Regulatory Ambivalence and the Limitations of Pharmaceutical Policy in Spain*

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Abstract

Broadly speaking, pharmaceutical policy in Spain has been unable to control either the price or the volume of drugs prescribed. Limited attempts have been made to bring together the regulation of the pharmaceutical market and policies, in pursuit of the desired goals of efficiency and quality. This paper assesses the regulation of the Spanish pharmaceutical market over the last two decades by examining regulation and policy and the available empirical evidence on their appreciable effects, and presents recommendations for policy design. Our findings suggest that policies aiming to improve efficiency and quality have not managed to contain costs, while cost-effectiveness is still overlooked. We argue that future policies should encourage broader participation in the decision-making processes and promote a higher degree of competition, especially from generic drugs.

Key words: Spain, generic penetration, reference pricing, negative lists, pharmaceutical regulation.

JEL: I18, L51, l52, l65

1. Introduction

Though health spending in Spain remains at a relatively low level compared to that of its European Union counterparts (7.5% of GDP in 2001), the life expectancy of the Spanish population – 75.6 years in males and 82.9 in females in 2001 – is among the highest worldwide. Pharmaceuticals accounted for 1.56% of GDP and 21.9% of public health care expenditure in 2001. On the one hand, in Spain pharmaceutical treatments have been given priority over other health care inputs (e.g., mental health care). However, on the other hand, the regulation of the pharmaceutical market and the policies implemented on both the demand and the supply side reveal significant "ambivalence", and taken together have been subject to notable limitations in pursuing their intended goals. Indeed, the Spanish National Health System (henceforth NHS) funds 92% of the total pharmaceutical expenditure and the regulation of the Spanish drug market has provided meagre cost-containment incentives for both consumers and providers. Furthermore, incentives to improve micro-efficiency and quality reveal little success.

As in other southern European countries (e.g., Italy), generic competition has been practically inexistent, generics accounting for roughly 6% of total sales in 2002. As we discuss further on in the paper, there have been intensive albeit limited demand-side incentives for the prescription and dispensing of less expensive drugs. Doctors are paid on a salary basis, and although capitation formulas are gradually being introduced into the financing of primary care, they do not apply to drug prescription costs (except for some geographical areas in Catalonia and Valencia). Although the NHS is a decentralised health system (López Casasnovas et al, 2004), price regulation is the responsibility of the central State, based on a rigid *case by case* cost-plus system and an untransparent negotiation system with the industry. Furthermore, reimbursement system reforms have led to the creation of a *reference price system*, which has not produced the expected results and has already been reformed. The effective sharing of the cost of prescribed drugs by the patient has been declining markedly since the early 1980s. In addition, some concern is expressed regarding the limited therapeutic efficiency and quality of new drugs. Nevertheless, significant institutional reforms have taken place. Especially, having to face the challenge of a European single market for pharmaceuticals has brought notable

changes in regulations (such as the split between licensing and reimbursement and the adoption of the EU patent legislation in 1992).

This paper aims to examine pharmaceutical policy and market regulation of medicines in Spain, and to evaluate both the achievements and the limitations of the last two decades by scrutinising relevant empirical evidence with regard to health policy debates. We also examine the conflicts that have arisen and assess the extent to which the government has succeeded in pursuing goals that serve the aims of both the health system and the industry. Furthermore, since the Spanish NHS is a decentralised organisation, we present a detailed examination of the role of devolution in the regulation of the country's pharmaceutical market.

The paper is structured as follows. Section 2 describes the Spanish pharmaceutical market and the key stakeholders. Section 3 examines trends in expenditure and consumption. Section 4 examines policies designed to influence demand. Section 5 is devoted to policies that affect supply, and Section 6 explores the regulation of the industry. The paper concludes with an evaluation of demand-side and supply-side policies and evidence in the context of current pharmaceutical policy debates.

2. The background

2.1 The government and regulatory bodies

The NHS is tax-funded and provides free health care coverage, with minor exceptions such as non-refundable co-payments for prescribed pharmaceuticals. The general rate of co-payment for drugs has remained at 40% since the early 1980s. However, prescription drugs for pensioners and drugs consumed in hospitals are provided free of charge, and the chronically ill (for example, diabetics) pay 10%, with a price cap of €2.64. 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. In the early 1980s the NHS underwent radical reform, with the gradual introduction of a decentralised model involving the creation of 17 autonomous regional health services, corresponding to the 17 Autonomous Communities (henceforth ACs) into which Spain is divided. These regional bodies

have political responsibility for health care, although, with the exception of Navarre and the Basque Country, they remain financially dependent on the State.

The process of regulating the pharmaceutical sector has been particularly interesting due to the devolution process that has taken place in Spain. Pharmaceutical regulatory bodies are highly specialised. The Directorate-General of Pharmacy and Health Products (henceforth DGP) of the Ministry of Health and Consumer Affairs (henceforth MoH) monitor product licensing at State level. The same applies to the registration of new products, although the recently created Spanish Agency for Pharmaceuticals has played a more active role since the year 2000. Patent regulation is the responsibility of the Ministry of Industry in conjunction with two special commissions for economic affairs. The Interministerial Commission on Drug Prices, following the guidelines set by the DGP[1], takes decisions on prices after reviewing the manufacturers' applications. The National Commission for the Rational Use of Medicines, which comprises representatives of the 17 ACs, the pharmaceutical industry, the medical profession, consumer organisations and trade unions together with experts appointed by the MoH[2], takes decisions on reimbursement. The MoH also sets the wholesalers' mark-up and, in conjunction with a special commission of economic affairs, determines the retail mark-up.

Because of the decentralisation process, responsibility for the regulation of the pharmaceutical market is shared between the State and the AC. However, most of the key regulatory bodies are run at State level in order to reduce diversity and to maintain overall control. The State oversees and authorises clinical trials, issues marketing authorisations for pharmaceuticals, controls the advertising of drugs and health care products aimed at the general public, licenses pharmaceutical laboratories, regulates the quality and manufacture of pharmaceutical products, sets drug prices and co-payments and decides which pharmaceuticals to include on the list of publicly

[1] Manufacturers are required to provide scientific and clinical data on each drug, demonstrate its benefits compared with other products, propose ex-factory and retail prices and transfer costs, and provide company financial statements and estimates of sales and prices in the country of origin and in other EU countries.

