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Abstract

How does the deregulation of medicine influence access to drugs? This paper provides an economic policy assessment of the effects of medicine deregulation drawing on the Peruvian experience between 1991 and 2006. As in other low-income countries, health insurance development is inadequate, drug expenditure is mostly paid out-of-pocket and approximately one third of the Peruvian population has limited access to 'essential medicines'. Market deregulation in this context can exerte an impact on prices and hence reduce access to medicines. Based on this evidence, we find that product and price deregulation of the medicines market appears to have reduced consumer trust of locally produced medicines, which in turn incentivised a switch to branded and more expensive drugs. The latter resulted in a further decreased access to medicines.

Key words: Access to drugs, Deregulation, Peru, Information Asymmetries, Price regulation.

1. Introduction

Regulation is often identified as a potential barrier to entry and a source of inefficiency (Pelzman, 1989); hence deregulation can be seen as a mechanism for improving access to new products without undermining product safety, efficiency and efficiency. From a risk decision-making perspective, if benefits from greater access (e.g., lower cost) do not come with a major loss in quality and safety, then deregulation might be welfare improving. However, the latter depends on whether the market fails after deregulation and whether deregulation engenders other external effects. We can usefully look to markets for medicines in order to test the effects of deregulation, given that such markets tend to be regulated to ensure consumer trust alongside quality and safety. Regulation is especially important when the demand for pharmaceutical treatments depends largely on experts (e.g., doctors, pharmacists etc) who face different pecuniary incentives, and exhibit an informational advantage. This is particularly striking in low-income countries, where health insurance is limited and generally providers are paid on a fee-for-service basis.

Rudimentary insurance and scant regulation provide limited incentives regarding quality of care[1]. Social insurance was as the primary model of health insurance in Latin

[1] Insurance schemes often act as risk pooling agents interested in obtaining better conditions from providers and accordingly counteract expenditure increases. Yet, when only concentrated in very affluent population groups as it seems to be the case in Latin American countries, underdevelopment of insurance stands as a drawback to the development of expected contractual incentives.

America before the insurance market opened for private providers (Mesa-Lago, 1991), especially as a source of funding for low-income groups (Cruz-Saco, 2001)[2]. Given that most social security programs exhibited low coverage, and faced both high administrative costs and some degree of corruption, this fuelled calls in the early nineties to deregulate the health care market.

Strategies for ensuring access to medical treatments include reducing the overall cost of health care (including manufacturing and distribution costs) as well as setting the policy agenda to focus on reduced drug costs both in developing and developed countries. In the pharmaceutical sector, some strategies to ensure access to drugs include financing and delivering health services in a cost-effective way. Mechanisms for cost-containment introduced in the market for medicines by industrialized countries have included national drug formularies, non-reimbursable drug lists, restricted reimbursement schemes, price regulation, promotion of generic prescribing and substitution, and surveillance of prescribing costs (WHO, 1993). However, the latter, insofar as it requires some degree of market regulation, is at odds with deregulation strategies to expand the role of market in the delivery of low cost treatments. The benefits of medicines deregulation have been much debated (Prayle and Brazier, 1998), but little evidence exists on the subject. The evidence from Peru can furnish us with some insights in this area.

[2] The WHO reports that unlike in wealthier countries, in 47 low-income countries, out-of-pocket payments represent more than half of total health expenditures, which means that some share of the population is deterred from using health services or from continuing treatment because they cannot afford to pay (WHO, 2007).

This leads us to the following puzzle: in the absence of large information asymmetries, deregulation would be expected to increase competition and cut prices, as well as lead to improved access to medicines. On the other hand, in the presence of informational advantages as in the the prescription and dispensation of medicines, regulation can be argued to play a key role in counteracting information advantages by guaranteeing quality standards (and enhancing consumer trust). Hence, whether de-regulation is welfare improving is an empirical question that calls for examining evidence from deregulation case studies around the world. The latter includes identifying the effect of deregulation of drugs authorisation and pricing on access to drugs. Given that we lack sufficient quantitative data from a full-scale evaluation, we can instead provide an assessment based on one or several markets.

This paper draws upon the deregulation of medicines authorisation in Peru to examine the impact on the quality of, and access to, medicines. We argue that medicines deregulation triggered two effects: a) it gave rise to some level of distrust towards cheaper alternatives to branded products, hence raised average medicines prices which in turn reduced access, and b) it reduced product surveillance, in turn leading to a lowering of the average quality of medicines. Therefore, we suggest, that medicines deregulation can exert detrimental effects by eroding trust in the quality of local products, to the benefit of international companies. The paper contains some additional policy recommendations and suggestions on potential effects of market deregulation.

