The Pharmaceutical Market Regulation in Spain: Is Drug Cost-Containment Under Question?

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ABSTRACT. This paper attempts to provide a critical examination of the regulation of the Spanish pharmaceutical market. We provide an extensive empirical evidence on the evolution of pharmaceutical cost-containment over the last two decades. Our findings suggest that policies aiming to improve efficiency and quality have not managed to contain costs, while cost-effectiveness is still overlooked. Cost-sharing has been progressively declining, the introduction of generics competition and reference pricing tools have not succeeded in bringing sizeable savings. At the institutional arena, the government industry negotiation process has been largely untransparent and descentralisation processes have not been aligned on achieving desired pharmaceutical goals.

KEYWORDS. Spain, generic penetration, reference pricing, negative lists, pharmaceutical regulation

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INTRODUCTION

Medicines expenditure in Spain has experienced rapid rises far ahead of general inflation (Puig-Junoy, 2004). In 2001, pharmaceuticals expenditure accounted for 1.56% of GDP and 21.9% of public health care expenditure, from which the vast majority (92%) is funded by the public sector budget. Spain's relative health expenditure is not far away from the European Union average (7.5% of GDP in 2001), from which 75% is tax-funded. The National Health System (NHS) provides free health care coverage,[1] with minor exceptions such as non-refundable co-payments for prescribed pharmaceuticals which has remained at 40% since the early 1980s, with the exception of pensioners, patients that consume drugs in hospitals are provided free of charge–and the chronically ill who pay 10%, with a price cap of €2.64. As in most European Union (EU) countries, the prescription market dominates pharmacists' sales while incentives to promote the prescription and dispensing (through generic substitution) of less expensive drugs have been limited and exhibit a limited impact on the cost-containment.

With the passing of the General Health Act in 1986, General Practitioners (GP) became integrated into the public network, and are paid a fixed salary with little incentive to prescribe efficiently. In fact, it was not until the 1990s that some contracts with health care providers included pharmaceutical expenditure on prescriptions. On the other hand, pharmacists are independently authorised bodies subject to strict regulation as far as they are solely in charge for dispensing prescription drugs. Pharmacists and distributors are paid a fixed proportional mark-up of the consumer price before tax, which offers incentives to increase revenues by selling more expensive drugs. Interestingly, the number of pharmacies has significantly increased in the 1990s by 9% (Farmaindustria, 2003).[2]

Prescription drugs dominate the Spanish pharmaceutical market and the market for generic drugs has been practically nonexistent in the last two decades, as up until 1992 Spain only recognised process (rather than product) patenting.[3] The first generic brands were registered for commercial distribution in July 1997 and generic penetration has experienced modest increases ever since. In 2000, generics accounted for 3% of total NHS sales and had only increased to 6.4% by 2003. However, generic drug penetration takes place in a few products (Asociación Española de Productores de Genéricos, 2002). Prices in Spain are subject to government authorisation and frequently price regulation has been used as a "once-for-ever" tool to cut costs.[4] Furthermore, price

regulation is based on a rigid *case-by-case* cost-plus system and the government-industry negotiations have been highly untransparent and the attempts of setting up a reference price system have not produced sizeable results.

One of the critical questions in Spanish pharmaceutical policy refers to explaining the relatively large and increasing share of pharmaceuticals in total public expenditure. On the one hand, one might argue that drugs are preferred inputs compared to other alternatives (e.g., mental health care services). On the other hand, because the Spanish pharmaceutical market is highly regulated, the specific mechanisms that have driven the regulation of pharmaceuticals in Spain might explain current expenditure patterns. This lead us to undertake a careful examination of the specific issues underlying the regulation of prescription drugs, price regulation, government-industry negotiation as well as the Spanish experience of the reference price system given the limited generics market penetration.

Given these features, this paper examines the details of the market regulation of medicines in Spain and provides a critical appraisal in the light of available empirical evidence of the developments in containing costs and increasing health care quality. The next section provides a brief description of the Spanish pharmaceutical market. Section 3 examines specific demand and supply side policies including the government-industry negotiation, and section 4 is devoted to examining trends in expenditure. Finally, the paper concludes with a discussion section that brings together most of the findings.