[2] Reimbursement is based on the agreed price, the severity, duration and effects of the illness in question, population needs, clinical and social value, cost and efficiency, potential therapeutic strategy and the cost of similar available therapies.

financed medicines. The Autonomous Communities 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 development 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. By law, they hold wide powers over the implementation of the legislation passed at State level in the pharmaceutical field. Furthermore, responsibilities for budgeting and management have been totally decentralised since 2002 and devolved to the governments of the Autonomous Communities. Nonetheless, public reimbursement mechanisms continue to be set at State level by the MoH, which is responsible for the co-payment scheme and partially responsible for the reference pricing mechanism.

The Pharmaceuticals Act of 1990 is the legal basis of pharmaceutical regulation in Spain. More recently, the Cohesion and Quality Act of 2003 explicitly established that "the State will retain full responsibilities for the authorisation, registry, safety and control of drugs". 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.

2.2 The Spanish pharmaceutical market

Spain is the fifth largest market in Europe for pharmaceuticals. In 2000 there were 262 manufacturers and 259 laboratories, figures similar to those of France and Italy. Total production amounted to €6,776 million in 2000 and the sector has some 38,700 employees. The size of Spanish labs is medium, since the vast majority of them employ between 50 and 250 workers (Farmaindustria, 2002). However, Spain is

a net drug importer: imports (€3,216 million) far outweigh exports (€1,810 million). More than half of the pharmaceutical market is under the control of foreign companies, which have increased their presence in the country by buying pre-existing local companies. A cursory look at market concentration reveals that the top ten laboratories have 28% of the market. However, if we take into consideration possible market collusion and existing holdings, concentration indices may actually rise to levels that suggest a degree of oligopolistic competition (Cabiedes, 1996).

Innovation in Spain trails behind that of other European countries. Indeed, Spain is not involved in substantial pharmaceutical innovation. R&D expenditure has been equivalent to between 7% and 9% of domestic sales during the last two decades – appreciably lower than in other EU countries. Measuring innovation in terms of the proportion of new active ingredients introduced throughout the EU, we see that in 2000 Spain accounted for 6.3%. Between 1985 and 1998, less than half of the new active ingredients marketed in Spain were classified as "innovative". Therefore, the reimbursement system seems to have great difficulty in rewarding pharmaceutical innovation.

The prescription market dominates pharmacists' sales. On average, prescription drugs are three times more expensive than OTCs[3]. The market share of prescription drugs is 85.5% of volume, and 92% of total sales; OTCs account for 14.5% of volume and 8% of total sales. In the 1990s, there was some debate on the hypothetical effects of cost-containment policies (such as negative lists and posing additional barriers to obtaining prescriptions for less expensive drugs) on the development of the OTC market, since OTCs can be advertised in the media whereas prescription drugs cannot. However, the volume of OTCs remained stable; though expenditure increased by 7.54% between 1990 and 2001, the market for prescription drugs increased significantly in terms of both packs (1.54% annually) and monetary sales (by 10.7%)[4]. OTCs refer mainly to dermatological drugs (11.87%), drugs to combat flu (17%), analgesics (19%), drugs for the respiratory system (16%), and laxatives and vitamins (6%). Not surprisingly, promotional campaigns focus on GPs

[3] Average prices in 2001 were €6.07 for prescription drugs and €2.05 for OTCs.

in the prescription market, and on the general public through TV advertising in the OTC market[5].

2.3 Licensing and market entry

In 2000 Spain came second only to Germany in Europe as a whole in terms of different presentations of drugs. This is due to the still considerable number of copies in the market and the extension of generics, along with the entry of new drugs. In 1995, there were 7,810 presentations marketed and by 2000 this number had risen to 8,736. Of all authorised products in 2000, OTCs accounted for 6.4%, prescription drugs for 77% and hospitals for 17%. The share of total registered OTC products was between 15% and 20% in the late 1980s and had declined to 8% by the late 1990s (Table 1).

[Insert Table 1 about here]

Overall, the average price of pharmaceuticals in Spain is low compared to other EU countries. 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. 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[6]. However, prices for new drugs are not much below 90% of the European average, and these are the drugs that account for the largest market share. Kanavos et al (2004) report that adjusting for DDD and product presentation, Spanish prices for new drugs

[4] Consumption of OTC drugs is related to self-medication, which is broadly considered by the MoH as a major problem – as 42% of the population recognises having a "private home pharmacy" – along with the 6% of prescription drugs that are dispensed without a prescription.

[5] Of total promotional expenses in 1997, 65% corresponded to personal promotion with GPs, though the figure fell to 54% by 2001. Visits to pharmacists represented 10-11% and visits to specialists 16-17% of total promotional expenses. Congress organisation and public relations rose from 0.7% in 1997 to 2.7% in 2001. Of OTC advertisements, 93% were TV commercials, 4% were placed in newspapers and 2% were on the radio.

[6] As a result of the existence of many "me-too" drugs in the Spanish market, 36% of total sales refers to products which have been 20 years or more in the market, although they represent only 12.6% of total sales.

(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.

3. Pharmaceutical expenditure

3.1 Trends in expenditure and expenditure determinants

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%[7] and OTC has risen to 4% (Table 2). 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 8% in the 1980s and 6% in the 1990s.

[Insert Table 2 about here]

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. Table 3 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

[7] 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.

prescriptions; this suggests that 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.

[Insert Table 3 about here]

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 4 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.

[Insert Table 4 about here]

Table 4 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 both 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.

From a policy perceptive, 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.

3.2 Price composition

Prices in Spain are subject to government authorisation. In the 1990s price reductions were frequently used as a "once-for-ever" tool to contain costs. Indeed, the price composition of pharmaceuticals varied slightly from 1986 to 2000 (Table 5). In the 1990s, nominal prices for drugs fell due to a reduction in taxes, a significant decline in wholesalers' margins and a slight decline in pharmacists' retail margins. The ratio between retail price and ex-factory price fell from 1.7:1 in 1986 to 1.6:1 in 2000.

