Institutional change, innovation and regulation failure: evidence from the Spanish drug market

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English

Scant evidence has been reported on the influence of institutional change in drug market regulation. This article draws on the evidence of Spanish drug regulation (1980-2005) with the aim of examining whether institutional (lack of) change affected (i) regulatory innovation and (ii) the propensity of regulatory failure (rent seeking). We find that the prevailing institutional design of Spanish drug regulation has been prone to regulatory failure as incentives were geared towards rent-seeking behaviour and inefficient drug use by older patients and doctors. Innovation was typically imported except for a government devolution which occasionally has prevented regulatory failure.

Français

Il y a eu peu de rapports sur l'influence des changements institutionnels sur la régulation du marché des drogues. Cet article se base sur les preuves de la régulation des drogues en Espagne (1980-2005) dans le but de discerner si le changement (ou le manque de changement) institutionnel a affecté (1) l'innovation régulatrice et (ii) la propension à l'échec régulateur (recherche de rente). Nous concluons que la conception institutionnelle en vigueur de la régulation des drogues en Espagne a souffert d'échecs de régulation lorsque les encouragements ciblaient la recherche de rente et l'utilisation inefficace des drogues par des patients âgés et des médecins. L'innovation était typiquement importée, à l'exception d'une dévolution du gouvernement qui a parfois fait obstacle à l'échec régulateur.

Español

Se ha presentado escasa evidencia sobre la influencia de un cambio institucional en la regulación del mercado de medicamentos. Este artículo se basa en la evidencia de la regulación de medicamentos en España (1980-2005) con el objetivo de examinar si (la falta de) cambio institucional afectó (i) a la innovación reguladora y (ii) a la propensión de fallo regulador (rent-seeking). Encontramos que el diseño institucional predominante de la regulación de medicamentos en España ha sido propenso a un fracaso regulador mientras se dirigían los incentivos hacia el comportamiento de rent-seeking y hacia el ineficiente uso de medicamentos por los pacientes mayores y los médicos. La innovación fue típicamente importada excepto por una devolución del gobierno que ocasionalmente ha prevenido el fracaso regulador.

Introduction

The issue of how best to strategically regulate industries for population welfare such as those that affect human health is at the core of public policy analysis. Certainly, regulation is justified to curtail 'market failure', but on the other hand, the existence of well-known information asymmetries and the difficulty of designing complete contracts might well entail further 'government failures' depending on the underlying rationale behind the institutional design. Critics suggest that rather than a 'means to an end', regulation results from rent-seeking activities attempting to exert an appreciable influence on the final power equilibrium, arguably to protect entrenched interests (Stigler, 1971; Peltzman, 1976). One of the weaknesses of standard (public interest) approach to regulation is that, at least in its pure format, it does not take into account that both regulation and absence of regulation. Regulation is typically the result from a multilateral bargaining process involving several interested stakeholders, all holding heterogeneous power and influence. Examples in the drug sector include distributors' lobbying practices to guarantee the protection of legally guaranteed mark-ups, manufacturers' attempts to influence physicians' prescription patterns or blockage of generic penetration policies by (non-innovative) national manufacturers.

We broadly encapsulate this feature as 'regulatory failure', defined by the inefficacy of public policy to achieve its targeted outcomes, arguably due to the institutional dynamics of the regulation process. That is, despite government attempts to shape regulation towards certain ends, the finally agreed regulatory framework fails to achieve the intended aims. There has been little research into the issue of the effects of institutional design in highly regulated industries such as pharmaceuticals. Compared to other industries, the drug sector is one of the most inscrutable in most Western countries (Grabosky and Braithwaite, 1986). Well-known information asymmetries exist in the demand for drugs (eg, patients cannot judge product quality, doctor–agency relationship etc) and its distribution (eg, informal discounts to pharmacists etc), the latter being the result of the vertical dependence of stakeholders' rent generation. Furthermore, drug regulation typically is implemented through ex ante regulatory instruments (eg, reference pricing, legally established mark-ups, product authorisation criteria etc) and in highly regulated countries the setting up of a new regulation resembles a 'multilateral bargaining' process whereby highly fragmented stakeholders attempt to influence governmental regulatory bodies. Indeed, even in countries where regulation is comparatively less stringent, such as the US, there is evidence suggesting that the power of interest groups in shifting drug regulations is considerable (Gokcekus et al, 2006).