THE PHARMACEUTICALS REGULATORY BODIES

Spanish NHS can be defined as a 'system of regional health services' (see Lopez-Casanovas et al., 2004). Indeed, as a result of the decentralization process which has taken about two decades to complete, responsibility for the regulation of the pharmaceutical market is shared between the State and the regions states so-called *Autonomous Communities* (AC). However, most of the key regulatory bodies are run at State level such as the authorisation of clinical trials, marketing and advertising of drugs, the quality and manufacture of pharmaceutical products as well as drug pricing and reimbursement and cost-sharing policy. The AC are responsible for the authorisation of pharmacies, setting the criteria for the opening or relocation of outlets, day-to-day administration, promoting the use of generics, designing prescription policies via the de-

velopment of prescribing guidelines and budget-setting, contracting pharmacists for primary and hospital care, setting the conditions of the agreements with pharmacies, and implementing cost-containment programmes.

The Directorate-General of Pharmacy and Health Products (henceforth DGP) of the Ministry of Health and Consumer Affairs (henceforth MoH) monitors product licensing and the registration of new products. Patent regulation is the responsibility of the Ministry of Industry in conjunction with two special commissions for economic affairs. Price regulation corresponds to the Interministerial Commission on Drug Prices, following the guidelines set by the DGP, and regulation is the responsibility of the National Commission for the Rational Use of Medicines.[5] The MoH also sets the wholesalers' mark-up and, in conjunction with a special commission of economic affairs, determines the retail mark-up.[6] Finally, the AC have specific general directorates responsible for the market regulation of prescription drugs and in certain matters, the regulation of the market for drugs in conjunction with central state bodies.

PHARMACEUTICAL POLICY AND MARKET REGULATION

In this section we provide a summary of the main policies undertaken both from the demand and the supply side to contain the costs of pharmaceutical expenditure and achieve quality objectives. Furthermore, we examine the details of the government-industry negotiations as regulation tools to promote efficiency goals.

Demand Policies

Demand side policies have progressively been introduced as a result of the policy reforms initiated in the 1990s. These policies aim on the one hand at moderating medicine prescriptions through information and pharmacological education campaigns, the introduction of smart cards to control prescription drug utilisation, prescription reviews as well as the creation of primary care pharmacies, which provides some guarantee that physicians follow official prescribing guidelines. In two AC, namely Navarre in 1998 and Catalonia in 1999, monetary incentives were introduced to foster primary care physicians to prescribe drugs with high therapeutic utility and generics, and GPs were subjected to stricter control over both efficiency and quality. The use of budgets is being progressively implemented to promote generics, although this

measure might act as an incentive to doctors merely to add generics to the prescription list rather than to substitute original products.

Some studies pointed out that physicians are unaware of the costs of drugs prescribed. Indeed, Alastrué and Meneu (1998) found that only 40.9% of physicians were aware of the exact price of drugs prescribed.[7] Caminal et al. (1999) found that 40% of antibiotic treatments were prescribed to patients who did not need them, and that 53% of those individuals who required antibiotics used them inappropriately. The effect of prescription errors, diverse interactions, treatment resistance and adverse effects have been estimated to increase hospital morbidity and health care utilization by 10% (Lobato et al., 2000). 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.[8] However, measures introduced to promote what is known as "generics culture" have been limited and still have not produced successful results. They take the form of favoring medical advertising of generic drugs; full subsidies; and dispensing only generics when the prescription is based on an active ingredient.

On the other hand, demand side policies aiming at influencing consumers' cost sharing have been non-existent and politically infeasible. Co-payments have remained stable in the last two decades although the effective cost sharing has halved in this period (from 15% in 1980 to 7% in 2003). The reduction in effective co-payments might be explained by the increasing ageing process and by the fact that pensioners often obtain prescriptions for other household members who are not exempt from co-payments. Interestingly, one part of the population (civil servants), covered by a special insurance scheme (known as MUFACE), pays lower co-payments across their entire life (30%). Now, surprisingly, MUFACE's effective co-payment rate remained stable during the 1990s at 21.7%, whereas for those covered by the general NHS, it fell from 15% in 1985 to 9.1% in 1995, and finally to 7.1% in 2000 (Puig-Junoy, 2004). Therefore, this evidence points out that there is scope for reform by reforming cost-sharing with potential effects on 'prescription fraud' by pensioners.

