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Incentives and pharmaceutical reimbursement reforms in Spain

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Abstract

The aim of this paper is to assess whether cost containment has been affected by recent pharmaceutical reimbursement reforms that have been introduced in the Spanish health care system over the period 1996–2002, under the conservative Popular Party Government. Four main reimbursement policies can be observed in the Spanish pharmaceutical market after 1996, each of them largely unintegrated with the other three. First, a second supplementary negative list of excluded pharmaceutical products was introduced in 1998. Second, a reference pricing (RP) system was introduced in December 2000, with annual updating and enlargement. Third, the pharmacies' payment system has moved from the traditional set margin on the consumer price to a margin that varies according to the consumer price of the product, the generic status of the product, and the volume of sales by pharmacies. And fourth, general agreements between the government and the industry have been reached with cost containment objectives. In the final section of this paper, we present an overall assessment of the impact of these pharmaceutical reimbursement policies on the behaviour of the agents in the pharmaceutical market.

Keywords: Spanish health care system; Negative list; Reference pricing; Pharmacy reimbursement; Pharmaceutical industry

1. Introduction

Although the Spanish health care system stands among the eight highest out of 191 countries as regards performance, according to the controversial results published by the World Health Organisation [6], health care reforms rank very high on the Spanish political agenda.

The Spanish health care system would appear to perform quite well in terms of aggregate financing and overall traditional health indicators. In 1999, Spain showed one of the highest life expectancies at birth in OECD countries (74.9 years for males and 82.4 years for females). At the same time, health expenditure remained at a relatively moderate level: total health expenditure accounted for 7% of GDP in 1998, and public health expenditure accounted for 5.4% of GDP.

However, what is observed at the macro level (relative efficiency) is not necessarily true at the micro level. Nowadays, in the Spanish health care system several problems negatively affect efficiency

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Table 1
Recent evolution of pharmaceutical expenditure in Spain

Year	Total expenditure per capita[a]	Public expenditure per capita[a]	Public/total expenditure (%)	Public health expenditure (%)	Public expenditure (as % of GDP)	Co-payment rate[b]	Average cost per prescription[b,c]
1990	145	104	71.7	16.2	0.8	11.0	100.0
1991	166	120	72.3	16.9	0.9	10.5	114.5
1992	181	132	72.9	17.2	1.0	9.9	129.0
1993	189	137	72.5	17.0	1.0	9.5	142.2
1994	188	142	75.5	17.8	1.0	9.2	154.4
1995	210	159	75.8	19.0	1.0	8.9	162.8
1996	226	173	76.5	19.6	1.1	8.5	171.8
1997	246	192	78.1	20.9	1.1	8.2	177.2
1998		207		21.2	1.1	7.7	178.3
1999						7.3	195.1
2000		224		21.7	1.2	7.1	200.0

Sources: OECD Health Data File 2002, National Institute of Statistics, and Farmaindustria [7].

[a] Per capita US$ purchasing power parity.

[b] Corresponding to the national health system.

[c] Consumer price less patient co-payment. Base year 1990: 100.

incentives at the organisational and at the individual level. There is a vast array of evidence of low allocative efficiency and absence of cost containment incentives in public procurement agencies, in publicly financed provider organisations and in clinical decisions. Some of the more outstanding of these problems are closely related to the level and composition of pharmaceutical consumption.

The more relevant recent trends in Spanish pharmaceutical expenditure can be inferred from the data depicted in Table 1. Political concern regarding Spanish pharmaceutical expenditure usually arises from the observation of what is interpreted as the high proportion of public health care expenditure devoted to pharmaceuticals. This proportion increased from 16.2% in 1990 to 21.7% in 1999, which represents an increase of 5.5 points in 9 years. It is the third highest in the European Union (EU), only Greece and Portugal showing higher levels. The average of this proportion for the EU countries, excluding Austria and Belgium, showed a more moderate level and trend, increasing only from 12.2% in 1990 to 13.5% in 1997 (1.3 points in 7 years). However, this measure simply represents the average relative combination of pharmaceutical and non-pharmaceutical inputs in health service production. Thus, the observed proportion of public health resources devoted to pharmaceuticals on the Spanish market cannot be easily interpreted as an efficiency indicator, given that the optimal proportion depends on the relative price and the relative marginal productivity of pharmaceuticals in relation to the other health care inputs.

Total pharmaceutical expenditure per capita in Spain was US$ 246 per capita in 1997, a figure that is slightly below the average of the European Union countries (US$ 260 in 1997). Private expenditure on pharmaceuticals, including co-payments, represented nearly 30% of total private health care expenditure in 1998. Two significant features of Spanish pharmaceutical expenditure should be highlighted from the point of view of public financing.

First, the most important difference between Spanish pharmaceutical expenditure and that of the European Union as a whole is the relatively high and increasing rate of public financing in the former. The proportion of pharmaceutical expenditure that is publicly financed increased from 71.7% in 1990 to 78.1% in 1997 (6.4 points in 7 years). This tendency does not only reflect a lower proportion of pharmaceuticals privately financed outside the public system; it was also accompanied by a major decrease in the effective co-payment rate from 11% in 1990 to 7.1% in 2000, which represents a 35.5% decrease in 10 years.

Second, average price per prescription has been increasing very fast in recent years, despite the fact that drug prices are under strict price control. Average cost per prescription doubled in current monetary units between 1990 and 2000. Drug prices in Spain are still

among the lowest in the EU [18] and the Spanish market is an important source of parallel trade in the EU. Although regulated market price increases fall short of the inflation rate, the average prescription price has risen steadily, owing mainly to drugs recently introduced on to the market at high prices.

As a result of these trends, public pharmaceutical expenditure per capita rose from US$ 104 in 1990 to US$ 192 in 1997, by which time it was 18% higher than the average for the EU, despite the fact that Spanish per capita income was 23% lower than the EU average. From the macro perspective, these data clearly indicate that the main difference between Spanish pharmaceutical and that of the EU countries as a whole lies in the level and trend of public financing.

Health care policy under the conservative Popular Party, in power since March 1996, has seen the introduction of important regulatory changes in pharmaceutical financing and regulation.[1] The main concern of recent pharmaceutical policies has been cost containment through the introduction of more complex public reimbursement or procurement mechanisms.

The aim of this paper is to describe and assess the likely effects of some recent pharmaceutical reforms that have been introduced in the Spanish health care system over the period 1996–2002, under the conservative Popular Party Government. Pharmaceutical public spending is recognised as one of the main cost containment targets in the financing of the Spanish health care system, and consequently it has deserved increasing political and media interest in recent years. Four main public policies can be observed in the Spanish pharmaceutical market after 1996. First, a second supplementary negative list of excluded pharmaceutical products was introduced in 1998. Second, a reference pricing (RP) system was introduced in December 2000, with annual updating and enlargement. Third, the pharmacies' payment system has moved from the traditional set margin on the consumer price to a margin that varies according to the consumer price of the product, the generic status of the product, and the volume of sales by pharmacies. And fourth, general agreements between the government and the industry have been reached with cost containment objectives. In the final section of this paper, we present an overall assessment of the impact of these pharmaceutical reimbursement policies on the behaviour of the agents in the pharmaceutical market.