Within Europe, southern European countries such as Italy and Spain share a tradition of tight regulation (Mossialos et al, 2004), and Spain is an especially interesting case as it has been reported for non-transparent drug regulatory practices by the European Commission (IP/05/1285, 17 November 2005). Furthermore, on institutional grounds, Spain is highly interesting given that the Spanish public sector has undertaken a specific form of political decentralisation incepted in 1981 with the transfer of healthcare responsibilities to Catalonia and completed in 2002 when all autonomous communities (ACs) received the same responsibilities. Spanish region states became politically accountable for the design of health policy. Multiple

regional governments pursuing heterogeneous goals have progressively been made responsible for the control of prescription drug demand primarily (eg, influencing physician reimbursement, regulation of distributors and even regional referencing pricing systems), although drug pricing and reimbursement regulation continued to be determined centrally. However, whether decentralisation and the institutional design brings policy dynamism, innovation and impact on regulation failure is largely unknown. Previous studies reveal that Spanish pharmaceutical regulation has proved unsuccessful in attaining cost containment and other health policy goals (Costa-Font and Puig-Junoy, 2004). Furthermore, in the last two decades Spain has progressively harmonised some of its market regulation to that of the single European market standards although not without conflict between public health and industrial policy goals (Permanand, 2006).

This paper article on the evidence from Spanish drug market regulation to address the determinants of regulation failure and policy innovation, and the influence of institutional change. We focus on regulatory changes between 1980 and 2005 and specifically the effects of political decentralisation and other institutional changes that took place in that period (López-Casasnovas et al, 2005; Rico and Costa-Font, 2005). We argue that regulation failure in the drug sector results from an institutional design (of the market regulation) that fosters rent-seeking. To do so we explore the incentives of the relevant stakeholders in the Spanish pharmaceutical sector and its underlying motivations. Besides, the article examines the extent to which institutional change (political decentralisation) influenced regularity innovation and regulatory failure. The Spanish example suggests that there is some scope for institutional change to improve innovation and prevent regulatory failure in the pharmaceutical sector.

Explaining regulatory innovation in the pharmaceutical sector

Policy analysts and economists are increasingly recognising the need to understand the underlying incentives for regulation and its implementation. Explanations range from pure partisan politics to path dependency theories and include underlying incentives and transaction cost approaches. However, while partisan theories sustain as an axiom that political choices make a difference to regulation, some evidence indicates that this is not necessarily the case (Castles, 2000, 2005). On the other hand, regulatory change has been explained by the so-called 'inheritance theories' (Rose, 1990) whereby political frameworks vary across societal history so that previous policies moderate regulatory innovation (Vatter and Ruefli, 2003). Therefore, routines of the regulation process ultimately constrain regulation, and accordingly political choice exerts little influence on final outcomes. The influence of government is limited by the fragmentation of the regulatory bodies in the drug sector, each one focusing on specific segments of the market.

To explain regulatory change and innovation, some scholars concentrate on innovation–learning processes (Greener, 2002). Following Hall (1993), the simplest – 'first order' – form of innovation comes from structural reforms, such as in the Spanish example, with externally driven changes towards the development of a single European market for drugs (Kanavos and Mossialos, 1999; Kanavos, 2000; Mossialos

et al, 2004). Pharmaceutical policies have pre-empted the introduction of new drugs and potential competition both from generics producers and from products legally launched in other European countries, which has brought about a structural change. Second order innovation (Hall, 1993) refers to changes in regulatory instruments (eg, coverage decisions, pharmaceutical budgeting, prescribing restrictions etc) that rely heavily on the transfer (adoption) of regulation experiences from other Western countries (eg, reference pricing schemes, general practitioner fundholding etc) despite being subject to a different institutional setting, and thus heterogeneous market restrictions. Finally, a more profound form of regulatory innovation can be seen in third order changes leading to a total or partial 'paradigm shift' (Hall, 1993, Greener, 2002).

An overview of drug regulation in Spain

Spain is one of the five largest markets in the European Union (EU) (classified as 'European Union-5'; EU-5). Relative to other European countries, drug treatments have been given priority over other healthcare inputs; for example, mental illnesses are highly medicalised relative to other countries. Therefore, it is not surprising that drugs accounted for 23.3% of public healthcare expenditure in 2004 (OECD, 2007). The vast majority of the drug market is made up of prescription drugs accounting for 85% of total volume and 92% of total sales. Competition in the market is limited; bio-equivalent generics represented only 7.5% in sales (15% in the EU) and 13.8% in volume (27% in the EU) in 2005 according to Ministry of Health (MoH) sources (MoH, 2007). Similarly, compared to the other EU-5 countries, Spain exhibits one of the highest penetration rates of newly launched drugs (Kanavos and Costa-Font, 2005; OECD, 2007). Drivers of pharmaceutical expenditure shifted from being price oriented in the period 1980 to 1990 to being volume oriented later (1991 to 2005), most likely as a response to the introduction of generic drugs (Costa-Font and Puig-Junoy, 2004).