Supply Policies

At the core of providers regulation is how pharmacists are paid. In 1997, mark-ups were established at 11% for wholesalers and 27.9% for pharmacies. A further unilateral reduction in margins for wholesalers was established at 9.6% in 1999, although accompanied with mild in-

centives to introduce generics. This led to an additional reform in 2000 that set a decreasing mark-up with increasing product price by introducing a monetary cap of €78.34 (ex-factory price) and increasing the mark-up for generics by 5.1%.[9] However, given that some generics are almost the same price as original products, this policy reform provided an incentive to dispense highly priced generics, which could in turn have created additional distortions into the market.[10] Some savings were obtained as far as the average mark-up decreases with the volume of sales (Puig-Junoy, 2004), especially in those ACs with the highest density of pharmacists (Puig-Junoy and Llop, 2004). However, overall the pharmacist payment system has not produced remarkable incentives to dispense low-priced drugs. Nor does it provide "equal treatment," given the significant heterogeneity of pharmacists in terms of costs, location and population.

Possibly the main supply side cost-containment attempts were two negative lists experiences. The first one took place in 1993 (Royal Decree 83/1993), which abolished the reimbursement of 1,692 products (e.g., food supplements, anti-obesity drugs, drugs for dermatological syndromes and drugs for minor symptoms). The second negative list experience was introduced in 1998 (Royal Decree 1663/1998) and excluded 834 additional drugs used mostly to cure minor symptoms, although certain exceptions were explicitly established according to the patient's severity. Yet, some drugs were not excluded in spite of their limited social utility due to their popularity among pensioners. Empirical evidence on the effects of negative lists (Martin et al., 2003) suggests that products included in the 1993 program had been on the market for 10.9 years whereas those included in the 1998 plan had been on the market for 20.1 years. By 2002, 40% of the medicines delisted in 1990 had subsequently disappeared from the market, together with 25% of those excluded in 1998. The 1993 plan excluded inexpensive products whose prices amounted to 23% of the average and the effects on pharmaceutical expenditure were marginal given that between 1994 and 1998, public pharmaceutical expenditure grew at a rate of 10%, and at a rate of 9% from 1998 to 2000.

An important supply side policy refers to the introduction in December 2002 of a reference price (RP) system to off-patent drugs with the same active ingredient. A total of 114 homogeneous therapeutic drug ceilings were designed, each including at least one equivalent generic product and reference prices were calculated until January 2004 as the weighted average sale price of a minimum set of drugs accounting for at least 20% of each market.[11] The total of 590 drugs included in the new

system account for 10% of pharmaceutical expenditure and only 14.6% of the market, of which slightly more than half (53%) are generics. In 2001, 44.7% of products were priced at the reference level and only 4 out of 228 were priced above it. Furthermore, it has not been effective in bringing down the price of products initially priced below the reference level (Puig-Junoy, 2002).

A radical change in this generic reference pricing system was introduced by the Cohesion and Quality Act 16/2003 (henceforth CQA) by introducing as a condition that each "group" should contain at least one generic product[12] and the reference price is now calculated as the average of the three lowest costs per day of treatment for each form of administration of an active ingredient, according to its defined daily dose.[13] Interestingly, if the prescription price exceeds the reference price and there are other generic products in the same "group," the pharmacist has to dispense the lowest-priced generic in the same "group." Finally, if the prescription price is higher than the reference price but there is no other generic product, the pharmacist has to dispense the prescribed medicine but at the reference price level.[14] Only when the generic drugs are not in stock can pharmacists dispense the prescribed drug without substitution. Overall, the reform of the reference pricing system has made the RP a sort of maximum reimbursement price that a drug may have without being excluded from the list of publicly financed medicines. Again the impact of this measure on price competition in the market of out-of-patent medicines is not clear as far as provides incentives for generics producers to offer competitive discounts to pharmacies rather than reducing consumer prices. Furthermore, the new method of reference price calculation might promote consumption as far as the profits increase with those presentations containing a higher number of units and dosages.