As in most social processes, it is difficult to evaluate pharmaceutical reimbursement reforms in Spain, i.e. to make a judgement on the effects and impact of the changes introduced. In addition to the intrinsic difficulty of relating effects to causes in a single historical process, the task is complicated by the limited number of formal rigorous evaluations, and by data availability.

2. Negative lists of medicines and co-payments

It appears that the co-payment system, so far only applied to pharmaceuticals, is not intended to be increased nor extended to other health services. However, there is evidence that the level of co-payment is low in comparison with other EU countries, and it also represents a decreasing proportion of the price financed by the patient (see Table 1). However, it may be argued that some low-intensity co-payments might also be considered as an alternative revenue source for the public health system with less negative distributive effects than indirect taxes, if suitably designed.

For pharmaceuticals, users pay 40% of the price of medicines prescribed by NHS doctors, with the exception of those aged over 65 and some specific groups (retired, handicapped and people who have suffered occupational accidents) and their dependents, for whom there is no co-payment. Another exception to drug co-payment is the case of chronic diseases. Only 10% co-payment is applied, with a maximum amount (€3.01 for the year 2000), when NHS doctors prescribe drugs to consumers identified as chronic patients. Another exception to this rule is that applied to civil servants who are under the Mutualidad de Funcionarios de la Administración Civil del Estado (MUFACE) insurance system. MUFACE insurees, both employed and pensioners, make a 30% co-payment for all pharmaceutical products. The 79/1998 and 128/2001 bills established the present regulation for orthopaedic prostheses: co-payment stands at 40%, with a minimum of €30, and each regional health service can decide the prices of orthopaedic products

[1] An overview of the Spanish health care reforms in the late 1980s and until the second half of the 1990s may be found in the literature published English in [5,10,17,18].

for outpatients. A catalogue establishes the products, the price and the public share (60%), including orthopaedic prostheses such as wheelchairs for the handicapped and special prostheses. For in-patient cases in which surgery is needed there is no co-payment for this process.

What do we know about the effects of this co-payment system? First, drug price elasticity is low but not negligible (a 10% increase in the co-payment rate will reduce expenditure by 2.2%). Second, despite invariant normative co-payment rates, effective co-payment rates show a decreasing trend (15% of the consumer price in 1985, 8.9% in 1995, and 7.1% in 2000). This trend can be attributed to the increase in exempted pharmaceutical consumption to a great extent due to population ageing, but it is also attributable to the existence of a notable level of fraud: a high proportion of co-payments are avoided by using elderly members for the family's prescriptions. Third, MUFACE pensioners pay 30% of the consumer price and their per capita expenditure is less than those included in the social security system, which indicates the potential scope for moral hazard. The effective co-payment rate for MUFACE insured population was 21.7 of the consumer price in 1991, and exactly the same rate in 1997. And fourth, current co-payments present a high level of concentration among individuals: 2% of the population accumulates one-third of co-payment revenue [9]. These observations clearly reveal that severe efficiency and even equity problems affect the present system.

Low co-payments per prescription (i.e. between €0.6 and 1) could also provide major additional revenues to regional governments even higher (i.e. between €249 million and 414 million in the year 2000). However, not only revenue but also efficiency objectives have to be considered in relation to co-payments. Low-intensity co-payments may reduce moral hazard by means of low transaction costs. Negative low-intensity co-payment effects on equity, which may appear when payments are concentrated on a small number of individuals, could be counteracted with the introduction of co-payment caps and a suitably designed deduction in the personal income tax (fiscal expenses).[2] However, co-payment policies restricted to drugs could produce a shift of consumption in other services, which should also be considered.

Negative lists have excluded some pharmaceuticals from public financing, being equivalent to setting a 100% co-payment rate. The Spanish Government used this policy for the first time in 1993 (when the Socialists were in power) and then again in 1998 (with the Popular party in power) to control public pharmaceutical expenditure. These two negative lists led to the exclusion from public funding of 29% of the total pharmaceutical brands registered on the market [5].

Both experiences have shown limited effectiveness of negative lists of drugs in reducing pharmaceutical expenditure. However, in addition to these control purposes, other clinical or epidemiological objectives are often used to argue in their favour. The Spanish 1993 bill was based on two main objectives: (a) to prioritise public financing for those drugs whose need or the severity of the illnesses for which they were used was greater, and (b) to exclude from public financing those drugs with low therapeutic value. Short-term effects showed a reduction in the number of prescriptions in 1994, but a substitution effect is probably responsible for a subsequent increase in the following years in the number of prescriptions, with a higher average price per prescription.

The government introduced a second list of excluded medicines in 1998 (834 products corresponding to 39 therapeutic groups). The delisting policy was agreed between the Ministry and the industry. Critics argued that cost containment criteria prevailed in the agreement, unlike in the case of the more pharmacologically oriented list introduced in 1993. In the 1998 list, even the short-term impact was not observed, given the high rate of increase in public expenditure occurring in this year (above 10%).[3] This second list was fiercely opposed by the Andalusian Regional Government, which decided to finance the consumption of excluded medicines with funds from its own budget [14].

The products included in the negative list of 1993 had been on the market for an average of 20.9 years,

[2] This measure could not properly work if a notable level of fraud resulted from it.

[3] This remains true despite the fact that some authors reported direct short-run savings indicating a decline in public spending in the therapeutic subgroups that contained the excluded medicines [2]. Substitution and innovations more than off-setted the direct savings.

and those included in the 1998 list had been on the market for 20.1 years. A large number of excluded medicines disappeared from the market in the following years: at the beginning of 2002, 40% of the medicines excluded in 1993 and 25% of those excluded in 1998 were not available on the market [12].

3. The reference pricing system

3.1. Reference pricing policy

In 1996 and 1997, a series of legislative reforms opened the way for the introduction of generic drugs and a reference pricing system in the Spanish pharmaceutical market. Reference pricing is equivalent to setting a co-payment consisting of a variable amount depending on the price of the selected drug, and which may be avoided if the drug price does not exceed the reference price.

An RP system was effectively introduced in Spain in December 2000. This system is applied to off-patent drugs with the same active ingredient (bio-equivalence). All the pharmaceutical products included in the same homogeneous group (identical RP) are bio-equivalent, and at least one of them has to be a generic product.