   On the demand side, as reported in Table 1, the individual's drug expenditure burden through cost sharing declined markedly in the 1990s, and it has literally halved since the mid-1980s: from 15% in 1985 to 7% in 2003. This has taken place despite the fact that the co-payment rate has remained the same,[1] but the share of expenditure on pensioners – who are exempt from cost sharing – has doubled (from 39% to 72% in the period considered), and overall, pensioners consume nine times more than the average (Puig-Junoy, 2002). On the supply side, local investment in innovation has been scarce and in fact the fifth edition of the European Innovation Scoreboard reveals that Spanish business sectors rank behind the EU average, with 45% lower private R&D spending and 20% lower patenting. R&D expenditure relative to sales declined from 8.6% in 1987 to 7.9% in 2001. The same picture emerges if we look at the share of the workforce, given that only 10% of employees work on R&D, compared to 43% who work in marketing (Farmaindustria, 2005).

   On institutional grounds, pharmaceutical regulatory bodies are highly specialised and fragmented. As Table 2 shows, three different governmental ministries participate in specific regulatory areas at the central level, and most healthcare services including pharmaceutical management were decentralised to the regional level from the early 1980s up until 2002 (López-Casasnovas et al, 2005). This stands as the key

Table 1: Pharmaceutical expenditure patterns

	Values (in € million)				% total pharmaceutical expenditure		
	NHS	OTC	Cost sharing	Total	NHS	OTC	Cost sharing
1990	2,524	143	312	2,979	85	5	10
1991	2,954	156	346	3,456	85	5	10
1992	3,395	163	373	3,931	86	4	9
1993	3,664	176	387	4,227	87	4	9
1994	3,902	185	393	4,480	87	4	9
1995	4,389	220	426	5,035	87	4	8
1996	4,887	237	453	5,577	88	4	8
1997	5,155	258	460	5,873	88	4	8
1998	5,700	281	474	6,455	88	4	7
1999	6,268	295	495	7,058	89	4	7
2000	6,800	315	520	7,635	89	4	7
2001	7,462	319	557	8,338	89	4	7
2002	7,996	325	605	8,926	90	4	7
2003	8,962	332	679	9,973	90	3	7

Notes: NHS = National Health System; OTC = Over the Counter
Source: CGCOF, 2005

institutional reform of the Spanish health system, although there is some isolated evidence of institutional innovation at the central level with the creation of the Spanish Drug Agency in charge of drug authorisation and quality assurance in 2000. The Interministerial Commission on Drug Prices is responsible for deciding on drug prices after reviewing manufacturers' applications, following the guidelines set by the Directorate-General of Pharmacy and Health Products (DGP). The National Commission for the Rational Use of Medicines, which comprises representatives of the 17 ACs, the pharmaceutical industry, the medical profession, consumer organisations and trade unions, together with experts appointed by the MoH, is responsible for reimbursement decisions (Table 2).

Major legislative reforms were introduced with the 1986 General Health Care Act, including the National Health System (NHS) guidelines, which were modified by the 2003 Quality and Cohesion Act immediately after the completion of the decentralisation process in 2002. The Pharmaceuticals Act was passed in 1990 and was modified recently in July 2006. However, both general legislation and specific regulation are issued after formal price negotiations and informal contacts between regulators and stakeholders, and power to influence the reform agenda exerted through several media sources including professional journals, conferences and professional organisations.

Table 2: Stakeholders in the Spanish drug regulation process

Responsibilities	Stakeholders
Drug regulation	
R&D promotion	Ministry of Science and Technology (MoST)
Product licensing	DG Pharmacy and Health Products (MoH)
Product authorisation	Spanish Drug Agency (MoH)
Patent registration	Ministry of Industry (MoI)
Price regulation	Interministerial Commission on Drug Prices (MoH + Ministry of Finance [MoF])
Reimbursement	National Commission for the Rational Use of Medicines
Distributors' mark-ups	Interministerial Commission (MoH + MoF)
Coordination	Interregional Council of Regional Health Services
Prescription, dispensing and healthcare provision	Regional Departments of Health
Industry	
International manufacturers	International companies who provide innovative drugs
Local manufacturers	Farmaindustria (Association of Spanish Local Drug Manufacturers)
OTC producers	Association of Over-the-Counter Drug Manufacturers
Generic producers	Association of Generic Drug Producers
Other health service stakeholders	
Doctors	College of Physicians
Pharmacists	College of Pharmacists
Wholesalers	Federation of Pharmaceutical Distributors
Consumers	Consumers' and Users' Association
Patients	Specific patients' associations
Scientists	Scientific associations for specific diseases
Trade unions	Specific trade unions