A final supply policy refers to price regulation. The government implements its pharmaceutical expenditure policy and pricing regulation through periodic negotiations with Farmaindustria (the pharmaceutical industry's representative body). Manufacturers negotiate to set the terms of pricing and reimbursement with the government. Price regulation for reimbursed drugs relies on controlling prices product by product on the basis of a cost-plus regime[15] whereby the agreed price is expected to provide a profit in the range of 12-18% of the invested capital (Badia and Magaz, 2002; Nonell and Borrell, 2001).[16] Now, during the 1980s, an agreement on discounts and on public reimbursement system was reached and renewed again (Chaqués, 1999). In the nineties, four agreements were signed on discounts to pharmacies,[17] negative

lists, pharmaceutical expenditure growth limits and generics promotion as well as a 3% reduction in prices that was supposed to guarantee that net spending growth would remain below 6.6% plus a rebate in ex-factory prices (Chaqués, 1999). Among the methods often used to obtain funds from the industry is what is known as repayment funds, which are often envisaged as an "unsolicited tax" for financing NHS expenditure. This tool was employed in 2001 when a new three-year agreement so-called 'Stability Pact' was signed whereby the MoH undertook accepted not to impose unilateral price reductions again in exchange for an agreement to finance a publicly managed re-payment fund which depends on nominal GDP growth and can be revised if drug prescription sales increase the maximum fixed level by more than 3% annually. Yet, although this agreement aimed at restricting sales, its effects are likely to produce unclear effects in the presence of tax deductions and inflation, reducing the effective amount of resources allocated to the fund.

EVIDENCE ON THE EFFECTS OF PHARMACEUTICAL EXPENDITURE ON COST-CONTAINMENT

This section brings together some of the issues discussed in the other sections in order to evaluate the effects of pharmaceuticals policy in constraining pharmaceutical expenditure. We therefore examine the general patters of expenditure and then move to the expenditure determinants, which might provide us with some clues on the likely effects of pharmaceutical market regulation in expenditure and cost-containment.

General Patterns of Pharmaceutical Expenditure

In the 1980s, the rise in health care spending was two points above pharmaceutical expenditure in nominal terms, but the trend was reversed in the 1990s. Total and public expenditure increased in the 1990s at an annual rate of above 10% (7% in real terms) and was most intense between 1987 and 1994. This feature could be explained by pressures from the industry and the passing of the 1986 National Health Act, which led to the creation of a universal health system, the integration of primary care physicians within the NHS–thus reducing barriers to access to the GP–and, arguably, the need to increase accountability in public health care spending. Indeed, since 1980, the share of pharmaceuticals in public health expenditure has remained between 16% and 23%[18] and

OTC has risen to 4% (Table 1). Therefore, public expenditure is the leading driver of pharmaceutical spending. Indeed, NHS expenditure accounted for 68% of total pharmaceutical spending in 1986 and reached 72% by the mid-1990s. In addition, real expenditure per capita increased at an annual rate of 8% in the 1980s and 6% in the 1990s.

Pharmaceutical Expenditure Determinants

In examining expenditure determinants, we should bear in mind that a small number of treatment groups represent a large share of the total spending. Recent evidence (Farmaindustria, 2002) suggests that products that have been on the market for less than 10 years (amounting to 37%) account for 65% of total pharmaceutical expenditure. Prices for relatively old drugs are significantly below the EU average in spite of the small market for generic drugs and, arguably, the existence of substantial parallel exports.[19] However, Spanish prices of new drugs (e.g., statins) are in line with those in other EU countries whereas old drugs, which are still under patent protection, are far below the EU average (Kanavos et al., 2004). Table 2 reveals that the mean price per prescription rose about 120% between 1990 and 2002–equivalent to an annual accumulated growth rate of 6.75%. Simultaneously, in this period there was a notable increase in the number of prescriptions; this suggests that

TABLE 1. Pharmaceutical expenditure patterns (Mill€)

	Total	OTC	Cost sharing	NHS expenditure	Real expenditure per capita
1986			212	1,288	52.68
1987			232	1,540	58.09
1988			265	1,824	64.59
1989			290	2,172	69.87
1990	2,979	143	312	2,524	74.93
1991	3,456	156	346	2,954	81.77
1992	3,932	163	373	3,395	85.85
1993	4,226	176	387	3,664	90.01
1994	4,480	185	393	3,902	88.57
1995	5,035	220	426	4,389	93.58
1996	5,577	237	453	4,887	99.67
1997	5,874	258	460	5,155	103.83
1998	6,456	281	474	5,700	111.76
1999	7,058	295	495	6,268	120.21
2000	7,635	315	520	6,800	123.43
2001	8,338	319	557	7,462	130.46

Source: Consejo General del Colegio de Farmacéuticos, 2003.

