
		> applications for the extension of patent valic (pipeline)	Pfizer	Brazil
		> application for the extension of patent validit (reformulations/recombinations)	Bristol Myers Squibb	Argentina
			Novartis, Pfizer Merck, AstraZeneca	Mexico
2	Breaking Bolar Rights	> allegation of illegitimate use of confidential information	MSP Singapore Co., Schering, Novartis	Argentina
3	Fear campaigns	> negative publicity on the quality of generic medicines > letters warning local laboratories about pendi patent applications		Chile

The Conundrum:

Penetration of Generics Medicine



Typology for Competition

1. Do generics exist?
2. Data availability
3. Do they include bioequivalency?
4. # of Laboratories in country capable of doing bioequivalency testing
5. Comparative cost of bioequivalency testing in country
6. Must bioequivalency be realized "in country"?
7. Doctors mandated to prescribe generics?
8. Pharmacy mandated to offer generic alternative?
9. Marketing: Generics marketed with only ISSN (chemical) name?
10. Marketing:Other regulation on marketing of generics?
11. % of population familiar with generics
12. % of population which trust generics
13. % of population with access to medicine
14. Generics medications covered by public health system?

Typology for Quality

1 Does a regulatory agency exist
2 Budget/population
3 # of agents per population
4 Perception of quality by population
5 # safety alerts per year