Stakeholders and the 'market for rents'

The power of the medical profession

The medical profession stands as a powerful stakeholder, largely monopolised by the College of Physicians, in most cases regionally spread across the country – to lobby each of the different regional health services more efficiently. One mechanism to explain regulatory failure is that the medical profession has a statute of immunity to most governmental regulations fostering efficiency. The universalisation of

the health system initiated in 1986 (although not totally completed until 1999) increased their market power as it led to the integration of primary care physicians within the NHS, thus reducing barriers to access for physicians, which in turn is consistent with an expansion of the number of prescriptions including high-cost drugs (Costa-Font and Puig-Junoy, 2004). Yet, part of this feature is exacerbated by the existence of a doctor gatekeeping system in Spain in line with other European countries, which gives the medical profession further power (Bachrach and Baratz, 1963). One might expect this to be more the case in countries like Spain where the majority of drug consumption is publicly reimbursed. In Spain, doctors are salaried (Lopez-Casasnovas et al, 2005), with limited efficiency incentives – to contain costs or to provide quality improvements – and they call upon the deontology code to protect themselves against regulations promoting efficient prescribing.

Distributors' rents

The drug distribution system is organised mainly by wholesalers (who distribute roughly 85% of all medicines), chiefly made up of cooperatives of pharmacists, accounting for 70% of total sales and 90% of retail sales. Therefore, *drug distribution is highly concentrated in the hands of pharmacists.* Pharmacy retailers are – as stakeholders – independently authorised agents, and unlike other European countries enjoy in Spain a markedly protective regulation that disallows competition at the distribution level and fosters the mechanisms of rent-seeking behaviour. Regulation restricts to pharmacists the dispensation of prescription drugs, which, joint with the institutional incentives mentioned above, explains regulatory failure. Competition is hampered by rules to prevent geographic concentration of pharmacies, opening hours and especially the need for a five-year university degree – not only to dispense – but to own a pharmacy, plus compulsory enrolment in the college of pharmacists. On the wholesale side, similar patterns are observed. The number of wholesalers has experienced hardly any changes despite the European single market integration process while sales have increased yearly (Costa-Font and Puig-Junoy, 2004).

Pharmacists' and wholesalers' payment system has remained protective of vested interests, relying on fixed and price proportional (ad valorem) mark-up of the consumer price before tax (see Table 3 for details). Accordingly, the system offers incentives to increase revenues by selling more expensive drugs – and the same applies to wholesaling. That is, distributors' reimbursement is based on publicly guaranteed rents that rely on a proportional mark-up of the price, and accordingly does not promote the dispensation of relatively 'cheaper drugs'. This was progressively changed after 1996, with the Conservative government conferring larger rents on manufacturers, as shown in Table 3. This has occurred as a gradual move towards the dispensing of new, more expensive drugs and a limited enforcement of generic substitution. In addition, reforms in 2000 introduced a non-linear mark-up and a very mild adjustment for generic drugs (Table 3). However, the decline in wholesalers' and pharmacists' mark-ups has given rise to unintended consequences in the form of the development of parallel exports to other EU countries, as an alternative rent to distributors (Kanavos and Costa-Font, 2005; Costa-Font and Kanavos, 2007).

Table 3: Medicine price structure (share of different stakeholders), 1986-2003 (%)

	1986-87	1988-92	1993-94	1995-96	1997-98	1999-2000	2001-03
Ex-factory price	59	58.2	59.9	59.3	61.7	62.7	63.3
Wholesaler's margin	8	7.9	8.2	8.1	7.6	6.6	6.5
Retailer's margin	27.3	28.2	29	28.8	26.8	26.8	26.4

Source: Farmaindustria (2005)

Manufacturers' rents

The Spanish NHS price regulation for reimbursed drugs relies on controlling prices 'product by product' on the basis of a cost–plus regime. That is, the agreed price is expected to provide a profit in the range of 12-18% of the invested capital (Nonell and Borrell, 2001). If sales exceed the predicted volume then prices are lowered to adjust profits to within the acceptable range, and some other factors are taken into account such as drug prices in other European countries (price indexation). However, price regulation has long been untransparent and suffers from the traditional asymmetric information between the regulator and the manufacturer, which may lead to a significant rise in transaction costs.