TABLE 2. Prescription, prices and share of retired consumers

	Prescriptions (thousands)	Average price per NHS prescription (constant 2002 prices) in €	% Retired consumers
1986	460,866	3.44	56.6
1987	470,390	3.99	57.8
1988	491,249	4.50	59.2
1989	509,875	5.11	60.3
1990	532,231	5.63	61.5
1991	541,057	6.45	62.7
1992	548,646	7.27	64.1
1993	534,559	8.01	65.4
1994	520,463	8.70	67.4
1995	553,788	9.17	68.3
1996	581,561	9.68	68.9
1997	593,046	9.99	69.3
1998	592,330	10.99	70.1
1999	599,604	11.88	71.0
2000	628,654	12.26	71.9
2001	653,917	12.90	72.2

Source: Consejo General del Colegio de Farmacéuticos, 2003.

the extension of access to the GP to obtain prescription drugs might be associated with part of the "volume effect" on pharmaceutical growth. However, volume effects may be explained not only by better access to primary care but also by several factors such as the ageing process and the possible moral hazard associated with retired patients. Indeed, the number of prescriptions per inhabitant has risen steadily from 12.2 in 1980 to 14.4 in 2000, at an annual growth of 0.8%. Interestingly, in 2000 pensioners received an average of 39.6 prescriptions, which might reveal some evidence of moral hazard as well as the effect of ageing.

Another important factor explaining trends in expenditure is cost sharing. Spain has experienced a gradual reduction in the *effective co-payment rate* from 15% in 1985 to 7% in 2002, responsible for an annual rise of 0.4% of the proportion of pharmaceuticals in public health care expenditure (Puig-Junoy, 2002).

After Austria, the United Kingdom and the Netherlands, Spain is the EU country with the lowest level of cost sharing. Simultaneously, the share of pharmaceutical spending of the retired population (who amount to around 15% of the total population and are exempt from co-payments) practically doubled (from 39% to 72%). Table 2 shows that the share of retired consumers rose significantly from around 60% at the end of the 1980s to 72% in 2001. This partially reflects an increase in

the number of pensioners, who spend nine times more than the average (Puig-Junoy, 2002). Whilst expenditure per active individual was below €60 in 2000, expenditure per pensioner in 2000 amounted to €140.

Table 3 presents a breakdown of public pharmaceutical expenditure determinants between 1991 and 2001. The change in real terms of public pharmaceutical spending was 74.7%, with an annual accumulated rate of 5.4%. In the annual accumulated growth rates, 58.1% refers to changes in general/specific inflation and quality, 11.4% to ageing, 5% to the reduction in cost sharing and 4.6% to population growth. Overall, of each €100 in pharmaceutical expenditure increase between 1991 and 2001, €8.40 can be attributed to demographic patterns, €3.10 to a rise in prescription intensity, €28 to the change in general inflation, €29.70 to changes in specific inflation and quality and €2.60 to a reduction in cost sharing.

TABLE 3. Breakdown of factors affecting public pharmaceutical expenditure in Spain 1991-2001

Year	Demographic factor		Weighted change in use intensity per person	Inflation and quality		Change in public financing	Change in public expenditure
	Population growth	Aging*		General inflation	Specific inflation and quality change		
1991	-	-	-	-	-	-	-
1992	0.23	0.88	0.00	5.30	7.30	0.65	14.96
1993	0.22	0.92	−3.82	4.90	5.30	0.41	7.90
1994	0.18	0.94	−3.57	4.30	3.45	0.35	5.60
1995	0.14	0.94	5.07	4.30	0.52	0.28	11.62
1996	0.14	0.91	3.79	3.20	2.59	0.41	11.49
1997	0.18	0.88	0.67	2.00	2.72	0.45	7.08
1998	0.27	0.84	−1.46	1.40	8.84	0.56	10.57
1999	0.44	0.76	−0.25	2.90	5.43	0.40	9.96
2000	0.76	0.59	2.63	4.00	−0.01	0.16	7.48
2001	0.85	0.55	1.84	2.70	1.73	0.06	7.94
Average accumulated growth rate	0.34	0.82	0.45	3.49	3.67	0.37	9.43
Accumulated index 1991-2001	103.46	108.50	104.58	140.96	143.39	103.76	246.19

Notes: We have calculated the weighted population by pharmaceutical expenditure by age and gender quintile. Source: Urbanos R (2002). The demographic factors show the change in the population and the effect of the age structure using the coefficient of pharmaceutical expenditure by age and gender in 1998. The change in intensity of use refers to the change in the number of prescriptions per person adjusted by age. Finally, specific inflation and changes in quality refer to the change in average price that exceeds the general price index.