[Insert Table 5 about here]

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. The government estimated the overall effect to be a cost reduction of €1,100 million from 1997 to 2000.

3.3 Devolution and regional heterogeneity

Spain's Autonomous Communities (ACs) have gradually become key agents in pharmaceutical policy, especially since the completion of the decentralisation process in 2002, though the regulation decisions are still made at State level. Their responsibilities cover the promotion of prescribing guidelines, inspection and regulation of clinical trials, quality control and information and communication policies. ACs also run cost-containment initiatives through the control of prescription and hospital health care. After the completion of the devolution process in 2002, coordination is now the responsibility of the Interregional Council, which is formed by representatives of each AC through specific commissions dedicated to pharmaceutical policy. However, the AC governments' attempts to increase their role in pharmaceutical policy have not been successful, as the new Cohesion and Quality Act (passed in 2003) establishes that the central State maintains full responsibility for the authorisation, registry, pricing and public financing of drugs, along with their safety and control. The recent proposals of some regional health services (Andalusia, Canaries and Catalonia) point to the need to increase regional responsibility for pharmaceutical policy. They defend the principle whereby "*those who pay should decide*", that is, those paying for health care should have some capacity to influence reimbursement, licensing and pricing decisions. Therefore, devolution has brought a new dynamism to pharmaceutical policy.

From 1981 to 1997 seven ACs took on health care responsibilities, thus taking charge of 60% of total public health expenditure. Up to 1997 pharmaceutical expenditure grew at similar rates in these communities (12-13%), but in 1993, the rate of increase began to fall, from 7.9% to 5.5% in 1997. Among the ACs, Andalusia and

Navarre had the lowest growth rates in the 1990s, while Galicia and Valencia had the highest ones. Spending growth from 1995 to 2000 was similar across ACs in both total expenditure and expenditure per capita. However, there is evidence of significant regional heterogeneity in the share of pharmaceutical expenditure in total regional health care budgets[8]. Prescription rates and values present major regional variations. According to the data from the Directorate-General of Pharmacy (2003) in 2001 the Spanish average for prescriptions was 1.45 per capita, the highest being 1.79 in Valencia and the lowest 1.36 in the Basque Country. In 2002, the Balearics was the AC with the lowest prescription rate per capita and Valencia the one with the highest. Not surprisingly, regional heterogeneity decreased when the data are standardised by age and gender, but still Valencia and Castile-Leon, followed by Murcia and Andalusia, display the highest number of prescriptions per inhabitant.

3.4 Distribution and dispensation of drugs

The distribution of drugs is organised mainly by wholesalers. According to Farmaindustria (2002), wholesalers distribute 77% of all drugs sold, hospitals 19% and the rest are distributed directly to retailers[9] (3%) and to governmental agencies (1%). The retailers (pharmacists) are independently authorised and are subject to strict regulation. Indeed, the regulation of pharmacists is a key issue in Spain. Prescription drugs are only dispensed in pharmacies, though retailers have certain freedom as regards opening times. Unlike in other EU countries, pharmacy owners in Spain must have a university degree in Pharmacy and the location of pharmacies must observe certain rules of geographic competition; for example, the number of pharmacies and the distance between them is laid down legally.

Spain experienced a notable rise in pharmacist density during the 1990s resulting from a rise in the number of pharmacies. In the 1990s the number of pharmacies increased by 9%, and sales by 44% (Table 6). The number of pharmacies operating in Spain in 2001 amounted to 19,768. However, there is some regional

[8] In Catalonia, pharmaceutical expenditure accounted for 24% of public health expenditure in 2001. Recent data suggest that the variation coefficient has fallen from 0.16 in 2001 to 0.15 in 2002.
[9] Some 98% of drugs distributed by wholesalers go to retailers and 2% to hospitals. In addition, 99% of drugs dispensed by retailers go to patients.

variability in pharmacist density[10]. In 1997 the minimum number of inhabitants required to authorise a new pharmacy was reduced, though again, there are certain differences between ACs (Table 6). In Navarre, for instance, the act passed in 2000 introduced decentralisation and restricted the number of pharmacies subject to NHS reimbursement but allows the creation of new pharmacies. Furthermore, different regional health services have adopted different criteria for opening hours in order to improve access to drugs. While the rest of the country still has a limit on the number of authorised pharmacies, in Navarre there is no restriction on opening a new pharmacy unless the maximum number of one pharmacy for each 700 inhabitants is exceeded. This opens the door to the liberalisation of pharmacies, since the 1997 act regulating the services of pharmacists established a benchmark number of 2,800 inhabitants per pharmacy.

[Insert Table 6 about here]

The number of wholesalers hardly changed during the 1990s. About one hundred wholesalers operate in the pharmaceutical distribution market. In 2000 Spain had 99 pharmaceutical wholesalers, the highest number in Europe after Greece (124) and Italy (193). Interestingly, Spain has 191 storage facilities for drugs, the highest after France (193) and Italy (283).

4. Demand-side policies

4.1 Information policies

One of the bases of the health policy reforms initiated in the 1990s was the implementation of information policies and pharmacological education campaigns for GPs and consumers. The Pharmaceuticals Act of 1990 spurred the introduction of effective procedures for informing primary care physicians of the costs of drugs prescribed and for adjusting pharmaceutical prices to production costs. Obviously, it is highly important to inform providers and patients of their health care costs;

[10] While in Extremadura and Castile-Leon there is a pharmacy for every 1,600 inhabitants, in the Basque Country and the Canary Islands there is one for each 2,600 inhabitants; the variation coefficient for all ACs in 2000 was 0.16.

pharmacists can be encouraged to promote substitution, patients to reduce fraud and physicians to promote "rational prescribing". More recently, some regional health services have introduced individual smart cards, which have become compulsory for obtaining prescription drugs in pharmacies and allow utilisation, prescription reviews and a more efficient ex-ante control of prescriptions. In Catalonia, the creation of primary care pharmacies provides some guarantee that physicians follow official prescribing guidelines.