Pricing dynamics have been shaped by periodic negotiations with manufacturers (or the manufacturers' representative bodies). Although most of the agreements date from the 1990s, some agreements were reached in the 1980s. Indeed, one agreement on discounts dates back to 1983 and a public reimbursement agreement was reached in 1986 (renewed in 1989), with Socialist governments (Chaqués, 1999). Between 1993 and 1999 four agreements were signed. In 1996, the Conservative government signed a new agreement that led to a 3% reduction in prices. In 1998 an additional agreement was signed leading to the creation of a general (repayment) fund to finance healthcare deficits and in 2001 a new three-year agreement known as the Stability Pact was signed. As a result, the MoH accepted not to impose unilateral price reductions, and in exchange manufacturers pledged to become involved in the promotion of generic drugs, the introduction of new homogeneous groups into a reference pricing (RP) system and the annual revision of RP. However, in 2005, new price reductions took place (not without opposition from the industry), leading to a 4.2% reduction in the price of patented drugs in 2005 and a 2% reduction in 2006. Overall the process seems to explain regulatory failure on the manufacturers side too; the latter is motivated by lack of compliance with agreements and intensive rent-seeking that are smoothed out by governmental unilateral price reductions.

Composition of local and other manufacturers' rents

With the development of generic products, the strategy of manufacturers has shifted to focus their main business on new patent products where in the absence of parallel trade there is no competition. As a result, the composition of the drug

market suggests that a small number of products that have been on the market for less than 10 years account for 65% of total pharmaceutical expenditure, and the average cost per prescription (in constant prices) increased from €6.69 in 1992 to €9.18 in 2002 (Farmaindustria, 2004). On the other hand, the market share of products that are not reimbursed by the NHS – namely, over-the-counter (OTC) – declined in size from 17% in 1980 to 6.4% in 2002 despite OTC producers backing further delisting of drugs from public reimbursement. Local manufacturers are specialised in generic drugs and copies and compete in off-patent markets with international manufacturers in their rent-seeking activities. Furthermore, local manufacturers have been key stakeholders against the further decentralisation of the health system, given that they do not have – or it would be too costly to have – a decentralised organisation that allows them to lobby regionally. Hence, their power has weakened as a result of the decentralisation process. Accordingly, one of the strong points of the efficiency effects from the decentralisation of political power has been the progressive weakening of the rent-seeking capacity of local manufacturers

Innovation and paradigm change

Although regulatory innovation has been the object of ample debates, innovation has systematically been synonymous with the introduction of new instruments consistent with the hypothesis of regulatory failure. Table 4 provides a description of the main regulation changes explained here. We have divided them into supply and demand innovation attempts, to better explain the objectives and goals of each reform and the extent to which there is evidence or regulatory failure, and finally we discuss the case of externally induced innovations.

Demand side innovation attempts

Demand side policies, fundamentally aimed at controlling the quantity and quality of prescription, have had limited repercussions and mostly correct unintended effects of the institutional regulatory structure (eg, reference prices, generic prescribing etc) as described in Table 3. In those areas where consumers are aware of regulation such as cost sharing, there has been simply no instrumental innovation. Cost sharing has not changed nominally in the last two decades, although effectively it has halved (Puig-Junoy, 2002). Physicians have very few incentives to prescribe efficiently; only some regions (Andalusia, Navarre and Catalonia) have introduced 'drug (reference) budgets' and other pecuniary incentives but normally these are not enforced. Furthermore, generic prescription policies typically result in the addition of 'relatively expensive generics' to the list rather than efficient prescription of 'cheapest generics'. In addition, some studies have pointed out that physicians are unaware of the costs of drugs prescribed (Alastrué and Meneu, 1997).