The next section contains a description of the Peruvian market, which is followed by a market overview as a result of the deregulation process. Section 5 explores barriers to entry.

2. The Peruvian Market

Since 1995, the 2006 Index of Economic Freedom has ranked Peru as "mostly free"[3], but still far from being a pluralistic democracy and a free market. Governance quality has been generally poor. More generally the public sector has remained significantly bureaucratic and underfunded which has led some to propose processes of deregulation. However, how deregulation impacts on access to health care is still an open question. One mechanism would suggest that poor governance quality could influence health care access. Drugs are essential inputs for effective health care delivery. Alternatively, limited insurance coverage and lack of institutional capacity to regulate the process from medicine authorisation to distribution throughout the country appears to be an insurmountable barrier. The Peruvian government in the period examined undertook institutional reforms through decentralisation, whereby some health care responsibilities were delegated to administrative provinces. However, it did not fundamentally change the way the public sector operates in the country.

Peru ranked in the period examined amongst the most deregulated markets in Latin America *with the Peruvian economy becoming increasingly market-oriented in the 1990s. In line with most countries in* the region, the health system could be characterized

[3] http://www.heritage.org/research/features/index/country.cfm?id=Peru

as being significantly fragmented. A poorly financed Ministry of Health service (MINSA) provided coverage to 40% of the population[4] (Arroyo, 2002), 25% would be covered by a social insurance scheme (Esalud), which in practice applies to those with formal employment, 3% are covered by the army and police fund, and 10-12% paid for coverage by directly contracting private sector providers. However, 25% of the population did go without insurance for medical treatment as the 35% of those partially covered by the Seguro Integral de Salud (SIS) specifically designed for mothers and children, did not provide access to drugs.

[Insert Table 1 about here]

Access to drugs not only depends on the prices of originator medicines as has been found in other markets (Gemmill et al, 2007), but also on factors such as the efficiency of drug distribution, and the proliferation and availability of generic substitutes (Costa-Font et al, 2014a,b), but more importantly on insurance (Pradhan and Prescott 2002) and the active participation of physicians. For instance, the institutional capacity to evaluate the quality of the products in the market is fundamental to ensuring adequate access to suitable treatments (e.g., prioritising which medicines are to be funded and ensuring safe distribution networks are key to efficient drug distribution). In other words, *improving access to drugs is not only a matter of lowering drug prices, but also, more fundamentally, of developing an adequate institutional capacity to distribute treatments*

[4] See http://www.minsa.gob.pe/portal/

to people in need, *enhancing consumers' trust* and improving insurance coverage[5] and market regulation tools.

3. Deregulation of Medicines in Peru

Peru, in the period under examination, had the most market-oriented and deregulated market for medicines of all the countries in South America. In the drug market sector, deregulation encompassed both *free pricing and limited public intervention* (with the Decreto Legislativo 757, November 1991). The practical implication was that the regulator exerted very minimal control of the drug market (Miranda Montero, 2004). The 1992 Decree (Decreto Ley 25596) and the General Health Bill 26842 passed in 1997 established that authorisation was to be granted automatically "after 7 days of a product application". The latter was a practical deregulation given the limited administrative capacity to swiftly process market authorisation requests. Under this system the *failure to notify a decision on a product application within the set term was interpreted as an acceptance of the application*[6]. Furthermore, a 5 year registry would bear a cost of barely 90 US $, which fell short of reasonable investment in guaranteeing product quality. Only a small proportion of products could be audited, which in turn created the opportunity for discretion in registration decisions.

[5] A comprehensive insurance package and private insurance stands as a product on the hand the richest quintile of the population along with some civil servants.

[6] Legal requirements to register a product are very loose and refer mainly to inclusion in seven international pharmacopoeia -drug lists from European countries, Japan and US - without the need of reporting evidence of effectiveness nor drug quality except for a personal declaration of safety and efficiency and, the registered drug must be commercialised in the country of registration.

Another knock-on effect of deregulation was on the market entry, as *it is not until within 30 days of market launch that it became compulsory for manufacturers to communicate the launch of a product to the health authorities.* Limited investment in information systems to exert some control over the quality of the medication hampered quality assurance even further (see **Table 2**).

[Insert Table 2 about here]

The 2997 General Health Bill (26842) regulated market authorisation conditions. However, the real capacity for influence of the General Directorate for Medicines (DGMID) was bypassed by other political authorities, and weakened by underfunding. The latter ensured that the Directorate had very little real capacity to intervene and was not an independent agency of the Ministry of Health.