For each homogeneous set of products a reference price is calculated on the basis of the weighted average (year on year) of the lowest-priced products that account for at least 20% of the market sales. If the difference between this calculated price and the highest price in the group is less than 15%, the reference price will be the result of applying a 10% reduction to the highest price (this achieving at least a 10% saving). If the difference between the calculated price and the highest-priced product is more than 50%, the reference price is recalculated as exactly 50% of the highest-priced product (some potential savings thus being foregone). In no case will the reference price be lower than the generic with the lowest price.

Given the conservative approach to RP adopted in Spain, a limited effect on expenditure is expected. The bio-equivalence requirement only allows the application of this system to a small market share, even though the Spanish pharmaceutical market is among those on which the market size of recently introduced drugs increases fastest. In fact, the Spanish market does not share two of the main features of the first countries to introduce an RP system (high prices and a well-developed generic market). However, RP was presented politically as a measure to promote the generic market, despite the fact that the effective result could be the reverse.

The RP system was applied to 114 homogeneous groups in December 2000. These groups totalled 590 products which accounted for 10% of public pharmaceutical expenditure. The RP system was updated and extended to another 28 homogeneous groups, comprising 113 products, in April 2002.

As has been observed in experiences with reference pricing in other countries, these systems have produced short-term reductions in the insurer's expenditure. However, they can only be applied to a small proportion of the pharmaceutical market. The result is that official estimated savings amount to only 1.2% of total public expenditure in pharmaceuticals in 2001. Saving estimates for the year 2002 reported by the pharmaceutical industry stand at €156 million valued at final prices (€145 million according to government estimates), which is nearly equivalent to 2% of public expenditure. Even with such low estimates, several factors clearly indicate that these figures are overstated. They include the effect of the compulsory price reduction imposed in conjunction with RP on all those products (copies) without demonstrated bio-equivalence. Furthermore, these estimations probably only include the pure price effect, and not other possible offsetting effects related to RP (higher prices for new products or delay in their launch, switching to non-referenced products, higher prices than without RP for referenced products because of reduced incentives for generic competition, etc.).

When the number of generic competitors is low, as was the case in Spain at the introduction of the reference pricing system, RP could be fixed arbitrarily above the marginal cost. If this were the case, then RP would perform against competition, given that when RP is fixed there are no incentives to price a product below the reference level if savings are accrued by the insurer [11]. Empirical studies on the impact of RP on prices for reference products in Germany and Sweden indicate that its contribution to decreasing prices is lower than direct observation suggests [4,15].

The RP system was implemented in conjunction with policy measures that compulsorily forced some

products under the RP system to reduce their market prices to the reference price level. All those pharmaceutical products not officially recognised as bio-equivalents (copies), but included in the homogeneous RP groups, were compelled to fix a price equal to the reference level. This price reduction affected 193 products in December 2000 and 25 products in April 2001.

In June 2001, the government reinforced the RP system with a compulsory 15% reduction in the market price of five active ingredients (enalapril, famotidine, atenolol, omeprazol and ziprofloxacin) in order to bring their prices nearer RP levels. Compulsory price reduction affected those products whose market price was more than 15% higher than the average of the three least expensive ones in the same homogeneous group. This measure clearly indicates that in some cases pharmaceutical firms maintained a price above the reference level, and it also indicates that, in fact, the government has been tempted to use this reimbursement mechanism as a price regulation system. The government's justification for this imposed price reduction was that there was not enough competition in these markets even after the introduction of the RP system.

The regional devolution of health services management to the autonomous communities (ACs) completed in January 2002 allowed all these regional authorities to introduce their own procurement mechanisms. In September 2001, the Regional Government of Andalusia[4] introduced a new pharmaceutical procurement mechanism based on RP, which competes with the RP system applied by the central government. In this regional RP system, product coverage is defined by all those active ingredients with more than two products on the market, which are being sold at different consumer prices. This regional RP system covers 239 active ingredients with 591 homogeneous groups (2900 products), sales of which account for 35% of the prescription market. Under this RP system, all products with the same active ingredient and presentation are considered homogeneous and the same reference price will be applied to them. Potential product coverage of RP as applied in Andalusia is wider than in the Spanish RP system; however, the main problem of this regional RP system is that it requires prescriptions to be made out using the name of the active ingredient and not the commercial name of the product. In June 2002, 9% of prescriptions in Andalusia were made out using the name of the active ingredient.

In Andalusia, the reference price level is set at the level of the higher price of the two lowest-priced products for each active ingredient. Reference prices are updated every 6 months or automatically if the price of the reference product is modified. This regional government agreed with the pharmacies to dispense the lowest-priced product for each active ingredient, independently of its generic status.

This reference price applied in Andalusia is on average 17% (€2.90 in June 2001) below the reference price fixed by the central government. It is important to note that the RP system set up in Andalusia covers all the ten top-selling products in this region, and that the RP system set up by the Ministry of Health only included two of these products.[5]

3.2. Price trends after the reference pricing system

In this section of the paper, we provide descriptive evidence of the evolution of consumer prices for each product covered by the RP system for a period of 10 months before and 10 months after the introduction of this policy in December 2000. As a selective illustration of this evolution, we concentrate our attention on a sample of four top-selling active ingredients out of those covered by the RP system since December 2000, which comprises 13 homogeneous groups and 228 products: ranitidine, captopril, omeprazol and fluoxetine. Descriptive trends for these four active ingredients are summarised in Tables 2–4, corresponding to the period February 2000 to September 2001.

In Tables 2–5, we examine the evolution of the number of suppliers on the market for each homogeneous group, the evolution of the lowest and the highest price in the group, the reference pricing at the national level and that applied in Andalusia, and the number of products with a price equal to or higher than the reference

[4] Health care services were devolved to the Regional Government of Andalusia in 1984. This AC included nearly 19.52% of the Spanish population in January 1999.

[5] As an example, the maximum reimbursable price for omeprazol 20 mg and 14 tablets in June 2001 was €24.89 according to the reference price level fixed by the central government, and only €5.95 according to the Regional Government of Andalusia.