  Generic penetration was been practically non-existent until the late 1990s. Up until 1992 Spain only recognised process but not product patenting (Lobo, 1997). After July 1997 – when the first generic brands were registered – generic penetration rose very steadily[2] and even in 2004, 30.9% of the population did not know what a generic drug was (Barómetro Sanitario, 2004). Interestingly, the market for generics is heavily concentrated: 15 active ingredients account for 50.3% of the total market

Table 4: Regulatory change in the Spanish drug market

Regulation	Period	Aims	Result
Supply side			
Prohibition and prosecution of price discounts	2005	Discounts are made illegal	Use of quantity or less transparent discounts
Compulsory price reporting on all products by all stakeholders	2005	To reduce parallel trade	Greater market transparency
Pharmacists' and wholesaler payment system update	1994-96	To reduce incentives to increase sales by dispensing overpriced drugs	Significant expenditure reduction
Industry repayments	1996-2004	To contribute to financing expenditure on research and healthcare	Short-term effects on expenditure
Delisting (selective financing)	1993 (Socialist government) and 1998 (conservative government)	Negative lists of drugs with limited therapeutic value	Limited effect on expenditure
Price cuts	1990s (3% in 1994-97 and 1998-99, 6% in 1999)	To reduce drug expenditure	Occasional 'one-off' effects
Demand and proxy demand side			
Education and awareness campaigns for physicians, pharmacists and consumers	1990s	To improve cost awareness, rational prescribing and drug substitution	Limited incentives besides awareness
Primary care pharmacists	1995	To assist prescription	Limited influence on physicians
Monetary incentives to physicians to prescribe generics	1990s	To promote generic substitution	Generics added to the list, with limited substitution
Generic promotion and substitution incentives	1996-2001	To improve market competition	Reduction of off-patent prices and rise in prices of generics

Prescription incentives	1996	To provide incentives to physicians for efficient prescribing	Little evidence to date
Reference pricing	2000-05	Expenditure reduction by reducing reimbursement to the reference price	Little impact on either expenditure or competition, and reduction of prices of some drugs included in the 'reference price'

for generics in Spain (CGOCF, 2005). This evidence is consistent with the aggregate evidence that generic penetration is lower in countries with tougher price regulation (Danzon and Chao, 2000). Hence, there is limited evidence of regulation meeting its intended goals.

Possibly one of the main regulatory innovations, introduced in most European countries including Spain in 2000, has been the RP system for off-patent drugs. The instrument sets the maximum reimbursement price of a drug within a certain therapeutic group. Since then it has been reformed three times and each time a progressively wider list of products has been included. Originally it included 98 groups, then 28 new homogeneous groups were added in 2002. Overall it affected a limited market share, which contained a limited number of generic drugs, so there were few incentives to reduce prices (Puig-Junoy, 2004). Another reform in 2003 made substitution by pharmacists compulsory when the drug exceeded the reference price, although it was not effectively enforced. This reform meant a 20% reduction in generic prices, which brought objections from local generic producers, although the competition game was played with untransparent discounts to pharmacies that led to an increase in volume (Costa-Font and Puig-Junoy, 2004), so that in the end it did not result in public expenditure reductions. Finally, the RP system was frozen in 2005 and re-established a year later with no real changes without a specific rationale besides that of a new government attempting to undo previous government policies. Hence, even when some regulation is imported from other countries, its implementation reveals evidence consistent with regulatory failure.

The main institutional innovations have taken place as a result of decentralisation incentives for experimentation and innovation. For example, the Andalusian regional health service introduced a prescription system based on international non-proprietary names (INN). Similarly, some regional governments have put in place other policies aiming at informing and training pharmacists to promote substitution, patients not to undertake prescription fraud and physicians to promote 'rational' prescription.

Supply side innovation attempts

On the supply side, the main innovation refers to two experiences of drug reimbursement delisting that did not attain its intended objectives. The 1990

Pharmaceuticals Act laid down that drugs may be delisted when other equally effective drugs were available at a lower price or lower treatment cost, or more generally in order to control pharmaceutical expenditure. The first delisting experience took place in 1993 and affected 1,692 products, but no entire group was delisted, giving rise to intra-group substitution. The second experience took place in 1998 and excluded 834 additional drugs, mostly old drugs to cure minor symptoms. However, although there was evidence of limited social utility of some other drugs, public authorities did not manage to delist them, mainly due to their fear of the public's negative response to these measures. Not surprisingly, 57% of the Spanish population disapproved of the first programme and the second led to controversy on a political level. Neither of these delisting experiences managed to contain expenditures. Their effect was mainly short term; the drugs excluded were of low therapeutic value and led to strategic drug substitution (Costa-Font and Puig-Junoy, 2004), for which reimbursement was maintained.