From a policy perspective, during the period examined, two delisting experiences (negative lists) have been tried. The first was conducted in 1993 by the Socialist government, and the second was implemented in 1998 by the conservative PP government. However, the effects of both plans were mainly short-term, and were unable to contain spending in the long run. This may have been due to the low therapeutic use of these drugs or to a strategic adaptation of prescription patterns to substitutes for which reimbursement was maintained. Other features to bear in mind are the reduction in the value added tax (VAT) applicable to medicines from 6% to 3%, followed by an increase to 4% in 1995, and the low level of drug competition in Spain in spite of the widespread presence of drug copies. Certain problems persist in the area of the negotiation process with the industry, the pharmacist payment system and the traditionally marginal role of generic drugs.

Finally, pharmaceuticals accounted for 59% of private health expenditure, which includes both co-payments and direct payment for prescription drugs and OTCs. In 1999, private pharmaceutical expenditure totalled €3,107 million, equivalent to €79.35 per capita. Given the decreasing role of co-payments, it might be argued that relative to other countries, there is scope for reform in the cost sharing of pharmaceuticals.

CONCLUSIONS

This paper has sought to examine the regulation of the market for drugs in Spain as well as the impact on cost-containment goals. In the light of this study, we find that cost containment has been a very recent concern in pharmaceutical policy, which instead has centred on price regulation while volume control has been poorly targeted. The aggregate effect of the pharmaceutical market regulation in constraining pharmaceutical expenditure has been modest, mainly due to the fact that most of the policies have been short-sighted (López Casasnovas, 2002). From the demand side, policies provide meager incentives for quality and efficiency in prescription and cost sharing has not been used to monitor demand. From the supply side, delisting experiences have produced negligible results and the market regulation has failed to promote the penetration of generics. The negotiation process with the industry has been excessively secretive and often blurred. Furthermore, though pharmaceuticals continue to be legislated by the State, devolution brings new challenges since the Autonomous Communities are now re-

sponsible for prescription and purchasing policies. Yet, the regulation of the pharmaceutical market might benefit from policies undertaken by AC, which stand closer to the reality of prescription practices and drug dispensing.

Although health expenditure in Spain is not much higher than in other systems with similar GDP levels, we find that a large part of pharmaceutical expenditure is driven by a comparatively small number of new products that rapidly achieve a high market share, along with a large (and increasing) quantity of prescribed medicines. Therefore, we can conclude that the current price regulation system encourages inefficient expenditure and over-consumption. Alternative ways of regulating prices, probably combining price regulations with profit regulations (Puig-Junoy, 1998), are to be recommended. Of all cost-containment policies introduced, only the reduction in pharmaceutical margins in 1997 has actually reduced expenditure (Farmaindustria, 2002). This evidence is consistent with the view that the reduction of margins may affect the volume of drugs dispensed. On the other hand, the Spanish experience of negative lists have been rather unsuccessful overall in containing costs.

Recent proposals range from establishing a fixed co-payment for the retired to increasing co-payment for active consumers. As noted above, cost sharing in pharmaceuticals is among the lowest in the EU countries, and while a relatively rich pensioner may pay nothing for drugs, a poor unemployed family with several children pays 40% of the prescription price. This situation may lead in the future to the inclusion of pensioners within the co-payment system. The current debate focuses on whether some additional co-payments possibly linked with income might improve the equity of the system (Costa-Font, 2003; Puig-Junoy and Llop, 2004). There is some evidence that co-payment tends to be concentrated in a small number of individuals: according to Ibern (1999), one third of co-payment revenue is concentrated in 2% of the population.

The introduction of reference pricing in Spain has led to ambiguous results in reducing expenditure and promoting competition. Although prices have fallen in some drug categories, this has not been accompanied by expenditure reductions due to the incentives to produce new and more expensive drugs, together with the quantity of medicines prescribed. Furthermore, short-term price reductions have not promoted price competition in the medium term, since incentives for the entry of generics may be negatively affected and result in higher prices in the future.

NOTES

1. Private health care accounts for 20% of total health expenditure. Around 15% of the population has supplementary private health insurance, which does not cover prescribed drugs.

2. The distribution and dispensing of drugs is organised mainly by wholesalers and pharmacists respectively. According to Farmaindustria (2002), wholesalers distribute 77% of all drugs sold, hospitals 19% and the rest are distributed directly to retailers (3%) and to governmental agencies (1%).

