financing reform at all, only the extension of a political stalemate.

Nevertheless, it is clear that some initial steps that will change the institutional foundations of health care financing have been taken. The introduction of the federal fund and the (however limited and contested) convergence between SHI and PHI point to an evolutionary change from competitive corporatism to the marketisation of health care (financing), accompanied by a changing role for state regulation. However, the *SHICS-Act* also represents a political stalemate in respect of the final design of health care financing (be it citizen's or flat-rate-insurance) in Germany. Health care financing reform, no doubt, will be a key issue in the electoral campaign of 2009.

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Pharmaceutical policy reform in Spain

Joan Costa-Font and David McDaid

Summary: There are many deficiencies in the operation of pharmaceutical policy in Spain. This article provides a brief overview of the way in which the market functions and highlights some structural problems. We describe and provide some insights on the main economic policy problems to be faced in the regulation of the Spanish market. Key measures introduced as part of new 2006 legislation intended to address some of these deficiencies are then discussed.

Keywords: Spain, pharmaceutical policy, generics, reference pricing, medicines, regulation

Spain has traditionally faced serious problems in containing pharmaceutical expenditure. Compared to other European Union countries, she has historically relied heavily on pharmaceutical treatments.[1] The pharmaceutical market has struggled with a number of deficiencies related to quality and performance including variability in clinical practice and limited use of clinical guidelines in prescribing. There are also inefficiencies at the provider level, including limited use of generics with few incentives to switch to generics, while at consumer level there is a high level of self medication and limited impact of co-payments.

Traditionally mark-ups to reimburse the pharmaceutical distribution chain have neither fostered cost-containment nor generic substitution; instead there have been subtle incentives including non-transparent discounts that benefit retailers and wholesalers but do little for the tax payer. The mechanism for distributing pharmaceuticals also heavily restricts competition between retail pharmacists, for instance by requiring the owner of the business to have a degree in pharmacy. Wholesalers are also linked to groups of pharmacies, rather than subject to wider competition. This system, compounded by strict price regulation based on unclear indexation and costs-plus formulae, leads to low average prices and explains why the country is involved in the parallel export of drugs.[2]

Physicians traditionally have had very few incentives to prescribe efficiently. Moreover generic prescriptions do not guarantee that the cheapest generic will be dispensed; economic incentives are not in place. There is also only a very limited role for cost-effectiveness analysis in guiding drug reimbursement and pricing.

While the responsibility for health generally has been decentralised to the 17 Autonomous Communities (ACs), pharmaceutical policy and regulation remains one the few areas much less affected by this process; although some steps have been taken to involve the ACs in quasi-federal decision making boards that look at pricing and coordinate some policies. Consequently, pharmaceuticals are a high priority for health policy reform.

There have been some recent attempts to break the cycle of stagnation in the pharmaceutical market through modest reforms that strive to accommodate all

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Table 1: Pharmaceutical expenditure in Spain (1990–2005)

	1990	1995	1996	1997	1998	1999
Drug Expenditure						
NHS Drug Expenditure (€m)	2,524	4,389	4,887	5,155	5,700	6,268
NHS Share of Total Drug Expenditure	68%	72%	73%	73%	73%	72%
Drug Expenditure Per Capita (€)	63.3	110.6	123.2	129.9	143	155.9
Drug Expenditure Drivers						
Price per NHS prescription (€)	5.63	9.17	9.68	9.99	10.99	11.88
Number of prescriptions	532,231	525,316	551,696	562,716	561,716	569,526
Population per pharmacy	2,172	2,101	2,098	2,084	2,073	2,068
% Patients who make co-payments	13.00%	8.90%	8.50%	8.20%	7.70%	7.30%
% Drug expenditure for older people	61.50%	68.30%	68.90%	69.30%	70.10%	71.00%

	2000	2001	2002	2003	2004	2005
Drug Expenditure						
NHS Drug Expenditure (€m)	6,800	7,462	7,996	8,962	9,530	10,075
NHS Share of Total Drug Expenditure	72%	73%	73%	74%	74%	75%
Drug Expenditure Per Capita (€)	167.9	181.5	191.1	209.8	220.6	228.4
Drug Expenditure Drivers						
Price per NHS prescription (€)	12.26	12.9	13.36	14.08	14.43	14.55
Number of prescriptions	596,891	621,593	661,402	706,737	728,722	764,884
Population per pharmacy	2,062	2,080	2,082	2,099	2,111	2,143
% Patients who make co-payments	7.10%	6.90%	6.80%	6.80%	6.40%	6.20%
% Drug expenditure for older people	71.90%	72.20%	72.10%	72.00%	72.10%	72.40%

Source: Consejo General del Colegio de Farmacéuticos, 2006[3] and own calculations.

stakeholders' interests involved. One significant measure implemented from July 2006 was the introduction of a law guaranteeing the rational use of pharmaceuticals and health care products (*Ley de Garantías y Uso Racional de Medicamentos y Productos Sanitarios – Ley 29/2006*). This law replaces the old 1990 Pharmaceuticals Act and contains a number of ambitious measures. This short article looks at the context for this legislation and highlights some of the recent innovative steps taken.