Table 2
The market for ranitidine before and after RP introduction (prices in €)

Ranitidine presentation	Variable	February 2000	November 2000	December 2000	September 2001
150 mg, 28 tablets	Number of suppliers on the market	16	20	21	25
	Lowest price	11.03	10.84	10.84	9.15
	Highest price	16.51	16.51	12.15	12.15
	Reference price at the national level	–	–	12.15	12.15
	Reference price in Andalusia	–	–	–	10.84
	Number of suppliers with price equal to RP	–	–	16	14
	Number of suppliers with price higher than RP	–	–	0	0
300 mg, 14 tablets	Number of suppliers on the market	15	19	20	25
	Lowest price	10.97	10.84	10.84	9.75
	Highest price	16.51	16.51	12.72	12.72
	Reference price at the national level	–	–	12.72	12.72
	Reference price in Andalusia	–	–	–	10.84
	Number of suppliers with price equal to RP	–	–	15	15
	Number of suppliers with price higher than RP	–	–	0	0
300 mg, 28 tablets	Number of suppliers on the market	14	19	20	25
	Lowest price	19.94	19.82	19.82	17.48
	Highest price	29.95	29.95	22.02	22.02
	Reference price at the national level	–	–	22.02	22.02
	Reference price in Andalusia	–	–	–	19.82
	Number of suppliers with price equal to RP	–	–	15	14
	Number of suppliers with price higher than RP	–	–	0	0
50 mg, 5 blisters	Number of suppliers on the market	8	8	8	8
	Lowest price	1.72	1.72	1.72	1.72
	Highest price	2.25	2.25	2.23	2.23
	Reference price at the national level	2.10	2.10	2.10	2.10
	Reference price in Andalusia	–	–	–	2.10
	Number of suppliers with price equal to RP	–	–	3	3
	Number of suppliers with price higher than RP	–	–	2	2

one. We provide information for the first and the last month in a period of ten months before RP introduction: February 2000 and November 2000. We also provide information on the preceding variables for the first month of application of the RP system (December 2000) and 10 months after its introduction (September 2001). Information on monthly individual prices was obtained from the database of the Directorate-General of Pharmacy and Health Products (Spanish Ministry of Health and Consumption) (Table 5).

Three main common descriptive trends can be observed. First, brand products, copies and generic products with a price higher than the reference price immediately reduced their price to this reference level in December 2000. In 11 of the 13 homogeneous groups examined, the reference level has acted as a price cap. RP has been very effective in reducing the highest price to the reference level, and its effect has, in fact, been very similar to maximum price regulation. In September 2001, only four products out of 228 were priced above the reference level. A total of 102 products (44.7% of the sample) were priced exactly at the reference level. And the remaining 122 products were priced below the reference level. Average non-weighted reduction of the highest price in the first month of RP use (December 2000) in relation to the preceding month was 19.2% for ranitidine, 23.8% for captopril, 0% for omeprazol, and 10% for fluoxetine.

Second, the number of suppliers on the market for these 13 homogeneous groups and four active ingredients continuously increased during both the period before and the period after the introduction of RP. In the 10-month period before RP, 33 generic products entered the market of these groups. In the 10-month

Table 3
The market for captopril before and after RP introduction (prices in €)

Captopril presentation	Variable	February 2000	November 2000	December 2000	September 2001
12.5 mg, 20 tablets	Number of suppliers on the market	3	4	4	4
	Lowest price	4.52	4.86	4.86	4.86
	Highest price	6.11	6.11	5.49	5.49
	Reference price at the national level	–	–	5.49	5.49
	Reference price in Andalusia	–	–	–	4.86
	Number of suppliers with price equal to RP	–	–	2	2
	Number of suppliers with price higher than RP	–	–	0	0
25 mg, 60 tablets	Number of suppliers on the market	15	17	17	18
	Lowest price	8.21	8.84	8.84	8.84
	Highest price	17.91	17.91	12.81	12.81
	Reference price at the national level	–	–	12.81	12.81
	Reference price in Andalusia	–	–	–	11.53
	Number of suppliers with price equal to RP	–	–	15	15
	Number of suppliers with price higher than RP	–	–	0	0
50 mg, 30 tablets	Number of suppliers on the market	15	17	17	18
	Lowest price	8.24	8.86	8.86	8.86
	Highest price	17.84	17.84	12.32	12.32
	Reference price at the national level	–	–	12.32	12.32
	Reference price in Andalusia	–	–	–	11.09
	Number of suppliers with price equal to RP	–	–	15	15
	Number of suppliers with price higher than RP	–	–	0	0
100 mg, 15 tablets	Number of suppliers on the market	9	9	9	9
	Lowest price	12.30	13.24	13.24	11.92
	Highest price	17.80	17.80	13.24	13.24
	Reference price at the national level	–	–	13.24	13.24
	Reference price in Andalusia	–	–	–	13.24
	Number of suppliers with price equal to RP	–	–	9	8
	Number of suppliers with price higher than RP	–	–	0	0

period after the change this figure was even higher: 49 generic products entered the market between December 2000 and September 2001. The price of new generic entrants in the period after RP was in all cases lower than the lowest preceding price. This is also a result of direct price regulation forcing new entrants to price below the lowest observed price on the market as a justification for its introduction. Individual price data after RP show that the only reason for decreases in the lowest price in each homogeneous group lies in the entry of new generic suppliers into the market with an imposed lower price.

Table 4
The market for omeprazol before and after RP introduction (prices in €)

Omeprazol presentation	Variable	February 2000	November 2000	December 2000	May 2001	September 2001
20 mg, 14 tablets	Number of suppliers on the market	10	14	14	17	24
	Lowest price	20.73	6.41	6.41	5.95	5.95
	Highest price	27.66	27.66	27.66	27.66	23.51
	Reference price at the national level	–	–	24.89	24.89	24.89
	Reference price in Andalusia	–	–	–	–	5.95
	Number of suppliers with price equal to RP	–	–	3	3	0
	Number of suppliers with price higher than RP	–	–	3	3	0

Table 5
The market for fluoxetine before and after RP introduction (prices in €)

Fluoxetine presentation	Variable	February 2000	November 2000	December 2000	September 2001
20 mg, 14 tablets	Number of suppliers on the market	13	18	18	26
	Lowest price	10.08	9.69	9.69	9.02
	Highest price	14.56	14.56	13.10	13.10
	Reference price at the national level	–	–	13.10	13.10
	Reference price in Andalusia	–	–	–	9.69
	Number of suppliers with price equal to RP	–	–	3	3
	Number of suppliers with price higher than RP	–	–	0	0
20 mg, 70 ml solution	Number of suppliers on the market	7	7	7	9
	Lowest price	10.57	10.57	10.57	9.02
	Highest price	14.06	14.06	12.65	12.65
	Reference price at the national level	–	–	12.65	12.65
	Reference price in Andalusia	–	–	–	10.57
	Number of suppliers with price equal to RP	–	–	3	3
	Number of suppliers with price higher than RP	–	–	0	0
20 mg, 140 ml solution	Number of suppliers on the market	8	8	8	10
	Lowest price	19.19	19.19	19.19	17.73
	Highest price	25.52	25.52	22.96	22.96
	Reference price at the national level	–	–	22.96	22.96
	Reference price in Andalusia	–	–	–	19.19
	Number of suppliers with price equal to RP	–	–	3	3
	Number of suppliers with price higher than RP	–	–	0	0
20 mg, 28 tablets	Number of suppliers on the market	13	19	20	27
	Lowest price	19.19	17.73	17.73	17.73
	Highest price	28.70	28.70	25.83	25.83
	Reference price at the national level	–	–	25.83	25.83
	Reference price in Andalusia	–	–	–	17.73
	Number of suppliers with price equal to RP	–	–	3	3
	Number of suppliers with price higher than RP	–	–	0	0

Third and last, the price of all products already on the market before the introduction of RP with a price equal to or lower than the reference level remained absolutely constant[6] during the period after, and did not experience any price competition effect because of RP or because of the lower price of new entrants.[7] At the same time, data suggest that RP has not been effective in reducing the price of products with a price initially below the reference level.