4.2 Cost sharing

One plausible demand-side explanation of pharmaceutical expenditure is the evolution of cost sharing. As noted in Section 3, during the two decades leading up to the year 2000 the effective co-payment rate was halved. This is often pinpointed as a plausible explanation of the rise in expenditure. 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. It is calculated that a 10% increase in the co-payment rate would reduce spending by 2.2% (Puig-Junoy, 2002).

Interestingly, one part of the population (civil servants) who are covered by a special insurance scheme (known as MUFACE) and who are obliged to make lower co-payments (30%) than the general population spend less than those included in the NHS. This finding suggests the co-existence of a level of fraud and to some extent overconsumption (the moral hazard effect) in the demand for pharmaceuticals in Spain. Additional evidence of moral hazard is found when comparing the effective co-payment of MUFACE beneficiaries and that found in the NHS. 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).

5. Provider regulation and policy

5.1 Prescription policies and clinical variability

One of the most often quoted tools for cost containment is based on the setting of incentives to moderate demand. Spain is currently experimenting with budgets and pecuniary incentives for GPs to reduce pharmaceutical expenditure. With the passing of the General Health Act in 1986, GPs became integrated into the public network. The act improved the general public's access to primary care. However, it has also led to an increase in the number of visits to the GP, a development that is likely to have some influence on the number of prescriptions. Furthermore, GPs are paid a fixed salary and have had little incentive to prescribe efficiently, and it was not until the 1990s that some contracts with providers included pharmaceutical expenditure on prescriptions. In Navarre in 1998 and in Catalonia in 1999, monetary incentives were introduced to encourage 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. Furthermore, in 1995 the figure of the primary care pharmacist was created to control prescription patterns and to advise on the most suitable pharmaceutical treatment[11].

As noted above, the largest rise in the 1990s was in cost per prescription, indicating that the group of drugs in the NHS reimbursement system were more expensive. Lack of cost-awareness on the part of physicians might have some influence in fostering moral hazard. Recent policies have focused on providing physicians with information on the price variability of different drugs and on complementing the information on new drugs provided by the industry. Some studies have pointed out that physicians are unaware of the costs of drugs prescribed: in an opinion survey Alastrué and Meneu (1998) found that only 40.9% of physicians were aware of the exact price of drugs prescribed[12]. Evidence from Catalonia shows that in 1995, 25% of prescriptions were regarded as being induced and of low intrinsic

[11] The information system to be developed in the near future for a national prescription monitoring system – through the so-called Independent Prescription Identification Terminal – might be used to identify and warn physicians who are judged to be overprescribing.
[12] 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.

therapeutic value. 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 utilisation by 10% (Lobato et al, 2000).

Recent estimates (2002) on the quality of pharmaceutical care are provided by the Spanish Hospital Pharmacy Society (*Sociedad Española de Farmacia Hospitalaria* or SEFH). They suggest that 13% of all medication in hospital care was inappropriate. Measures to reduce errors include avoiding giving similar names to different products, avoiding verbal prescriptions and ensuring greater involvement of hospital pharmacists in the process. In order to control quality of prescription, both regional governments and the central government impose what is known as the *inspection visa*, i.e., ex-ante authorisation for prescribed drugs. This is intended to improve the use of certain innovative drugs that are subject to special medical control, but in practice it is employed as a toll to contain pharmaceutical expenditure.

A recent policy proposal to promote the use of generics is prescription by active ingredient (henceforth PAI). This proposal was launched in Andalusia and followed by Extremadura, Madrid, Aragon, Castile-Leon and Cantabria. The use of PAI has increased significantly in Andalusia since its implementation in September 2001, and within roughly a year the Andalusian health system had saved around €9.88 million. The share of drugs in the PAI system easily exceeded the share stipulated for 2001. This proposal represents a radical change in the philosophy of the prescription system in the NHS. It has been well accepted by patients and is expected to affect 35% of Andalusian pharmaceutical spending. The result is that the average expenditure is €11.20 per prescription, around 1% below the Spanish average.

5.2 How pharmacists are paid

The pharmacists' payment system has traditionally been based on a fixed proportional mark-up of the consumer price before tax. This system offers incentives to increase revenues by selling more expensive drugs – and the same applies to distributors. This might explain the gradual move towards the dispensation of new,

more expensive drugs. The system has often been criticised as providing protective measures that confer illegitimate – though legal – market power and excessive revenues taking into account the dispensation costs and the stock of capital invested.

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 incentives 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%. 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.

The pharmaceutical reimbursement reform may have moderately increased the penetration of generics, but because some generics are almost the same price as original products, this provided an incentive to dispense highly priced generics which could in turn have created additional distortions into the market. Vaquero (2003) reported that 76% out of all substituted prescriptions of omeoprazole 20 mg were expensive generics. However, substantial savings may be achieved because the average mark-up decreases with the volume of sales. Thus, overall, the evidence suggests that pharmaceutical expenditure increased by 7.43% in 2000, while without this change it would have increased by 8.47% (Puig-Junoy, 2004). Interestingly, the greater savings were in ACs with the highest density of pharmacists (Puig-Junoy and Llop, 2004).

Some one-off attempts have been made to reduce pharmacists' margins, but they have had little impact on total expenditure. Generally speaking the pharmacist payment system has not produced incentives to dispense low-priced drugs. Nor does it provide "equal treatment", given the significant heterogeneity of pharmacists in terms of costs, location, population, and so on.

5.3 Payment and reimbursement of drugs consumed in hospitals

Medicines consumed in public hospitals are fully reimbursed by the NHS and rank second among hospital outlays. Drug use normally follows a prescribing protocol that is determined periodically by a "multidisciplinary committee on pharmaceutical and therapeutic agents". Furthermore, the Interministerial Commission on Drug Prices determines maximum prices of drugs supplied to hospitals. Hospitals normally work on an annual budget for drugs which is updated on a monthly basis, and physicians may be required to justify expenditures that exceed those defined in the prescribing protocols. The specialist staff at the hospital pharmacy purchase drugs directly from the manufacturers on a tender basis – and occasionally from drug distributors – and are also responsible for dispensing and further auditing.