4. Effects on Medicine Affordability and Prices

The affordability of medicines is an important market barrier to access to medicines in low-income countries given that50-90% or more of pharmaceutical expenses are out-of-pocket purchases (WHO, 1998). That much of the cost of medications falls to the individual is exacerbated by drug prices being higher in low-income countries relative to high-income countries. For instance, as Figure 1 below

shows, even when medicine taxation was jettisoned, medicine prices failed to fall. **Figure 1** reveals that until 1990, as expected, consumption of medicines followed a similar trend to that of sales and prices of medicines. However, after the deregulation and price liberalisation of the 1990s *there was a significant fall in volume and rise in average drug price, which suggests that prices after the deregulation process tripled whilst volume declined*. Peru experienced a decline in number of units sold in 2000 (Valladares, 2001), which did not follow the pattern of sales in other countries. The real costs per medicine unit was estimated to be 1.04US$ in 1980 and increased to 5.4US$ in 2000 (AIS, 2003). Overall, Peruvian patients experienced greater difficulties in *the accessing medicines after market deregulation*.

Explanations for this phenomenon include the expansion of product copies, which meant that only products manufactured by leading international companies were trusted[7]. In such a scenario, the strategy of such companies was to focus solely on the share of the population that revealed a solvent demand, which explains why branded products represented 35% of the market through the period. Secondly, deregulation encompassed market failures in the drug distribution system such as inefficiencies in the drug prescription system[8], and a study by Cruzado (1998) demonstrated that from all drugs registered in 1996, 40% had no therapeutic value.

[Insert Figure 1 about here]

[7] IMS data suggests that international companies attained during the period about 75% of the market share
[8] In addition, 20% of total drugs consumed were illegally sourced; namely they have not been approved or registered whatsoever.

Finally, deregulation exerted a spill-over effect in reducing access to generic product. Indeed, given the limited warrantee that generic products are bioequivalent to originators, they were regarded as a whole as low quality products, which did reinforce even more the incentive's to keep prices of branded products higher than ever. The latter is the case insofar as high prices signalled quality.

5. Effects on Medicines Access

Expenditure per capita on drugs ranged between 4-27 US $ according to the Encuesta Nacional de Hogares 2003-2004, though *only 50% of patients that obtained prescriptions were able to fill them in 1997* (Ministerio de Salud, 2005). Similarly, 98% of patients in need of HIV treatments had no access to medical treatment (Vargas, 2002). Households were allocating 43-77% of their budgets to medicines (Petrera, 2003), and more specifically data from the Encuesta Nacional de Hogares 2000 shows that 60% of the health budget was devoted to drugs.

Medical treatments for certain conditions, such as bacterial meningitis, could cost as much as 164% of the average household income in Lima and 185% elsewhere in the country if originator drugs were consumed. However, costs could drop to 17.2-11.5% if the cheapest drug was prescribed instead (AIS, 2001). That is, *access to generic drugs did make a significant difference for the Peruvian population*. However, possibly the most important barrier to access was limited insurance coverage, both for its direct effects

on drug costs (Costa-Font et al, 2012) as well as its indirect effects over doctors' prescription guidelines.

The *vast majority of the market for drugs referred to products purchased out-of-pocket (70%*) (DGMID, 2005). Distributors (wholesalers and retailers) managed to attract mark-ups ranging between 24-30%, and on top of that they could even obtain additional discount. Some studies indicate that lack of regulation was responsible for such arbitrariness in price formation (Valladares, 2002; AIS, 2001). Unsurprisingly, given the proliferation of out-of-pocket medications and limited insurance coverage, *self-medication became common* practice despite consumers' very limited knowledge and the information asymmetry benefiting doctors and pharmacists (e.g., consumers were often subjected to the "self-interested advice" of pharmacists). Generic use was not an option given the limited bioequivalence warranty, which led people to place their trust in originator products. The latter posed significant barriers to the dispensation of low-cost alternatives (market penetration by unbranded generics was limited to less than 8% of the total volume), insofar as they were perceived as low-quality products in those circumstances as has occurred in other markets (Costa-Font *at al*, 2014b). .

Finally, drug market deregulation seems to be associated to market fragmentation. Only, a few companies managed to compete with originator products and as **Figure 2** exhibits, the penetration of large and vertically integrated distribution chains achieve 52% of the market share, suggesting competition at the distribution level was poor.