What are the implications of these descriptive trends in the evolution of prices for ranitidine, captopril, omeprazol and fluoxetine after the introduction of RP? The RP system does not seem to have provided effective incentives for consumer price competition as was intended. However, the observed increasing number of suppliers on the market should be considered as an indication of potential higher competition in the market. In our opinion, there is strong dynamic price competition in the Spanish generic market (at least for the four active ingredients observed in this paper). However, as a result of certain features of the implementation of the RP system (i.e. the level of the reference price, its updating lag, the substitution authorisation, etc.) and the regulated payment system for pharmacies (higher generic mark-up for pharmacies), price competition is mainly taking the form of lower acquisition costs for pharmacies rather than lower prices for the public payer and the patients (competitive discounting to pharmacies). It could even be hypothesised that the

[6] Individual maximum prices for each product are directly regulated in Spain, and this is true even for generics. Therefore, price regulation prevented price increases for generics with prices lower than the reference level.

[7] The number of generics in the active ingredient group is habitually used in the literature as a measure of competition.

effort of the regulator in forcing lower prices for new generic entrants could represent a competitive disadvantage for these suppliers.

The generic market share was very low until 1999, but it rapidly increased from 2.1% in January 2000 to 3.9% in December 2000, according to IMS data. However, the generic market share has not increased since the introduction of the RP system in December 2000. The size of the generic market was 3.3% in April 2001.

As Danzon [3] observed in a comparative analysis of RP policies, there is international evidence of the limitations of RP systems in encouraging price reductions below the reference level, and this is one of the main problems in the design of this policy for off-patent bio-equivalent drugs. For example, there is evidence in The Netherlands that the RP system and the substitution authorisation to pharmacists resulted in competitive discounting to pharmacists and failed to benefit payers and patients [3].

Public information from Spanish wholesalers offered to retail pharmacies provided information on the existence of large discounts on the price of generic products. Given that Spanish law does not allow discounts in the pharmaceutical market, generic suppliers offer additional free quantities of their products to the pharmacy. For example, in May 2002 one major wholesaler was offering two free packages of some generic presentations of omeprazol, ranitidine, enalapril, ciprofloxacin and amoxiciline with clavulanic acid when the pharmacy bought four packages at the official price (4 + 2). The equivalent discount on the price of the generic product implied by this transaction would be 33%.

It appears to be very contradictory to attempt to solve some of the problems related to the details of a policy designed to improve price competition for off-patent drugs, such as the RP system, by augmenting the level of intervention in the pharmaceutical market, without addressing the inefficient incentives that remain at the root of these problems. The fact that the prices of some products covered by the RP system remain above the RP level has been interpreted by the regulator as a result of insufficient competition in the market, and in some cases additional price regulation measures have been adopted. The existence of unequivocal signs of price competition in the form of lowered generic acquisition costs for retail pharmacies, and even the implicit incentive to dispense higher-priced generics to the patient, was simply responded by the Ministry of Health, for example in June 2002, with statements to the effect that, according to the Spanish law on medicines, this practice amounted to committing administrative offence that could be punished with a fine of between €600 and 3000.

A paradoxical example of increased regulation to supposedly reinforce RP may be found in the compulsory price reduction imposed in June 2001 on the prices of enalapril, famotidine, atenolol, omeprazol and ziprofloxacin presentations included in the RP system. Consider the case of omeprazol as a representative example of this situation. In May 2001, 6 months after the introduction of RP, only three omeprazol products (20 mg, 14 tablets) out of 17 were priced above the reference level. Seven new generics of omeprazol 20 mg, 14 tablets entered the market between May and September. The reference price level established centrally in December 2000 was €24.89, but the lowest price in September 2001 was 4.2 times lower (€5.95, the reference price adopted in Andalusia in September 2001). Anecdotal evidence of implicit discounts to retail pharmacies for omeprazol acquisitions could be observed on the market at this time. In this situation, the central government argued that consumer prices did not descend precisely because of a lack of competition, and imposed a unilateral 15% price reduction in June 2001. This imposed price reduction not only affected products priced above the reference level but also reduced the price of generic products with a price more than three times lower than the reference level in May 2001.

4. Changes in the pharmacies' payment system

In the Spanish health care system, prescription medicines can only be distributed through pharmacies. The density of pharmacies is one of the highest in the world: there is a pharmacy for each 2000 inhabitants. Even the actual number of pharmacies has been rapidly increasing in recent years: from 15,000 in 1977 to 20,000 in 2001. Pharmacies are still strictly regulated; a degree in pharmacy is required in order to be the holder, and there are several limitations in the maximum number of pharmacies according to the population and the distance between pharmacies.

Table 6
Pharmaceutical distribution margins in Spain since January 2000

	Wholesalers	Retail pharmacists
Generics		
Ex-factory price (€) ≤ 78.34	9.6% of the wholesaler' s price	33% of the retail price including taxes
Ex-factory price (€) > 78.34	€8.32 per package	€33.54 per package
Non-generic proprietary medicinal products		
Ex-factory price (€) ≤ 78.34	9.6% of the wholesaler' s price	27.9% of the retail price excluding taxes
Ex-factory price (€) > 78.34	€8.32 per package	€33.54 per package

Source: Farmaindustria [7].

Regulatory changes introduced in 1996 and 1997 slightly relaxed some imposed limitations: the minimum number of inhabitants to authorise a new pharmacy was reduced, with different criteria operating in each CA; and at the same time, the pharmacy's timetable for attending the public was made more flexible.

The payment system for pharmacy services has until now been based on a mark-up calculated as a fixed proportion of the consumer price before taxes. This system provides incentives to increase pharmacy revenues by selling medicines with higher prices. The Ministry of Health has yielded to the temptation to unilaterally reduce mark-ups using monopsony power; however, these measures have had only short-term effects, as incentives remain unaltered. For example, in 1997 mark-ups were reduced to 11% for wholesalers and 27.9% for pharmacies. This measure represented a margin reduction of one point for wholesalers and two points for pharmacies. In 1999, a further unilateral reduction of the wholesale margin to 9.6% was introduced.

This margin payment system, and the linear changes made to it, does not consider any relationship between marginal costs of pharmacy services and marginal revenues. The result is that it does not provide incentives for the dispensation of lower-priced drugs, and does not treat with equity the significant heterogeneity between pharmacies (population served, location, costs, etc.).