5.4 Delisting and negative lists

The 1990 Pharmaceuticals Act laid down that drugs may be delisted when other equally effective drugs at a lower price or lower treatment cost were available, or more generally in order to control pharmaceutical expenditure. The aim of promoting a more "rational use" of drugs led to the approval of Royal Decree 83/1993, which regulated the first experiment with negative lists. Indeed, the exclusion decision aimed to take into account the specific needs and severity of certain population groups. Reimbursement was abolished for 1,692 products (e.g., food supplements, anti-obesity drugs, drugs for dermatological syndromes and drugs for minor symptoms). However, no entire group was delisted. Thus, as expected, this led to the substitution of one set of drugs for another within the same group. The second negative list was introduced in 1998 (Royal Decree 1663/1998), which excluded 834 additional drugs used mostly to cure minor symptoms, although certain exceptions were explicitly established according to the patient's severity.

Nevertheless, negative lists were never compiled with sufficient care. Indeed, some drugs were not excluded in spite of their limited social utility because of their popularity among pensioners. Examining the quality and costs of publicly financed pharmaceutical supply, Martin et al (2003) highlighted a pattern towards an increase in the intrinsic value of single component pharmaceuticals resulting from the

implementation of a 1993 programme which undertook a selective revision of all drugs even if it meant rising costs. The other problem is the persistence of "me-toos". There is a disproportion between the number of pharmaceutical products and the number of active ingredients registered, and the inclusion of innovative active ingredients is minimal. Products included in the 1993 programme 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. Furthermore, by 2002, 40% of the medicines delisted in 1990 had subsequently disappeared from the market, together with 25% of those excluded in 1998 (Martin et al, 2002).

Another significant issue was the public's negative response to these measures. Not surprisingly, 57% of the Spanish population disapproved of the first programme and the second led to controversy on a political level. Andalusia, an Autonomous Community governed by the Socialists, and Navarre, ruled by a minority conservative party (PP) government, refused to apply the plan and approved a budget increase to cover delisted drugs. Parallel to the political controversy, the National Commission for the Rational Use of Drugs, the government body created in 1992 to provide expert advice on selective financing, was inoperative from the outset. And in addition to the difficulties involved in applying government policy, the pharmaceutical industry lobbied to ensure that certain drugs were not delisted[13]. In fact, in general terms the pharmaceutical industry benefited from the shift in reimbursement from old to new products.

Although selective financing experiences also had therapeutic aims, they were mainly envisaged as cost-containment tools. The 1993 plan excluded approximately a fifth of all drugs supplied, on the whole inexpensive products whose prices amounted to 23% of the average. In fact exclusion had little or no influence on expenditure: at best it was merely transitory. This was even more the case of the second plan, which was expected to reduce spending by €210.4 million. The result was that after the first programme, between 1994 and 1998, public pharmaceutical expenditure grew at a rate of 10%, and at a rate of 9% from 1998 to 2000. However, it is difficult to

[13] With the support of the government of Catalonia – at that time ruled by nationalists – who argued that they were defending Catalan industry.

evaluate the effects of these policies as they were combined with other features such as price reduction and political pressure to reduce prescriptions.

5.5 Promotion of generic penetration

The market for generic drugs in Spain has been practically inexistent in the last two decades, as up until 1992 Spain only recognised process (rather than product) patenting[14]. The 1990 Pharmaceuticals Act was modified by the 13/1996 General Budget Act and the 66/1997 Regulation Act, which opened the door to the introduction of generic drugs[15]. The first generic brands were registered for commercial distribution in July 1997 and generic penetration has risen steadily (although leisurely) ever since to meet the EU standards (that is, 15% of the total market). In 2000, generics accounted for 3% of total NHS sales and had increased to 6.4% by 2003. However, 75% of generic consumption was concentrated in four products, and there was significant regional heterogeneity. Whereas 12-15% of total prescriptions (8-10% of sales) in Madrid and Catalonia corresponded to generics, in Galicia the figure was less than 3% (Asociación Española de Productores de Genéricos, 2002).

Measures have been introduced to promote what is known as "generics culture". They take the form of favouring medical advertising of generic drugs; full subsidies; and dispensing only generics when the prescription is based on an active ingredient. Since the approval of the Cohesion and Quality Act, pharmacists are supposed to play a wider role in the promotion of a rational use of drugs by working in collaboration with other health professionals to promote generics. Currently, only 2.83% of the drugs that can be substituted by generics have actually been replaced and savings deriving from their use are contentious.

[14] 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). However, the market penetration of copies is expected to decline gradually until 2012.

[15] 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.

5.6 The Spanish reference price system

Although Spain is a low-price country with limited generic penetration, the reference pricing (RP) system was introduced in December 2000 and reformed in 2003. This system was applied to off-patent drugs with the same active ingredient (a situation known as bioequivalence, defined by the Spanish Agency for Pharmaceuticals)[16]. A total of 114 homogeneous therapeutic drug ceilings were designed, each including at least one equivalent generic product. The reference price (RP) for each ceiling and the composition of the set of drugs included was determined by the MoH and revised in December 2000 in conjunction with a commission of the Ministry of Finance. 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.

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%. The total of 590 drugs included in the new system account for 10% of pharmaceutical expenditure and 14.6% of the market, of which slightly more than half (53%) are generics. Prices have been examined for 98 homogeneous groups. Of these, in 10 the reference price was the minimum price, but in 64 it was only 10% lower than the highest price, in 13 groups the price was 10-20% lower than the highest price, in 9 groups it was 20-30% lower and in 2 groups 30-50% lower. In 2002, 28 new homogeneous groups were added, comprising 113 products.