Externally induced innovations

Spain, as member of the EU, has been enforced to adjust its market regulation including the adoption of product patenting and liberalisation of the distribution system. Indeed, the adoption of single European market regulations, led to some institutional changes that resulted in a re-equilibrium of the political power of stakeholders (Hall, 1993; Spiller and Tommasi, 2003). Indeed, the adoption of product patent protection in 1992 and the entry of generic products led to a reduction in the power of national manufacturers and the introduction of competition in the market respectively. However, given the low visibility of drug policy, governmental reforms have had limited success in changing the political culture, and instead policy has continued to be driven mostly by power interests (Rico and Costa-Font, 2005).

Decentralisation and regulatory innovation

The advent of decentralisation introduced additional dynamism into the process of drug regulation and stands as the main institutional innovation. Spain's ACs have gradually become key agents in pharmaceutical policy – mainly in control of the demand for drugs – since all heath care responsibilities have been transferred to the 17 ACs. This new wave of institutional and policy reforms resulting from the decentralisation process adds to the previous waves of decentralisation in healthcare, namely 1981 (Catalonia), 1984 (Andalusia) and 1991-94 (Basque Country, Navarre, Canary Islands, Galicia, Valencia) and since 2002 all ACs have full healthcare responsibilities. These institutional reforms have taken take place at a time of structural changes to adapt the Spanish pharmaceutical market to the requirements of a European single market (eg, the split between licensing and reimbursement and the adoption of the EU patent legislation in 1992).

   Throughout the decentralisation process, ACs have played an active role in putting forward demands for greater decentralisation of drug policy (see Table 5). Indeed, the governments of Andalusia, the Canaries and Catalonia have repeatedly defended the right of regional health services in a decentralised setting to participate in the definition of drug pricing and reimbursement, and have gradually become key agents

in pharmaceutical policy in volume-related policies such as outpatient and inpatient prescription guidelines, inspection and regulation of clinical trials, quality control and information and communication policies. Policy coordination became the responsibility of the Interregional Council, and in particular a specific commission for drug policy. The Interregional Council supposedly conveys the interests of the regions with the aim of coordination, communication and information sharing. A caveat of the Spanish decentralisation process lies in the risk of re-centralisation through excessive coordination. Given that the two main parties in Spain have ample representation in several regions, regional incumbents become agents of their parties rather than agents of their constituents.

Table 5: Decentralisation and regulatory innovation

Policy	Original region	Subsequent region(s)	Description
Pharmacovigilance	Andalusia (2001)	Basque Country	Documentation and vigilance of drug use
Prescription by international non-proprietary name (INN)	Andalusia (2001)	Canary Islands, Extremadura, Madrid, Aragon, Castile-Leon and Cantabria	Guidelines for prescription forms based on the active ingredient rather than the trade name
Drug dispensing at home	Galicia (2000)	Andalusia	Programme reducing barriers to drugs for patients with chronic conditions
Health Technology Agency	Catalonia (1994)	Andalusia	Evaluation of health-related technologies

The key effect of decentralisation takes place in fostering innovation and further dissemination. Table 5 displays the main policies that can be attributed to the decentralisation process in Spain. Probably the clearest example of policy innovation as a result of decentralisation has been the prescription by INN, as the maximum prices for each active ingredient may be lower than that of the MoH lists. This proposal was launched in Andalusia in 2001 (Puig-Junoy, 2005) and followed by the Canary Islands, Extremadura, Madrid, Aragon, Castile-Leon and Cantabria. The proposal represents a radical change in the philosophy of the prescription system in the NHS. It has been well accepted by patients and is expected to affect 35% of Andalusian pharmaceutical spending. However, some evidence suggests that it does not necessarily cut prices (Puig-Junoy, 2005). Interestingly, the new regulation reforming the previous Pharmaceuticals Act in 2006 explicitly introduces prescription by INN as being compulsory in drug dispensing throughout Spain.

Decentralisation has had an impact on areas where at the central level there is evidence of regulatory failure such as the regulation of pharmacists. Valencia, Castile-La Mancha and Cantabria have removed the geographical requirements to set up a pharmacy (minimum distance of 250 metres from another pharmacy)

for small towns (fewer than 1,500 inhabitants). Some ACs such as Navarre have restricted the number of pharmacies authorised to sell prescription drugs, at the same time expanding the creation of new pharmacies, which opens the door to the liberalisation of pharmacies. Interestingly, these innovations have the potential to give rise to significant efficiency improvements. While ACs that were active in the implementation of drug policies such as Andalusia and Navarre had the lowest expenditure growth rates in the 1990s, the Galician and Valencian health services that exhibit limited innovation relative to the rest displayed the highest expenditures in Spain.