Expected outcomes

Results: Levels of Depth in State Regulatory Role

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						

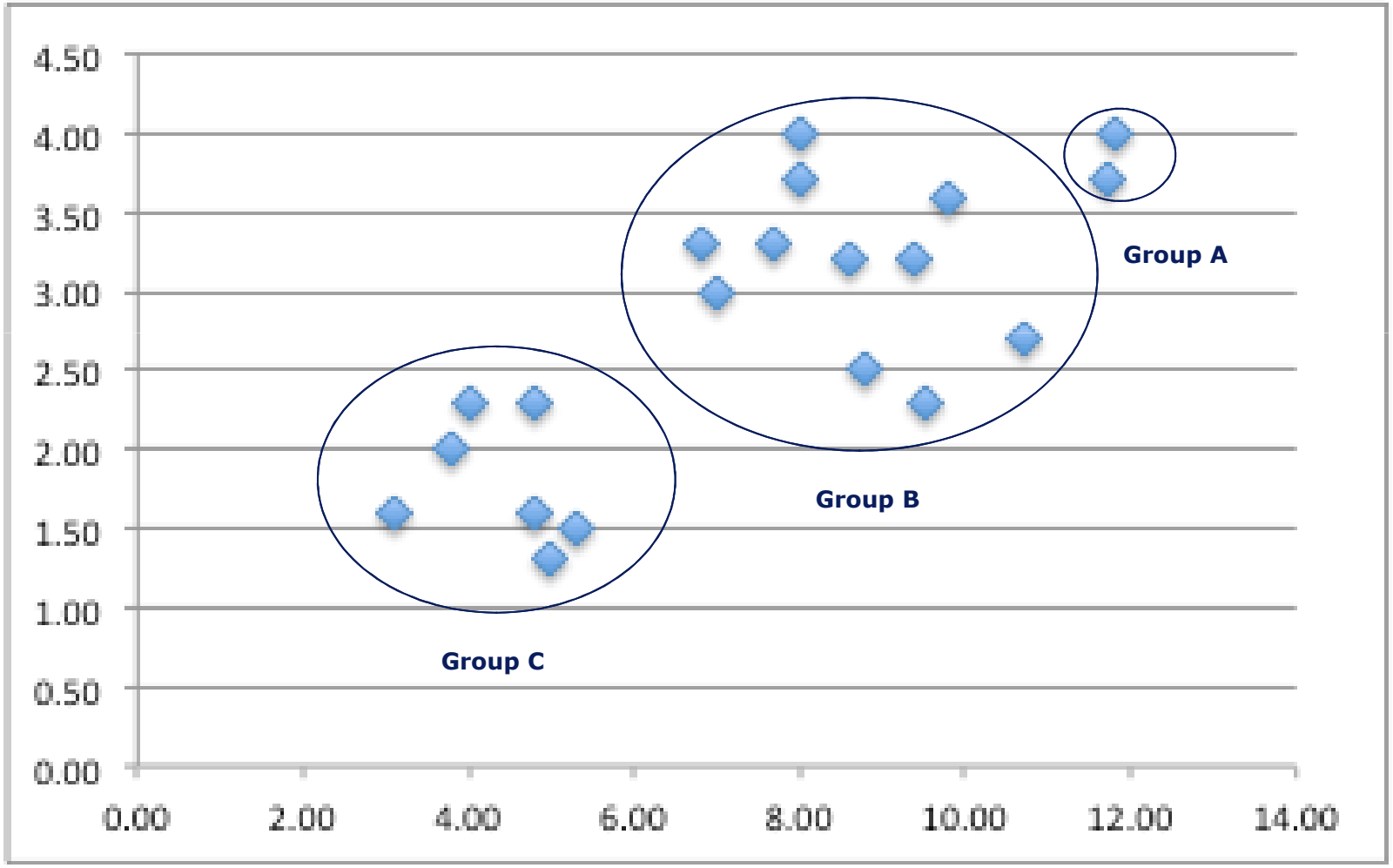
Results: Competition

	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

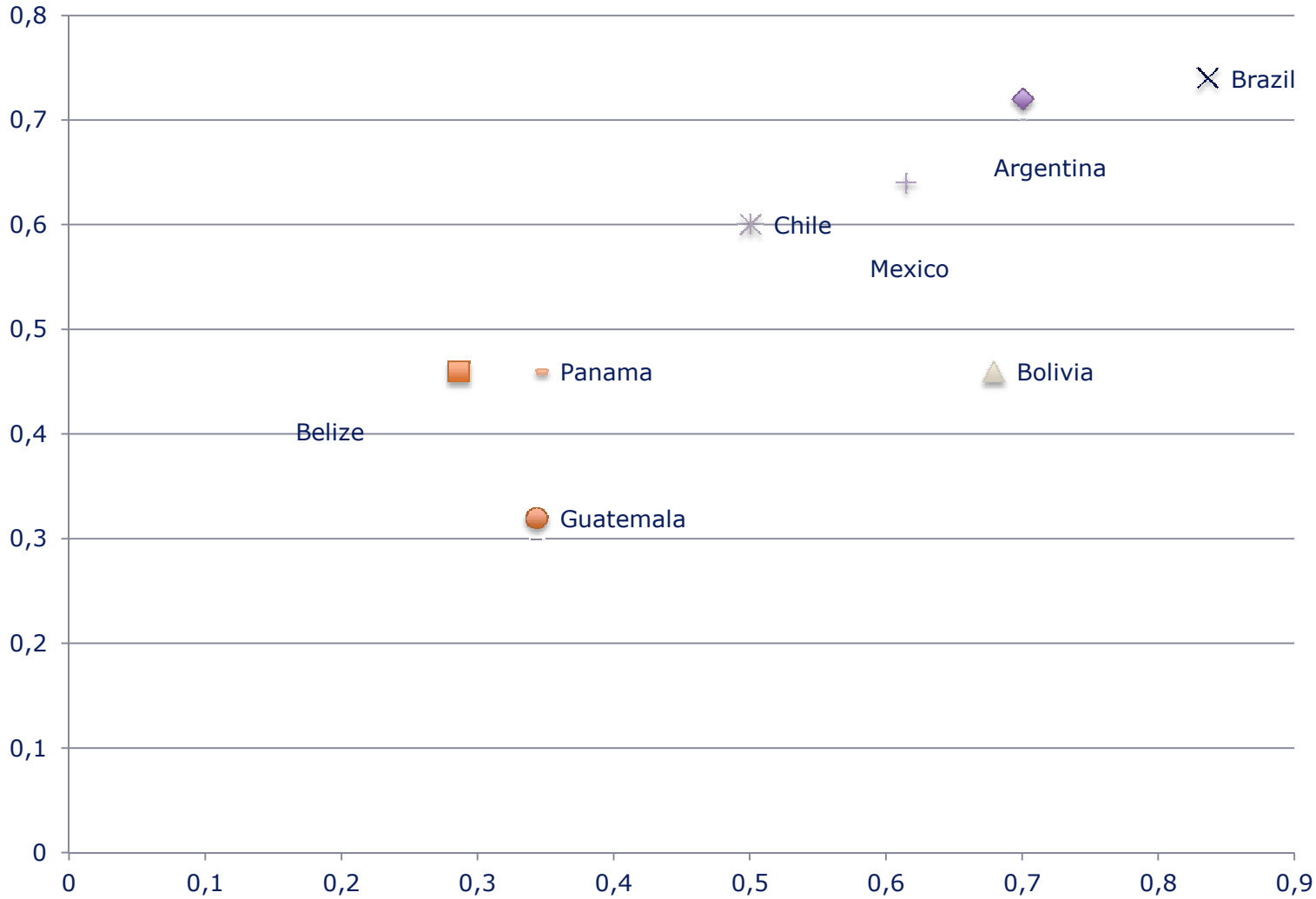
Results: Quality

	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

Results: Cumulative



Results: Cumulative



Conclusions

- Until recently pharmaceutical markets in Latin America were highly unregulated. This paper points to a regional shift in public policy with tighter monitoring of pharmaceutical firms and products.

- Yet, the current wave of institution building has been highly uneven. Our results show that definitions and standards for generics quality exhibit significant cross-country variation.

- This variation accounts for some of the difficulties of regional intra-state coordination.

- Moreover, the paper provides evidence that the current emphasis in access literatures on intellectual property is insufficient. Weak or non-existent oversight of quality may be an important factor in explaining high costs and lower medical efficacy.