The main problem of RP is its limited application to a small proportion of the market. In fact, official savings amounted to 1.2% of total public expenditure on pharmaceuticals in 2001 and to 2% in 2002. However, saving estimates include compulsory price reductions imposed in conjunction with RP, some of which

[16] All the pharmaceutical products included in the same homogeneous group (identical reference price) are bioequivalent, and at least one of them has to be a generic product. This system was updated each year and it was eventually extended to most out-of-patent medicines.

correspond to copies that have not demonstrated bioequivalence[17]. In 2001, in order to reinforce RP and hypothetically to improve competition, the government imposed a 15% compulsory reduction in market prices for 5 ingredients[18]. However, due to the small number of generic competitors in Spain, this may lead to the RP being fixed above the marginal cost, and as a result it might act against competition. In 2001, 44.7% of products were priced at the reference level and only 4 out of 228 were priced above it. However, it has not been effective in bringing down the price of products initially priced below the reference level (Puig-Junoy, 2002). The net result of a year of reference pricing combined with other measures was an appreciable reduction in pharmaceutical prices during 2001 – prices rose by 1.9%, some way below the general price index (2.7%). However, rather than declining, expenditure rose by 7.93% in 2001.

A radical change in this generic reference pricing system was introduced by the Cohesion and Quality Act 16/2003 (henceforth CQA). The details for the implementation of the new approach were actively debated in the Spanish health policy arena until the act's final approval in October 2003 (SCO/2958/2003, 23 October). The CQA explicitly excludes patented products from RP and all presentations of the same active ingredient are grouped together in order to determine a reference price. The only condition for each "group" is that they have to contain at least one generic product[19]. The reference price is 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. 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

[17] Other limitations that might have been caused by reference pricing are higher prices for new drugs, the switch to non-referenced drugs and a possible delay in launching products.
[18] Compulsory reduction affected the price of products whose price was 15% higher than the average of the three least expensive ones in the same homogeneous group. This evidence confirms that some manufacturers kept the price above the PR.
[19] 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.

any medicine calculated according to these criteria will be one that corresponds to an ex-factory price of €2.

The new regulation considers three cases for pharmacy substitution when the physician has prescribed a commercial brand name (as opposed to the name of the active ingredient). If the prescription price is equal to or lower than the reference price, the pharmacist has to dispense the prescribed medicine. 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[20]. Generic medicines cannot be sold at a price higher than the reference price level[21].

Spanish producers of generics objected strongly to this radical reform of the reference pricing system because the reform implies a sudden, large-scale reduction of consumer prices for a significant part of the generic products in the market (an average 20% decrease). Some companies are facing an expected decline in revenues of 40 to 70%. Therefore, this policy works against the promotion of generics in Spain, which have not increased their market share since the introduction of the reference pricing system. Consequently, generic producers will not be able to invest in the production of new active ingredients that will be out-of-patent in the coming years. The expected result will be a reduction in price competition in the out-of-patent market and higher prices being paid by the consumer and public insurers in the near future.

[20] 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.
[21] The Spanish Economic and Social Council previously supported reference pricing, but recently it issued a very critical report on the new reform of this system. Its main objections were the fact that the products used to calculate the new reference pricing level have to be registered products but they are sometimes not on the market. This may result in supply shortages for some active ingredients because no firms price their products at the reference level. Additional concerns were heterogeneity in grouping medicines with different numbers of units, dosage and form of presentation, and the possible bias resulting from the use of defined daily doses in the calculation of prices. Finally, compulsory substitution by the pharmacist when a product with a price above the reference price is prescribed means that public financing of these products is excluded.

According to a study undertaken by the Official Association of Pharmacists of Valencia and the National Pharmaceutical Centre Foundation, the new reference pricing system is estimated to bring savings of about €623.3 million in retail sales, a reduction of 24.23% of the market of these active ingredients and 5.2% of the total prescription market. This figure emerges from the new formula for calculating the reference price (the average cost of the three least expensive treatments). The measure has been criticised as it weakens the incentives of the industry to provide discounts and promote generic drugs. As a result of pressure from manufacturers a price limit of €2 has been introduced. In addition, the CQA makes substitution compulsory when the drug exceeds the reference price. Only when the generic drugs are not in stock can pharmacists dispense the prescribed drug without substitution.

Generally speaking, 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[22]. Patient choice has been reduced if the avoidable co-payment for a medicine priced above the reference level is removed by compulsory substitution by the lowest-priced generic. The impact of this measure on price competition in the market of out-of-patent medicines in Spain is not clear. Although in the past the reference prices set were clearly above the marginal cost, price competition between generics producers took the form of offering competitive discounts to pharmacies rather than reducing consumer prices. The result was that price competition did not lead to reduced public expenditure, and that having a lower price than other generic competitors did not mean a competitive advantage. Furthermore, the new method of reference price calculation will provide incentives to increase consumption in terms of the number of defined daily doses. The reason is that the new method assumes linearity in the relationship between number of units and dosage of the active ingredient and price, and so the marginal benefit will be higher for presentations of the active ingredient with a higher number of units and dosages.

[22] In addition, the use of defined daily doses to fix the reference price for an active ingredient, contrary to the recommendations of the WHO, biases prices in favour of presentations with higher dosages and higher numbers of units. In fact, the lower ex-factory price limit of €2 will only be effective in very few cases because the reference level is mainly fixed using those presentations with a higher number of units and dosage of the same active ingredient.

The introduction of the RP system presents some interesting regional policy initiatives due to the major role of the ACs in monitoring health policy. In September 2001 the Andalusian health service introduced a new procurement mechanism that competes with the RP system applied nationwide. The Andalusian RP system defined a reimbursement system based on the active ingredient when more than two products in the market were sold at different prices. The system extends to the ten top-selling products, whereas the nationwide RP system covered only two of them at that time. The system covers 239 active ingredients and 591 homogeneous groups involving 2,900 products that account for 35% of prescriptions. The novelty of the system is that prescriptions are not made under the name of the product but under the composition of the active ingredient. The RP is determined by the highest price of the two lowest-priced products for each active ingredient and is updated every 6 months. Interestingly, the average Andalusian RP was 17% lower than the national one in 2001 (Puig-Junoy, 2004).

6. Industrial policy and the negotiation process

6.1 The Spanish pricing policy

Manufacturers negotiate to set the terms of pricing and reimbursement. The Spanish NHS price regulation for reimbursed drugs relies on controlling prices product by product on the basis of a cost-plus regime[23] 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). 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. Finally, since 1998 prices of non-reimbursed products have not been controlled, though it is rare for a new product to be launched without being included on the NHS reimbursement list.