Discussion

This article has attempted to examine the existence of regulation failure and the influence of institutional change in promoting regulatory innovation in the Spanish drug market (1980-2005). The Spanish experience is consistent with the idea of regulatory failure. Paradoxically, we find that structural reforms have been 'externally enforced' as a result of the creation of a single European drug market although stakeholders seem to have managed to re-equilibrate their interests with limited final change. Interestingly, only an institutional – although structural – change namely political decentralisation, seems to have introduced some dynamism into the regulation of the drug market (regulatory innovation) and some evidence suggests that that could potentially prevent regulatory failure.

Regulatory failure in the Spanish drug market has been motivated by power structures directed at protecting a certain allocation of rents of interested stakeholders (Rico and Costa-Font, 2005). In particular, we find that during the period examined (1980-2005) there have been very moderate changes in the distribution of guaranteed rents to pharmacists. We find that governmental change did not have a significant effect on policy outcomes. Vested power of the medical profession succeeded in defending its interests against attempts to promote 'efficient prescribing'. Symptoms of regulatory failure are found in the negotiation with both manufacturers and distributors as regards both active policies (eg, RP, price cuts and delisting primarily) and passive ones (eg, no change of co-payment rates) that suggest that drug policy has had short-term objectives, and there has been a limited attempt at a change in the regulatory paradigm. Prevalent regulation has been markedly untransparent and seldom tackles competition at the ex-factory level. Instead, we find evidence of protective policies for non-innovative local manufacturers (eg, freezing the RP system without reason). The politics of drug regulation in Spain reveal poor innovation at central level, and interestingly policy instruments employed by different governments do not appear to differ widely.

Not surprisingly, lack of political incentives for reform are behind the persistence of an inequitable cost sharing system that has overprotected certain population groups such as older people. While a relatively rich pensioner may pay nothing for drugs, a poor unemployed family with several children will pay 40% of the price of the prescription. The latter suggests that the complexity of the market goes far beyond the scope of most political agendas, given the traditionally short-term scope of political appointments. Instead, regulation falls within the routines of bureaucrats and other governmental stakeholders, who allocate the rents resulting from unstable

and short-term-driven regulatory demands. Regulation seems to change for not very good reason at times, and often has to do with governmental change with very limited benchmark in evidence. An example of the latter seems to have been the case after a change of government in 2003, with new policies aimed at controlling discounts at the distribution level and a tax on sales to control volume, the main driver of pharmaceutical expenditure (Puig-Junoy, 2004; Costa-Font and Puig, 2004). One of the explanations for regulation failure lies in the existence of information constraints. Information is usually in the hands of distributors and manufacturers, who tend to be quicker than regulators (Moynihan, 2002), and Spain is no exception to the rule.

As for regulatory innovation, political decentralisation as an institutional change seems to have provided dynamism to the system, and appears to be a driving force for change (Costa-Font and Rico, 2006). Devolution of healthcare responsibilities has changed pharmaceutical policy making, which now requires consensus at the regional level and coordination takes place centrally at the Interregional Council (with includes representatives of all ACs). Besides institutional change, one way to improve regulatory innovation has been by increasing voice and participation. That is for the regions to participate in the drug evaluation undertaken by the Spanish Drug and Health Product Agency (Agencia Española de Medicamentos y Productos Sanitarios or AEMPS).

The implications of this study are important given the costs of regulatory failure to the economy. Typically, risk-averse governments are unwilling to introduce reforms that despite bringing efficiency gains might threaten their political support. A clear example is the Spanish drug cost sharing, among the lowest in the EU countries and possibly the most inequitable. Other examples are the protective regulation of drug distribution and manufacturers' rents as well as incentives for physicians to prescribe efficiently in a setting that a third party, namely the NHS, 'pays the bill' and that drug policy is not visible to the public. Finally, the evidence from Spain suggests that there is scope for institutional design to introduce institutional incentives in health systems that could directly increase the potential of policy experimentation and innovation, and indirectly improve the efficiency of the health system.

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Notes

[1] Drug co-payment has remained at 40% since the early 1980s with the exception of pensioners and drugs consumed in hospitals, which are provided free of charge, and

the chronically ill (for example, diabetics) who pay 10% of the price, subject to a price cap of €2.64.

[2] In 2000, generics accounted for 3% of total NHS sales (3.2% in volume) and had increased to 6.8% (8.8% in volume) by 2003 and 6.6% in sales (12% in volume) in 2005, while the EU average is 15% in sales and 27% in volume (CGCOF, 2005).

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