[Insert Figure 2 about here]

Evidence suggests an increasing concentration of economic activity at the retailer level as well, consistent with Figure **3**. *The number of pharmacies has declined since the late nineties, possibly as a result of the deregulation of the drug market*. Retail pharmacists were subject to very limited constraints and had an ever-higher capacity to influence patients' medicine purchasing decisions. Although patients could apparently choose from a range of drugs, in practice the influence of retailers was remarkable (e.g.,. they could decide to offer only a small selection of products). In addition, pharmacy retailers could even influence the prescription by employing doctors.

[Insert Figure 3 about here]

Another constraint to medicines competition lies in the development of quasi-generics. Originator companies developed their own generic products to counteract the effect of mainstream generic products. Furthermore, although doctors should by law prescribe the generic version of a medication, evidence suggests that only about 48% of drugs were indeed generics (Vargas Giron, 2002). Again this phenomenon can be traced back to the absence of quality assurance arising from the introduction of the deregulation process. Overall, medicine deregulation seems to have kept medicines prices artificially high, thus reducing access.

5. Discussion

This article has sought to examine the question of market deregulation on access to medicines. I draw upon evidence from Peru from 1991 to 2006 to argue that the Peruvian experience provides important lessons on the role of institution-building, and moreover on the role that market regulation exerts when insurance coverage is limited and consumers rely on trust when selecting products.

The deregulation of both drug authorisation and pricing in the context of significant information asymmetries is argued to have exacerbated the market failures that already existed in the market for medicines. More specifically, limited regulation and poor quality assurance may have reduced consumer trust in medicines. The beneficiaries of such an erosion of market trust we argue results from international pharmaceutical companies offering extra quality assurance compared to local substitutes. The latter produced counterproductive effects on aggregate prices: average medicine prices more than tripled in the period examined, and the market share of branded products increased dramatically. The latter has important ramifications on allocative efficiency of health care resources, as low priced bioequivalent products are not consumed.

We conclude that price regulation and product authorisation are essential features of the efficient working of the medicines market in low-income countries. Unlike in other markets, when insurance coverage is limited, individuals are key agents in the medicine consumption process and not insurance institutions. Hence, consumer trust in non-

branded products can be potentially eroded as a result, and influence prices by reducing the number of trustworthy products. Hence access and the mechanisms of product competition between stakeholders are strongly affected by price deregulation.

It seems reasonable to argue that in view of the evidence gathered, some form of product and price regulation system should be re-introduced for publicly reimbursed prescription drugs, and incentives to enhance consumer trust in non-branded products could potentially influence the expansion of generic drug consumption. The main way to reduce the financial burden of the costs of medicines on households is to ensure that prices are brought to the lowest attainable level. That can be accomplished variously by promoting competition among quality generic medicines where off-patent items are concerned, negotiation of prices, and therapeutic competition for on-patent medicines. A new regulation (Law 29459 in 2009) has been put in place to tackle some of these issues; the consequences of market deregulation dynamics are expected to have long-lasting effects. This is an area for further quantitative research.

The Peruvian experience suggests that regulation requires a minimum institutional size to satisfy with efficacy the demands for both efficiency and safety of a modern health system. The latter is not incompatible with guaranteeing the respect for property rights but also essential rights such as safety and access to quality of health care. In this study we find that without a minimal dimension and some institutional capacity to guarantee regulation enforcement it is unlikely for a health system to manage to improve health care efficiency. More specifically, judging by the Peruvian evidence, self-regulating market

mechanisms seem to have failed in attaining the expected goals they should deliver under high information asymmetries and poor insurance coverage. Reforms in such a setting should instead prioritise the modernisation of the health system to improve the information systems, expand insurance coverage expansion, regulate authorisation to ensure competition, and promote further competition in the distribution sector.

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References and Tables

Table 1. Drug expenditure distribution in 2005

	% Pop	% Drug Consumption	Drug. Expe US$ (Total)	Drug. Expe US$ (Urban)	Drug. Expe US$ (Rural)
Extreme Poor	21%	4.7	3.9	5	3.4
Poor	31%	18.6	10.1	10.9	8.8
Not poor	48%	76.7	27.2	28.7	21