Because price regulation has tended to freeze prices and leads to a decreasing pattern over time in real terms, the market share for old drugs is considerably smaller than that of expensive new ones. Indeed, the price regulation system might itself explain the fact that prices in Spain are lower than in other EU countries. The dynamics of the introduction of new, more expensive products may have helped to increase the cost per prescription. According to Danzon and Chao (2000), countries that regulate prices strictly and have a weak generic penetration show lower prices for new drugs, but consumption is then re-directed towards new and relatively new products.

One of the criticisms of the way the Spanish Agency for Pharmaceuticals sets the prices for new drugs is that the procedure is excessively secretive. The current system does not provide incentives to reduce prices. In addition, asymmetric information between the regulator and the manufacturer may lead to a significant rise in transaction costs. The recently passed Cohesion and Quality Act (2003) establishes that pharmaceutical pricing will remain the responsibility of the State; the Interregional Council will have a more important role but the vote of each AC will have the same weight, and this in turn reduces flexibility for accommodating policy diversity across heterogeneous ACs. Furthermore, cost-containment policies in the late 1990s led to considerable market intervention which placed excessive emphasis on reducing prices at the expense of other, possibly more important, expenditure determinants.

However, the primary concern, which reflects the lack of coherence of pharmaceutical policy, is that the debate remains limited to the role of prices rather than addressing the real problem, which, since the early 1990s, has been volume.

6.2 The government-industry negotiation process

The government implements its pharmaceutical expenditure and pricing policy in Spain through periodic negotiations with Farmaindustria (the pharmaceutical

[23] This includes production costs, promotional costs up to 16%, R&D, administrative and general costs

industry's representative body) on the basis of balancing industrial innovation targets with health policy goals. During the last two decades, agreements with the pharmaceutical industry have been the most common mechanisms for setting limits to expenditure increases. However, most of the agreements date from the 1990s; during the 1980s the Socialist government did not believe that negotiations with the industry would be helpful as they were envisaged as a way of granting privileges and thus increasing the power of the industry.

During the 1980s, an agreement on discounts was reached in 1983, and an agreement that laid down the economic and technical conditions by which pharmaceutical products could be included within the public reimbursement system was reached in 1986 (Chaqués, 1999). It was renewed in 1989. Between 1993 and 1999 four agreements were signed. The first agreement affected discounts to pharmacies and the introduction of selective financing in 1993. The next one was signed in 1995 to ensure that pharmaceutical expenditure growth would be in line with GDP growth, a 3% reduction in prices and a 1% discount in hospital provision; in exchange, it was agreed that policy on generics should not affect the legitimate interests of manufacturers and that the supply of reimbursed drugs should not be modified. In 1996, a new agreement was signed by the conservative PP government, which led to a 3% reduction in prices; it was guaranteed that net spending growth would remain below 6.6% (Chaqués, 1999) and a 4% rebate was established on ex-factory prices. 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%[24]. 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. In 1996 the industry agreed to provide €177.3 million, a figure which rose to €390.7 million in 1998.

In 1998 an additional agreement was signed leading to the creation of a general (repayment) fund to finance health care deficits resulting from drugs consumed under NHS prescriptions. Discounts disappeared and the 3% price reduction was maintained. In 1998 repayments totalled €235.3 million – equivalent to

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and finally a margin computed on the basis of projected sales volume.

4.1% of public pharmaceutical expenditure. However, some firms, among them firms that were not members of Farmaindustria, did not sign the repayment and started negotiations with regional governments and hospitals. The agreement was finally terminated in June 1999 due to disagreements on the introduction of the reference price system, and in November the government reacted with the imposition of a compulsory, unilateral 6% price reduction.

In 2001 a new three-year agreement known as the Stability Pact was signed. The agreement reduced the traditional uncertainty and allowed some prediction of future expenses. The MoH undertook not to impose unilateral price reductions and, in exchange, the industry pledged to become involved in the promotion of generic drugs, the introduction of new homogeneous groups into the RP system and the annual revision of RP. The agreed public expenditure reduction could not be more than €105.18 million and in exchange the government agreed to soften the effect of parallel trade on the industry, extend protection for data included in the official drug registry, and implement tax reductions for R&D expenses. Farmaindustria agreed to finance a publicly managed fund amounting to €60.1 million for 2002 and 2003 which could be increased according to the annual increase in pharmaceutical expenditure with a cap of €99.17 million.

Contributions to the fund depend on nominal GDP growth and can be revised if drug prescription sales increase the maximum fixed level by more than 3% annually. Interestingly, this agreement aimed to include incentives to restrict sales. However, some issues remain unsolved, such as the fact that repayments will be lower under this agreement in monetary terms or that tax deductions might reduce the effective amount of resources allocated to the fund. Finally, there might be problems in allocating repayments regionally; Andalusia, for instance, has refused to accept the agreement with the industry. Funds are supposed to be distributed by the Interregional Council assigned to laboratories to promote innovation.

6.3 Parallel Trade

[24] The maximum marginal discount could not be set above the gross profit margin.

Spain is one of Europe's leading parallel exporters of drugs. However, empirical evidence from Spanish sources on the volume of parallel traded drugs is scarce. Kanavos et al (2004) provide a stakeholder analysis on parallel trade in the European Union countries. It is interesting to note that Spain is frequently either the last or the second last country for some relatively new drugs, and together with Greece and Italy is responsible for a large share of parallel exports to other EU countries such as the Netherlands, the UK, Germany and the Scandinavian countries.

The conservative PP government initiated a plan aimed at abolishing parallel trade. In 1999, the government introduced a dual pricing system that allowed the maintenance of low pricing in Spain and a subsequent higher price for products that were to be exported elsewhere. This move led to legal action by the European Commission. More recently, in May 2003, the MoH presented a proposal (Decree 725/2003 modifying Article 100 of the Pharmaceuticals Act) aimed at containing parallel trade. This law essentially introduced the requirement for wholesalers to provide information to manufacturers on the destination of the drugs purchased, following the move by Glaxo to set up double pricing for drugs that are bought for later sale in other EU countries.