The first major attempt to partially modify this linear margin system was introduced in the year 2000[8] (Table 6). The changes introduced in this year were intended to fix a decreasing margin according to the product price and the pharmacy's volume of sales, and to promote generic sales. First, mark-ups for wholesalers and pharmacies were maintained at the prevailing level (9.6 and 27.9%, respectively) only for products with an ex-factory price equal to or lower than €78.34. Second, a monetary margin cap was established for products with an ex-factory price above €78.34 (a fixed margin of €33.54 for pharmacies, and a fixed margin of €8.32 for wholesalers). Third, the mark-up applied to generic products with an ex-factory price equal to or lower than €78.34 was increased to 33% in order to encourage generic sales. And fourth, a discount scale was introduced that increased according to the monthly volume of sales to the public payer, valued at the consumer price including VAT. The monthly discount ranges from €673.13, applied to pharmacies selling more than €37,263.75, to a maximum of €22,153.31, for volumes of sales above €252,425.08.

The changes made to the pharmacies' payment system in the year 2000 introduced a variable mark-up according to two criteria, which modified the long-standing consumer price proportional margin in Spanish pharmacies. First, the new system was designed to encourage generic drug sales by introducing a margin 5.1 points above that of non-generic products. This is probably one of the main reasons for the increase in the generic market share. However, the efficiency of this measure is clear only when generic prices are significantly lower than those of non-generic products. Unjustified market distortions may appear when generic prices are nearly equal to that of the innovative product, or even worse, when the generic price is higher than that of other products with the same active ingredient, as occurs in some cases. The higher margin for generics provides

[8] Real Decreto-Ley 5; 23 June 2000.

incentives to sell the generic with the highest price. A variable margin independent of generic status and based on differential prices seems more efficient.

And, second, the average mark-up for pharmacies decreases continuously with the volume of sales. In the case of non-generic drugs with a consumer price of up to €78.34, the average marginal rate is 27.9% of sales valued at consumer prices when the pharmacy's monthly sales are not above €27,646.56. This group may include up to 60% of Spanish pharmacies. The average margin decreases to 19.124% for those pharmacies whose monthly sales reach €252,425.08. The marginal rate ranges from a maximum of 27.9% to a minimum of nearly 14.9% for the highest volume of sales, according to the consumer price before taxes. The financial effect of this measure on pharmaceutical public spending has been very significant. During the period of application in 2000, it amounted to €63 million,[9] which is nearly equivalent to an annual decrease of more than 2% in public expenditures (and an average discount rate over the preceding pharmacy reimbursement of over 7%).

This represents a typical one-off measure whose effects are limited to the short-term. Public pharmaceutical expenditure increased 7.46% in 2000, but without the change in pharmacy margins established in June 2000, the increase would have been 8.47%. Regional savings accrued from the application of this measure will be higher in those regions with a larger population per pharmacy (such as the Canary Islands and the Basque Country).

Anecdotal evidence suggests that in some cases pharmacies have responded to this policy by artificially redistributing sales from one month to another, and also from one pharmacy to another, when they report to the public insurer, in order to avoid lower marginal mark-ups and obtain a higher average remuneration. Given the observed cyclical trends in monthly pharmaceutical sales, it would probably be more suitable to consider yearly sales as the basis for establishing marginal mark-ups for pharmacies.

Mixed payment systems for Spanish pharmacies have been proposed by some analysts [13] with a view to reducing inappropriate marginal incentives. A mixed system could consider different components in the payment system: a fixed amount per dispensed prescription [1], the reimbursement of the cost of the product, a fee for some pharmacy care services under contract, a minimum guaranteed revenue for pharmacies located in small towns, etc.

5. General agreements between the government and the industry

The Ministry of Health and Consumption and Farmaindustria (the Spanish Pharmaceutical Manufacturers Association) signed agreements in 1996, 1998 and 2001 that involved increased repayments by the industry to the public health care system. In 1998 repayments by the industry totalled €235.3 million, equivalent to 4.1% of public pharmaceutical expenditure. The 1996 agreement established a 4% rebate on laboratory prices, and an increasing scale of discounts on additional sales when sales of publicly financed medicines increased annually more than 2.6%. The maximum marginal discount could not be above the gross profit margin (56.7% on the consumer price) for additional sales. A similar agreement was signed in 1998. These are overall ex-post agreements and are not related to price-volume agreements.

However, this policy has been challenged by non-Farmaindustria members, and also by firms that did not sign the repayment agreements. These firms have been agreeing to large rebates on sales of single drugs with the regional NHS authorities and with hospitals. Farmaindustria cancelled the government–industry agreement unilaterally in July 1999 after disagreement with the government over the introduction of the reference pricing system. The government reacted with a compulsory price reduction introduced in November 1999 (around 6%), which was designed to more than compensate the previously agreed repayment [14].

A new industry–government agreement was signed in 2001 with the intention of providing a steady 3-year framework for the pharmaceutical sector. The Ministry of Health and Consumption accepted to voluntarily limit cost containment policy measures to those included in the agreement and not to adopt any other unilateral measure. The agreement involved the promotion of generic drugs, the introduction of new homogeneous groups into the reference pricing system, and the annual revision of the level of reference prices.

[9] Farmaindustria. Memoria Annual; 2000.

The maximum annual reduction in public expenditure attributed to these measures cannot be above €105.18 million. Lower impacts will not be compensated by the industry. At the same time, the Ministry of Health and Consumption undertook to adopt measures to soften the negative impact of parallel trade; and to propose to the government tax deductions for expenses and investments in research, development and innovation in strategic lines.

In the 2001 agreement, Farmaindustria undertook to finance a publicly managed research fund. The minimum amount to be paid by the industry to this new fund is €60.1 million in 2002, €60.1 million in 2003, and €30.05 million in 2004. This amount could be augmented according to the annual rate of increase in public pharmaceutical expenditure. The maximum annual payment to the fund cannot be above €99.17 million. The annual amount to be paid by the industry to the fund will be calculated as follows. First, a maximum annual increase in the amount of NHS prescriptions (excluding hospital consumption) valued at laboratory prices is established. This maximum annual rate depends on the nominal GDP growth rate. If the GDP growth rate is lower than or equal to 5.5, then the maximum increase in drug sales to the NHS will be the GDP rate plus one point.[10] If the GDP growth rate is above 5.5, then the maximum increase in drug sales to the NHS will be 6.5. Second, the industry's annual contribution to the fund will be calculated as €33.06 million for each point above the maximum agreed increase, which depends on the rate of increase of the GDP. A fixed contribution will be deducted from this figure. And third, the agreement will be revised if drug sales to the NHS increase annually more than 3 points above the maximum fixed level.