Pharmaceutical expenditure

Pharmaceutical expenditure has continued to grow between 1990 and 2005 (see Table 1). The price per prescription rather than the number of prescriptions has been responsible for much of this increase. The market strategy of the industry has been to concentrate their promotional efforts on new and sometimes highly innovative products that command higher prices. This is one reason for the increasing share of pharmaceutical revenues enjoyed by manufacturers (see Table 2). On the other hand, from the turn of the millennium there has also been some increase in the number of prescriptions; this may be due to greater penetration by generics, as well as the introduction of a reference price system; this might foster the expansion of more intensive treatment. This also opened up the market to competition between generics.

The data also indicate that there have been few changes in the geographical concentration of pharmacies. This is consistent with the protected and highly regulated retail pharmacy market. Co-payments for medications have reduced; older people who are exempt from such payments and represent 18% of the population account for 72% of drug expenditure.[4]

Market structure

Prescription drugs account for approximately 85% of total volume and 92% of total sales in the pharmaceutical market. Generics only represented 9% of total volume in 2003. Locally based industries have only a limited research and development capacity. Research and development expenditure relative to sales declined from 8.6% in 1987 to 7.9% in 2001. Only 10% of employees work in this area compared with 43% engaged in marketing.[5]

Table 2: Average share of revenues for pharmaceuticals 1991–2005

	1991–1992	1993–1994	1995–1996	1997–1998	1999–2000	2001–2003	2004–2005*
Ex-factory price	58.2	59.9	59.3	61.7	62.7	63.3	64.2
Wholesaler's margin	7.9	8.2	8.1	7.6	6.6	6.5	5.9
Retailer's margin	28.2	29	28.8	26.8	26.8	26.4	26.1
VAT	5.7	2.9	3.8	3.9	3.9	3.8	3.8

Source: Farmaindustria, 2004[5]

* After 1 March 2005 a non-linear margin system is in place so that products with a price below €89.62 had a wholesale margin of 8.62% and a retail margin of 27.9%. Products priced above €89.62 had a wholesale margin of €8.43and a retail margin of €37.94.

The share of revenues from pharmaceuticals for each of the principal stakeholders is shown in Table 2. Interestingly, whilst reforms that were put in place in the early 1990s did not have any significant impact, those introduced after 1996 under conservative administrations appear to indicate that a greater share of revenues have accrued to product manufacturers compared with distributors, both retail and wholesale.

Generics market

The market for generic drugs in Spain has been practically nonexistent over the last two decades. Until 1992, the country only recognised process (rather than product) patenting. The 13/1996 General Budget Act and the 66/1997 Regulation Act, which opened the door to the introduction of generic drugs, modified the 1990 Pharmaceuticals Act. The first generic brands were registered for commercial distribution in July 1997 and generic penetration has risen steadily (although leisurely) ever since. In 2000, generics accounted for just 3% of total national health service sales. This increased to 6.4% by 2003 and 7.5% (13.8% in volume) by 2005. This compares with an average 27% shares of sales volume across the EU as a whole, although this varies markedly with rates well over 40% reported in the Netherlands, Poland, Slovakia, Slovenia and the UK.[6]

The market for generics is typically dominated by local manufacturers, with few international players operating in the market. This implies that there are very few incentives for competition. Generic prescriptions depend heavily on information being provided to general practitioners and patients; initiatives in this regard remain small. In 2001 whereas 12–15% of total prescriptions (8–10% of sales) in Madrid and Catalonia were for generics, in Galicia the figure was less than 3%.[7] Policies to promote the greater use of generics have taken the form of promotion and advertising campaigns for physicians, as well as subsidies and requirements to only dispense generics when the prescription is based on such an active ingredient. Since the approval of the most recent General Health Act reforms (so called Cohesion and Quality Act), pharmacists should play a wider role in the promotion of the rational use of drugs by working in collaboration with other health professionals to promote generics. However, both the enforcement of these requirements and incentives to promote generic substitution fall short compared with other European countries such as France.

Key reforms

A number of measures set out in the new pharmaceuticals law are intended to address some of the deficiencies in the current system. In some areas there is a paradigm change, but in others the regulations offer the prospect of reform of measures that have already worked in the past.

A new system of reference pricing will come into operation from March 2007. This is slightly more transparent than its predecessors though it in essence follows similar rules. It essentially brings together all off patent drugs financed for more than ten years by the national health service. These are grouped by form and active ingredient and include at least one generic equivalent. The reference price for each group of drugs is computed as the average of the three cheapest products regardless of market share. This is an improvement on previous requirements which were dependent on the market share obtained by these products or the overall cost of treatment.