According to this initiative, manufacturers are obliged to sell at the fixed prices if these drugs are to be sold within the NHS channels but not if they are to be sold in other countries. However, the Competition Defence Court upheld an objection from the wholesalers' association Fedifar, and ruled that this requirement was contrary to the principles of free competition. Nevertheless, the last round of negotiations between the NHS and the industry concluded with an agreement whereby the MoH accepted to implement rules to put a brake on parallel trade in exchange for the acceptance by the industry of new reference pricing arrangements and the creation of a general fund for pharmaceutical innovation and research. Finally, the MoH has stepped down by saying that this was just one of the possible options under study. Some additional issues in the development of parallel exports from Spain are the emergence of pharmaceutical shortages and potential future price increases for new on-patent drugs.

7. Discussion

This paper has sought to examine the regulation of the market for drugs in Spain, at the same time evaluating pharmaceutical policies in the last two decades. We argue 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 policy tools in containing 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 meagre incentives for quality and efficiency in prescription. Furthermore, cost sharing has not been used to monitor demand and delisting experiences have produced negligible results. The market regulation has failed to promote the penetration of generics and efficient prescription. The negotiation process with the industry has been excessively secretive and consumers and providers are not aware of the costs. Furthermore, though pharmaceuticals continue to be legislated by the State, devolution brings new challenges since the Autonomous Communities are now responsible for prescription and purchasing policies.

[Insert Table 7 about here]

Although health expenditure in Spain is not much higher than in other systems with similar GDP levels, we argue that 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 overconsumption. Alternative ways of regulating prices, probably combining price regulations with profit regulations (Puig-Junoy, 1998), are to be recommended. Table 7 presents the main policies implemented to control pharmaceutical expenditure. 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. The experiences of negative lists have led to a therapeutic revision of drugs reimbursed by the NHS rather than attempts to contain 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 pay 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, we have argued that short-term price reductions do not promote 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.

Policies that seek to raise consumer and provider awareness have been limited and have not produced significant results. Quality of prescription stands as one of the main issues, together with the regulation of drug promotion. The Cohesion and Quality Act passed in 2003 established the conditions of medical prescription and new responsibilities for the Spanish Agency for Pharmaceuticals in order to increase (by evaluating) the therapeutic value of new drugs. On the other hand, the share of generics still does not reveal impressive results. However, the health barometer published by the Centre for Sociological Research (CIS) in 2002 reveals that 64.2% of the Spanish population are in favour of generic substitution, 73.8% agree that pharmaceutical cost containment requires the participation of society and only 20.8% believe that cost containment is the responsibility of public authorities. Regarding generic consumption, 81% of those interviewed stated that they would prefer to consume generic drugs and 66% support generic substitution by pharmacists.

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Tables.

Table 1. New registered drugs 1992-2000 (in packs)

	Prescription (%)	OTC
1988	325	62
	(84%)	(16%)
1989	273	101
	(73%)	(27%)
1990	337	83
	(80.2%)	(19.8)
1991	304	59
	(83.7%)	(16.3%)
1992	297	55
	(85.4%)	(15.6%)
1993	351	19
	(94.9%)	(5.1%)
1994	361	29
	(92.4%)	(7.4%)
1995	261	46
	(85%)	(15%)
1996	317	60
	(84.1%)	(15.9%)
1997	397	42
	(90.4%)	(9.6%)
1998	493	38
	(92.6%)	(7.2%)
1999	560	47
	(92.3%)	(7.7%)
2000	751	70
	(92.5%)	(8,5%)

Source: Directorate-General of Pharmacy and Health Products, 2001.

Table 2. Pharmaceutical expenditure patterns

	Total (Mill€)	OTC (Mill€)	Cost sharing (Mill€)	NHS expenditure (Mill€)	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 3. 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
2000	628,654	12.26	71.9
2001	653,917	12.90	72.2

Source: Consejo General del Colegio de Farmacéuticos, 2003.

Table 4. 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	Age-ing*		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.

Table 5. Medicine price structure (share of different stakeholders) 1986-2000

	1986-87	1988-92	1993-94	1995-1996	1997-1998	1999-2000
Ex-factory price	59	58.2	59.9	59.3	61.7	62.7
Wholesaler's margin	8	7.9	8.2	8.1	7.6	6.6
Retailer's margin	27.3	28.2	29	28.8	26.8	26.8
VAT	5.7	5.7	2.9	3.8	3.9	3.9

Source: Farmaindustria, 2001.

Table 6. Evolution of pharmacies, density and sales

	Number of pharmacies	Inhabitants/pharmacy	Sales per pharmacy (Mill€)
1986	17,138	2,251	118.59
1987	17,240	2,244	130.34
1988	17,415	2,271	143.85
1989	17,651	2,202	153.88
1990	17,896	2,172	163.07
1991	18,031	2,161	176.98
1992	18,217	2,144	184.25
1993	18,429	2,124	191.28
1994	18,593	2,108	186.85
1995	18,747	2,094	198.36
1996	18,911	2,079	207.32
1997	19,082	2,064	214.13
1998	19,224	2,056	229.08
1999	19,441	2,044	243.92
2000	19,643	2,043	252.13
2001	19,768	2,044	266.71

Source: Consejo General del Colegio de Farmacéuticos, 2003.

Table 7. Main cost-containment policies: goals and effects

Policy	Goals	Effects
Delisting experiences in 1993 and 1998	Savings and expenditure reduction	Short-term effects on expenditure and renewal of drug supply
Price reductions (several years)	Reduction in prices and expenditure	Reduction in prices but limited effects on expenditure
Information policies (several years)	To improve awareness of costs	Limited effects on agents
Generic promotion and substitution (1996-2001)	To improve market competition	Reduction of off-patent prices and rise in prices of generics
Revision of pharmacists' payment system	Reduction of incentives to increase sales by dispensing overpriced drugs	Significant effect on expenditure reduction
Prescription incentives (1996)	To provide incentives to physicians for efficient prescribing	Little evidence to date
Reference pricing (2000)	Expenditure reduction by reducing reimbursement to the reference price	Little impact on either expenditure or competition, and reduction of prices of some drugs included in the "reference price"
Industry repayments (1996-2004)	Contribution to financing expenditure on research and health care	Short-term effects on expenditure