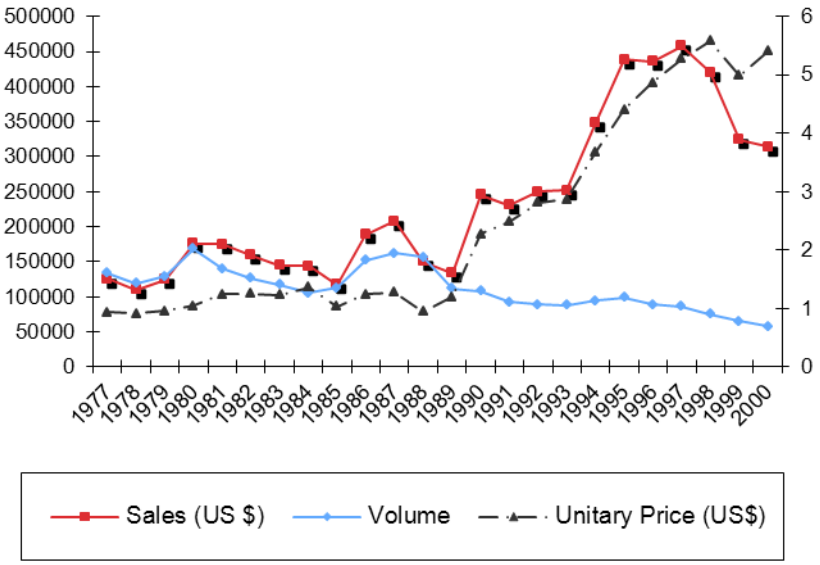
Source: DGMID, 2005.

Table 2 . Drug Regulation Criteria

	Organisation	Process
Registration	DGMID	Automatic after 7 days
Reimbursement	Only for Esalud	No
Distribution	DGMID	No requirement with a sworn declaration
Quality Assurance	DGMID	Post-commercialisation auditing of product quality in the market

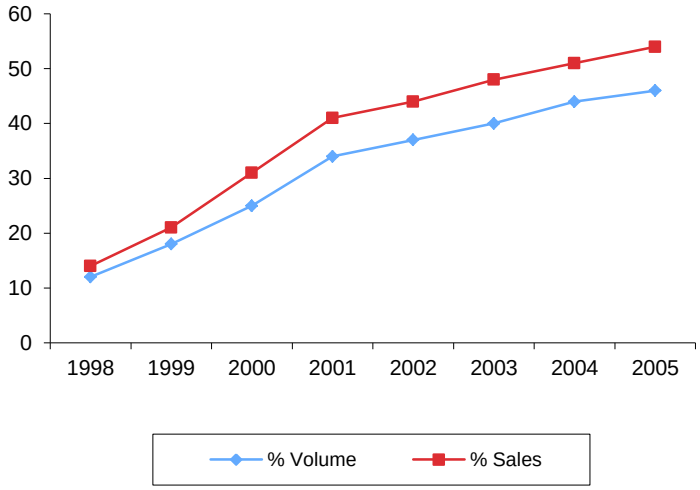
Source: DGMID, 2005.

Figure 1. Pharmaceutical Market Prices (local currency) in Peru 1977-2000



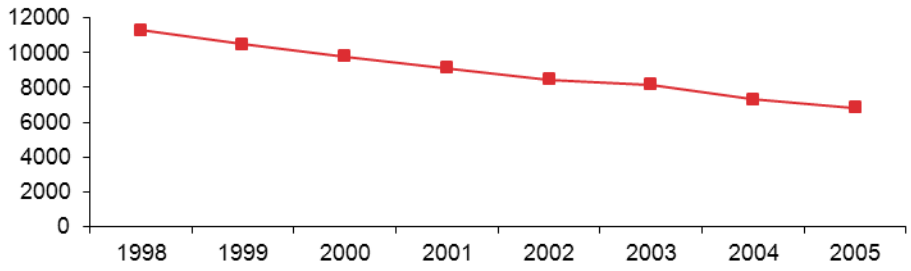
Source : Vargas Giron, 2002.

Figure 2. Market share of drug distribution chains in Peru



Source: ADIFAN, 2006.

Figure 3. Number of Peruvian drug retailers (pharmacists) 1998-2005



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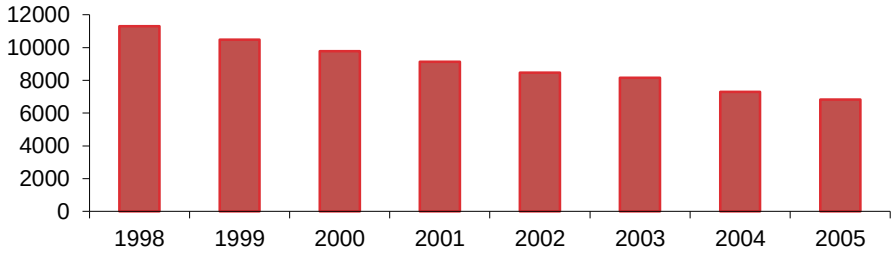

Source: ADIFAN, 2006.