To improve the efficiency of the reference pricing system, the new system has slightly expanded the number of therapeutic groups to 135. No significant reform though has been introduced to promote competition with innovative drugs. Indeed, drugs that are considered to be 'innovative' can be exempted from the system. Reference prices can be revised as regularly as every year. All, in principle, must be revised every three years.

"incentives to promote generic substitution fall short compared with other European countries"

To promote generic competition, the new law also has put in a place a 20% reduction in the price of products that after ten years of registration have a generic equivalent in another European country. The so-called 'bolar provisions' will also be implemented. Clinical trials for the development of new generic drugs will be able to start eight years after drug authorisation.

One paradigm change has been the introduction of a contribution, in the form of a tax on manufacturers based on their sales volume. This will be used to help fund the national health service. Through this mechanism, the system ensures that some of the proceeds of pharmaceutical companies are shared with the state and thus stands as a form of ex-post regulation.

The new law does not, contrary to some expectations, have a significant impact on the way in which pharmaceuticals are dispensed. As a concession to pharmacists it introduces the concept of 'pharmaceutical care' services that are to be provided

within pharmacies. The law also permits drug substitution by pharmacists in some circumstances and prohibits the sale of most drugs without a prescription. High levels of self medication have been a particular problem in the country.[8] Under the new law penalties of up to €90,000 can be imposed on those pharmacists who ignore this prohibition. At the same time, the law permits electronic prescriptions for people living with chronic conditions; this will reduce their need to travel to a health care centre in order to obtain a prescription.

The new regulation has also sought to reform the distribution system by enforcing a product traceability system throughout the whole product distribution chain (at the manufacturer, wholesale and retail level). The main rationale for this has been to eliminate the shortages that have often been commonplace in pharmacies in the past and reduce the continuing expansion of the parallel trade market.[9] Agreement was reached after one company proposed setting up its own distribution network so as to avoid the further development of a parallel distribution chain. Spanish wholesalers argued that they should still have a right of access to manufacturers' products. The new regulations enshrine this right and in exchange the industry will have some control over the distribution network and most likely will be able to apply differential prices; that is a discounted price upon justification of local sale and a European price for all others.

Discounts on products from wholesalers have also been banned, other than those related to early payment or sales volume. They can no longer be used to encourage the purchase of any one specific product. Prior to the law, discounts that effectively meant 'buy one get one free' (and variants thereof) were commonplace. However, from prior experience, the interpretation of the law always ends up allowing some flexibility to maintain discounts of some sort. Indeed, one of the problems of Spanish decision making is the frequent recourse to the courts to interpret policy set out in legislation. This is already happening in respect of discounting. New obligations have also been imposed upon the pharmaceutical industry with respect pharmacovigilance; in addition to maintaining the system they must report any adverse events to the Ministry of Health, thus enhancing the information system with regards to medicines.

Discussion

Given the nature of the pharmaceutical market in Spain and the extent to which it is subject to regulation, changes in the regulatory environment are critical to achieving improvements in practice. The market in Spain has been shown to react significantly to changes in incentives; however until now there was no significant paradigm change. The shape of regulatory measures have always been an issue for bargaining and lobbying between the different stakeholders, the Ministry of Health and the ACs. Such measures are then typically enshrined in law, as in the case of the new Act and resemble a rent-seeking process where the final equilibrium typically implies only modest change.

"Another key issue to be addressed is the lack of transparency in the way drugs are initially priced and reimbursed"

The new legislation has undoubtedly introduced reforms intended to improve the efficiency of the distribution system as well as foster competition in the generics market. However, how this regulation is finally implemented will be the key to its success. Careful evaluation of the reforms will in time be required but clearly limitations remain. Retailers, nonetheless, continue to control roughly 70% of the wholesale market, limiting competition. While there are now some incentives in place to promote the use of generics, as well as support for innovative products, one continuing challenge will be to design a system that makes, once and for all, the reference price efficient. This implies devoting particular attention to preventing unjustified substitutions from products included in the reference price to those exempt from the system.[10]

Co-payments can be an obvious way of containing drug expenditure, yet the use of such cost sharing measures in Spain has not changed in the last twenty years; possibly due to a lack of political support and the unpopularity of such reforms. An increasing share of total drug expenditures now fall on groups that are exempt from such co-payments, which creates significant equity concerns (a rich older person will be exempt from co-payments whilst a poor middle age woman with children would have to pay 40% of their costs). This may be an issue for further reform, whilst being mindful of efficiency and equity concerns. Another key issue yet to be addressed, and one which is a bone of contention for the European Commission, is the lack of transparency in the way that drugs are initially priced and reimbursed. Ultimately, the best way to reduce rent-seeking behaviour and prevent government from being captured by vested interests of any sort is by defining clear rules and enforcing them.

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