The most important positive aspect of this government–industry agreement is that of reducing uncertainty; it provides a steady and predictable financial perspective for agents, pharmaceutical industry and public insurer, for the period 2002–2004. Another advantage of the 2001 agreement is that a certain proportion of the repayment is related to the overall growth rate in pharmaceutical sales to the NHS. This introduces overall incentives to restrict sale increases, despite the fact that the incentives at the firm level depend on the distribution criteria for the repayment among firms, and are difficult to predict. There are also aggregate incentives not to exceed the maximum allowed sales increase according to the agreement, because in this case firms will face regulatory uncertainty. Also in this case, individual firms' incentives may be different.

It should be noted that the 1998 agreement between the pharmaceutical industry and the Spanish Government established a fixed repayment amount. This agreement specified a total repayment for each year, which would be apportioned, for example, according to the market share. This case could be compared to the effect of fixed revenue taxation. An increase in the sales of firm *i*, without a reduction in the sales of the rest of the firms, will reduce the average tax on revenues. In this case marginal taxation for firm *i* will be decreasing and lower than average taxation. Then, incentives to increase pharmaceutical consumption will not disappear.

Let the average repayment rate per euro of prescription sales be *t*. If a firm makes an additional sale of €1 without reducing other companies' sales, in the fixed revenue taxation case, the industry's overall repayment burden will not be affected. Then, it is clear that an increase in the volume of sales reduces the value of *t* because the marginal repayment rate is lower than the average (and equal to zero). Under the 2001 agreement, given the existence of a fixed prepayment, the average repayment rate is decreasing for overall sale increases not above 1.8 points over the maximum reference level. However, above this growth rate, the overall marginal repayment rate is increasing and higher than average. In fact, at the aggregate level and above the preceding growth level, repayments act as a profit sharing mechanism. Of course, firm incentives will depend on the criteria applied in the distribution of the repayment among individual firms.

Notwithstanding, some important problems remain to be solved by the agreement, and also, some potential problems may arise from its application. First, the maximum annual repayment coming from this agreement is lower than that obtained in 1996, 1997 and 1998, even in monetary terms; furthermore, it is also decreasing in real terms. The net financial impact for the public budget will be lowered by fiscal deductions in the taxation on firms' profits in the corporate tax. The repayment is considered as a cost and

[10] The official estimate for the expected nominal GDP rate of growth in 2002 is 5.3%.

it will correspondingly reduce taxable firms' profits. A new 10% deduction on research, development and innovation has been introduced in the Spanish profit tax in 2002. This deduction will represent a major reduction in the cost of the agreement for the industry.

Second, under the new agreement, repayments will be compulsorily devoted to public medical research, which limits the autonomy of resource allocation decisions by central and AC governments and introduces instability in the availability of public medical research funds. The amount of the repayments depends on the level of regional pharmaceutical expenditures, but repayments are not made to those regions with higher increasing pharmaceutical expenditure rates. The agreement means that drug consumption has to increase for more public funds for medical research to be obtained.

Third, the agreed repayments may not be enough to discourage marginal sales by individual pharmaceutical firms in all circumstances. The reason for this is that, given the existence of a fixed agreed repayment amount, the optimum increase in pharmaceutical sales is 1.8 points above the maximum fixed level for 2002 and 2003. As an example, if the annual increase in nominal GDP is 5.0% in 2002, then public pharmaceutical prescriptions valued at laboratory prices will optimally increase 7.8 points, which represents an elasticity of pharmaceutical spending to GDP of 1.56. Elasticity of pharmaceutical expenditure valued at consumer prices to GDP was 1.78 during the period 1990–1997.

Fourth, some problems may appear when allocating the repayment contribution to individual firms. If the amount of the repayment is allocated to individual firms according to annual sale increases or their market share, then, for example, generic producers with an increasing market share will be penalised by this system. Incentives remain for individual firms such as generic or low-price producers not to adhere to the agreement and to offer rebates to wholesalers and pharmacies.

Fifth and finally, the 2001 government–industry agreement means that the public third-party payers forego adopting other so-called "structural measures" (cost containment) aimed at controlling public pharmaceutical expenditure. In fact, the industry argues that even the meagre estimated effect of RP is enough to damp the maximum yearly impact of these so-called structural measures as established in the 2001 agreement.

It is important to be note that the agreement with the pharmaceutical industry was obtained by the central Ministry of Health and Consumption at the same moment as, in January 2002, the devolution of health services management to regional governments was completed, along with a reform in the regional mechanism of allocation of public funds (intergovernmental grants, tax revenues and fiscal accountability). Thus, some problems in the relationship and distribution of powers between central government and ACs may arise. First, some decentralised ACs complain that the agreement puts an arbitrary limit on their autonomous right to implement cost containment measures in the near future. And second, there may be problems regarding the regional allocation of this repayment, especially when the repayment is understood as a rebate on pharmaceutical sales to the various ACs. In fact, the AC of Andalusia has refused to accept this agreement with the industry.

At the end of 2001, the central government reached agreements for the period 2000–2004 with the two interest organisations of pharmacies (Consejo General de Colegios Oficiales de Farmacéuticos and Federación Empresarial de Farmacéuticos Españoles) and also with the interest organisation of the wholesalers (Federación de Distribuidores Farmacéuticos). In both cases, the Ministry of Health and Consumption renounce the introduction of changes in the payment system (mark-ups) in exchange for some repayments related to sales increases.

6. Concluding remarks

In addition to the intrinsic difficulty of relating effects to causes in pharmaceutical policy evaluation and the multiplicity of goals, the limited number of formal rigorous evaluations complicates the task. Moreover, the debate on Spanish pharmaceutical policy is very hot in the political arena. Spanish politicians' view of the appropriateness and the effects of pharmaceutical policies tend to represent more their present position on the political scene—government or opposition—than evidence-based criteria. Clearly, this is not the best environment for an objective and scientific

evaluation of changes in pharmaceutical reimbursement (evidence-based policy).

It is very common in health care analysis to confuse the price and cost of health care with the observed expenditure level. This is especially true in the case of Spanish pharmaceutical expenditure. In the Spanish political debate, the high proportion of public health expenditures devoted to pharmaceuticals (see Table 1) is often taken as an indication of inefficiency. We argue that this measure does not provide any insight as to the efficiency of pharmaceuticals in the Spanish health system. It can be argued that some new technologies such as oral antibiotics, and medications to treat ulcers or mental illness may have helped to reduce in-patient costs, but this is not true for a large number of new products introduced on to the market with high prices. High pharmaceutical expenditure levels could be very efficient if they provide significant health improvements. Equally, lower expenditure levels may be very inefficient when financing pharmaceuticals without demonstrated effectiveness.

There is a vast amount of evidence of over-consumption, inadequate prescription, and a high cost of negative effects associated with pharmaceutical consumption in Spain. It has been reported that problems related to the use of medicines account for 12% of urgent admissions in a tertiary hospital [16]. However, the success of pharmaceutical policies cannot be measured only by its cost containment contribution; "robbing where the money is"—that is, in the overall pharmaceutical expenditure—is not always the best guide for efficiency improvement. It is even more important to be selective, and to observe the impact of pharmaceutical policies on the behaviour of patient, prescriber, industry, wholesalers and pharmacies in order to introduce incentives that are more oriented to clinical effectiveness, service quality and efficiency.