3. In Spain three distinct types of pharmaceutical products coexist: original products under patent (which might be marketed either by the patent holder or a licensee), generic drugs, and drug copies when the patent has not yet expired (Lobo, 1997).

4. The trends in prices can be explained by the agreements between the MoH and the pharmaceutical industry in 1993, which led to a 3% reduction in 1993 and were extended over two periods covering 1994-1997 and 1998-1999. In 1999 a 6% price reduction was imposed.

5. 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, takes decisions on reimbursement.

6. In addition, the regulations define the responsibilities of a new Agency for Pharmaceuticals and Health Products (*Agencia Española del Medicamento y Productos Sanitarios*, AEMPS) responsible for the evaluation and authorisation of drugs, while the Directorate-General of Pharmacy deals with both price setting and public reimbursement once the products have been authorised by the AEMPS. Since 2003, the Agency's steering committee has involved representatives of the Autonomous Communities in decisions concerning the reimbursement of new drugs. Furthermore, in conjunction with the AC governments, the MoH is responsible for policies relating to the rational use of drugs and for the provision of education for both the general public and health care professionals.

7. Costs not only refer to the selling price but to possible administration costs, pharmaceutical security costs and follow-up, possible adverse effects and other indirect costs.

8. A generic drug is defined as being interchangeable with the original product; thus, proof is required of its "bioequivalence," which ensures the same quality, safety and efficacy as the original product. In addition, all generic drugs are distinguished from those of copy licensees by containing the abbreviation EFG in its label. Initially, authorisation was subject to previous authorisation in other EU countries or a ten-year period whereby its clinical use was proven.

9. This meant that drugs priced above €78.34 displayed a wholesaler's margin that remained at 9.6%, a retailer's margin for generics of 33%, and 27.9% for originals and copies. Furthermore, with drugs priced above €78.34 the wholesaler's margin was set at €8.54 per pack and the retailer's margin €33.54 per pack. Finally, a proportional discount scale was introduced for retail sales.

10. Vaquero (2003) reported that 76% out of all substituted prescriptions of omeoprazole 20 mg were expensive generics.

11. Originally three restrictions were imposed in the calculation of the RP. First, the RP should always exceed the minimum price of the drug category. Second, the minimum difference between the RP and the highest-priced drug was to be 10%, and finally, the maximum difference from the lowest-priced drug was to be 50%.

12. New pharmaceutical forms are excluded from the reference pricing system. Paediatric forms of the active ingredients under the reference pricing system are considered as a separate "group" in order to calculate the reference price. A separate "group" may also be established when there is a significantly different dose for a specific indication of an active ingredient.

13. In addition, different companies must produce the three lowest-cost medicines. In order to guarantee that all medicines under this system are supplied to pharmacies, the medicines selected to establish the reference level (those with the three lowest treatment costs per day) must not have an ex-factory price lower than €2. The minimum reference price (consumer price) for any medicine calculated according to these criteria will be one that corresponds to an ex-factory price of €2.

14. When the prescription has been written using the name of the active ingredient, the pharmacist has to dispense the lowest-priced generic medicine in the same equivalent "group." If there is no such generic in the "group," the pharmacist has to dispense the brand name medicine at the reference price level.

15. This includes production costs, promotional costs up to 16%, R&D, administrative and general costs and finally a margin computed on the basis of projected sales volume.

16. If sales exceed the predicted volume, then prices are lowered to adjust profits to within the acceptable range. However, in determining prices, there are some additional factors to bear in mind, such as therapeutic innovation, scope of R&D, licensing agreements, and especially prices elsewhere, including EU countries such as Germany, the United Kingdom, France and Italy.

17. In addition, discounts were linked to consumption patterns so that an increasing scale of discounts was introduced when sales of publicly funded drugs increased by more than 2.6%.

18. Compared with other EU countries, this is the highest share after Portugal (29.9%), though other OECD countries such as the Czech Republic (25.3% in 1997) and Hungary (22.6% in 1997) have similar health care expenditure distribution patterns.

19. That is, drug prices have fallen steeply over time. According to Farmaindustria (2003), while the average weighted price in the year 2000 for new drugs (those on the market for less than 5 years) was €11.42, it was €8.11 for products authorised between 5 and 10 years previously, and older products–those on the market for more than 20 years–had an average price of €1.41.

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