In this paper, without any pretension to comprehensiveness, several recent reimbursement policies applied to pharmaceuticals have been analysed: the second negative list, the reference pricing system, the payment system to pharmacies, and the industry–government agreements. All these measures represent a renewed and notable effort to improve public purchasing of pharmaceuticals and to introduce efficiency oriented changes in the incentives of the agents in the Spanish pharmaceutical market. Notwithstanding, not only the overall impact of these measures, in terms of cost, efficiency and health effects, remains to be established, but also several likely limitations of these interventions have been highlighted in this paper. All these recent measures share some limitations at their origin that probably affect and impose limits on their effective impact: they are more industry than demand-side oriented; they are designed more as directive regulation measures than as incentive pricing policies; the goal of short-term cost containment appears to be their only criterion for success; they are directed at controlling prices rather than reducing quantities and improving quality; and they are designed to influence pharmaceutical expenditure as if it were an isolated input in the health care production process.

Recent cost containment policies in Spain have been focused especially on measures oriented to the industry side, which for the most part have been supported by the monopsony purchasing power of the public sector. The reverse is that demand-side policies—based on patient and, more importantly, on prescriber incentives—have been very weak. This is due mainly to the stricter short-term budget constraints imposed on health care expenditure, and the fact that public pharmaceutical expenditure shows the highest rates of increase among health inputs in Spain. In fact, recent reform trends appear to be guided (sometimes confused) by observed monthly rates of increase in pharmaceutical expenditure rather than by incentives to improve efficiency. Nation-wide pharmaceutical policies have had scant influence on prescribing decisions with prescribing guidelines, prescribing budgets, treatment protocols and rational prescribing. Organisational reforms in the Spanish health care system should promote physician capitation including prescription drug costs in order to align physicians' interests with resource constraints.

Until very recently, price regulation has been the most important cost containment measure in Spain. In theory, the present price regulation system, established in 1990 [18], regulates the price of each individual product based on its costs, and it is intended to regulate the rate of return. Additionally to the inherent difficulty (indeed, impossibility) of establishing the cost of each input for every product in a market characterised by extremely high and non-separable and internationalised costs of innovation and development, the conditions on the EU market are in effect weakening the use of this regulation system and giving more

importance to the observed price in other European countries (external reference pricing).

In fact, the price for innovative products entering the market is established at a similar level to the observed price in those EU countries with lower prices (France and Italy). However, the price of the products that have been on the market for some years suffers a progressive erosion because there are no automatic or explicit criteria for yearly updates to this price. The result is that many old and very effective products show a low level and a decreasing trend in real prices, and this situation creates strong incentives for the pharmaceutical companies to introduce new higher-priced products on to the market that do not represent any significant improvement in effectiveness. Promotional efforts are then concentrated by the industry on these new and more expensive products, and high-powered incentives exist for products recently introduced on to the Spanish market to acquire a large market share very fast. The distribution of pharmaceutical sales on the Spanish market according to the date of approval indicates that in the year 2000, 39.5% of these sales corresponded to medicines with 5 years or less on the market, and 42.5% corresponded to medicines with 6 years or less on the market [7].

It may also be stated that, despite the introduction of a reference pricing system in 2000, pricing regulation and reimbursement decisions have been neither adequately related nor clearly separated. This fact has become even more important following the completion of the devolution of health services management to regional governments in January 2002. In fact, now that the devolution is complete, the central government remains as the regulatory agency of the pharmaceutical market, but purchasing power and budget responsibility belong exclusively to regional governments acting as insurers and payers. Purchasing power may be exerted in a decentralised environment by each regional government; however, given the small size of some regions, the pure decentralised model may not always be the best option for regional governments to negotiate with pharmaceutical suppliers.[11]

[11] An alternative could be to retain a centralised purchasing agency to negotiate with the industry, as in the case of the not-for-profit Pharmac in New Zealand, which was formerly owned by regional authorities and since 1997 has been owned by the financing agency.

Negative or positive lists (coverage decisions) should be more guided by evidence-based criteria, including information from economic evaluation. Health economic evaluation criteria are absolutely insufficient and unreliable for practical use in the Spanish health care system. Reimbursement should be designed to favour the use of effective drugs and avoid payment for ineffective ones. In the same way, reimbursement should be more guided by differences in reimbursement rates representing differences in effectiveness. The present prevailing use of the short-term rate of increase in Spanish public pharmaceutical expenditure to guide non-co-ordinated coverage decisions, both at the regional and at the national level, may represent a potential threat for effectiveness and efficiency, may introduce significant inefficient distortions into the market, and may increase the administrative burden, when they provide incentives to confuse price with the cost of health care. Pharmaceutical coverage decisions appear to be excessively influenced by these short-term budgetary implications, as may be observed by the introduction of barriers to the prescription of some expensive medicines in the form of special authorisations, the price level being used as the only (arbitrary) criterion for reducing effective coverage, without any consideration of effectiveness or cost-effectiveness criteria.

Given that there is no reason to restrict post-patent competition, RP applied to off-patent and bio-equivalent medicines may represent an optimal insurance policy in the Spanish pharmaceutical market. However, the challenge with this reimbursement policy is how to design appropriate stimuli for the effects of price competition to be captured by the payer [3]. This problem is related to generic substitution and not only strictly to RP systems. Incentives for suppliers to set prices below the RP would require increased pharmacy revenues when selling products priced below the reference level. Revenues should be directly related to price difference, and they should be independent of generic or brand status, and related exclusively to the price. However, incentives for competitive discounts to pharmacies will remain if pharmacists do not receive the whole difference. Then, another requirement would be to establish a Spanish reference level closer to the lowest observed price on the market at any moment.

There is wide variation internationally in the criteria used to set the reference price. However, from the

theoretical point of view, for RP systems applied to off-patent products the reference level should mimic the competitive price (the marginal cost). Then, usually, there is no reason not to fix it at the level of the lowest observed price on the market. Huskamp et al. [8] even suggest establishing the reference level in a competitive tendering process rather than on the basis of observed prices. Reference levels in Spain, as can be observed in Tables 2–5, have remained markedly above the observed lowest price.

As a procurement mechanism and to split public procurement from regulation, price-volume agreements negotiated with each pharmaceutical firm could fix the volume that may be sold (micro approach), according to the budget impact established in the application. This price-volume could be designed as an incentive regulation tool and could be negotiated by public purchasing organisations (payers): for example, sliding scales sharing the risk (price decreases) of higher reimbursement costs between the firm and the third-party payer.

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