

Challenges to Achieving Value in Drug Spending in a Decentralized Country: The Spanish Case

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ABSTRACT

Objectives: This article presents an overview of the Spanish health sector variables and drug policies as well as highlights the perspectives of new reforms.

Methods: Initially, the text frames the health sector in the sociodemographic context; it describes the past two decades of demographic changes noting particularly the very low birth rate and the growth in the proportion of the elderly. It also summarizes the main aggregate economic trends emphasizing the gross national product growth of near an annual 4% for the past 10 years and the decrease in the unemployment rate from high values of approximately 20% to half that rate in the same period, together with a stabilization of the inflation rate around 4%, still higher than EU average values. Second, this article describes the Spanish health sector organization and financing, underlining that it is mostly a publicly funded system (approximately 80% of total health-care expenditures are public) and that the universal coverage is financed out of general taxation after two decades of transition from social security-based premiums. Simultaneously to that universalization of the health-care rights, Spain started a political decentralization process in almost all the spheres of the public administration, health issues included. The article describes the changes in budgeting, management, and funding that nowadays fully belong to the regions.

Results: An essential part of the text is devoted to the

pharmaceutical sector and its policies. Drug budgets represent almost 25% of the total public health expenditures; this proportion is approximately 50% of primary care expenditures. The incentive payments to achieve a more efficient prescription are approximately 2% of primary care physicians' gross salary. Doctors in hospitals have scarce incentives related to this issue. Some examples are presented of how this decentralization process affects the pharmaceutical policies that are designed and implemented by both the central and the regional governments. Regions are currently developing health technology assessment departments that will also perform activities on the economic evaluation of drugs.

Conclusions: The planned reforms will still retain at the central government level the control of three major drug policies: authorization, pricing, and reimbursement. Several policies are currently focused on increasing the 6% share of generic drugs in the total drug market toward the EU average. The decentralization will allow the regions to modify some reimbursement policies and mainly to establish new incentives on prescription and purchasing procedures of drugs by the hospitals. The new drug agency is foreseen to assume the utilization of cost-effectiveness studies to provide economic information in the pricing and reimbursement processes.

Keywords: drug budget, Spanish drug sector, cost-effectiveness.

Introduction

This article will discuss different issues related to the drug budget management in Spain. After reviewing the main features of the Spanish health system, both socioeconomic indicators and health-care financing issues in comparison with other European Union (EU) countries, this article will

focus on the drug expenditures and drug management. The article concludes with some perspectives on different future reforms.

Recent Demographic Changes

The Spanish demographic evolution is very striking. During the 1960s, the population grew at one of the highest rates in the world, nearly 25 persons per 1000. However, during the 1990s, a slowing down process put Spain at almost the last position in the world. This rapid reversal will have long-term consequences on the health indicators, health-care services use, and social behavior, as well as in public

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Table 1 Population trends

Indicators	Year			
	1990	1993	1996	1999 (estimates)
Population (millions)	38,851	39,086	39,270	40,100
% over 65 years	13.4	14.2	15.5	16.7
% with secondary education or higher	39.3	44.4	50.3	52.0
Crude birth rate (per 1000 population)	10.3	9.9	9.0	9.3
Crude death rate (per 1000 population)	8.6	8.7	8.8	9.3
Total fertility rate	1.36	1.27	1.15	1.15
Life expectancy at birth				
Women	80.4	80.9	81.8	81.9 (in 2000)
Men	73.4	73.3	74.5	74.9 (in 2000)
Infant mortality (per 1000 live births)	7.6	6.7	5.5	5.4

Sources: OCDE Health Data Base, 1999; Spanish National Institute of Statistics, 2000.

finance (Social Security budgets). Table 1 shows the evolution in the past decade, with a remarkable increase in the proportion of elderly (over 65 years) and high life expectancy for both women and men.

Spain has a male and female life expectancy at age 65 of 16.1 and 20.0 years, respectively; these figures are among the highest in the EU, near the French values and closely followed by the Swedish values (Eurostat 2000). The age structure shows the typical profile of a developed country—that is, a low proportion of population under 20 years, 22% in 1999, and with a negative trend, compared to other neighboring EU countries, 25% with a stable trend. However, the proportion of elderly is growing slightly faster, approximately 17% more than in other EU countries (OCDE, Health data 2001).

Recent Aggregate Economic Trends

Table 2 shows that the Spanish gross domestic product (GDP) had a high and stable rate of increase—over 4%—during the second half of past decade. In fact, it is one of the highest in the EU and one of lowest values during the first half. The almost chronic high inflation rate in Spain con-

verged to EU average values to fulfill the criterion of the Treaty of Maastrich in 1998. However higher values—around 4%—started to rise afterward, although it is generally agreed that these rates are acceptable for an economy with a high rate of GDP increase. The activity rate (i.e., labor force participation) is not too high—about 50% compared to other EU countries. This is mainly due to cultural factors that have kept a low market activity for women. The unemployment rate, as measured by international criteria from the International Labour Office, has been relatively high for the past 25 years—near 20%. More recently, a reduction to 14% has been registered mainly owing to a high increase in GDP and to demographic factors; the incorporation to the labor force of the baby boomers has already ceased.

The activity distribution by sectors means that Spain is no longer an agricultural country and participation in the gross national product (GNP) of this sector is similar to that in other developed countries (4%). Industrial activity contributes a lower proportion to the GNP (18%), and the services are the dominant element in this distribution (over 60%).

Table 2 Spanish macroeconomic variables

Year	GDP per capita (market prices 1995), in euros	Economic growth	Inflation rate*	Activity rate*	Unemployment rate*
1990	10,280	3.8	6.7	49.4	16.3
1991	10,524	2.5	5.9	49.1	16.3
1992	10,601	0.9	5.9	48.9	18.4
1993	10,476	-1.0	4.6	49.0	22.7
1994	10,715	2.4	4.7	49.0	24.2
1995	11,001	2.8	4.7	49.0	22.9
1996	11,260	2.4	3.6	49.6	22.2
1997	11,705	4.0	2.0	49.8	20.8
1998 (P)	12,206	4.3	1.8	50.0	18.8
1999 (P)	12,703	4.1	2.3	50.2	15.9
2000 (A)	13,215	4.1	3.4	51.3	14.1

Source: Spanish National Institute of Statistics, 2002.
P, provisional; A, advance.

Health System Organization and Financing

The Spanish health-care sector is mainly public, in terms of both financing and delivery. Approximately 80% of health care is funded and provided by public institutions. The public insurance coverage of the general population is over 99.5%. This public coverage law includes all but a few groups of independent professionals, such as lawyers, and some other groups, such as immigrants under special situations. The Spanish public health system began in 1944 as a social security system. There was compulsory insurance for the employees that gradually expanded to include more and more groups until reaching almost the whole population in the late 1980s. Funding of this system was initially based on premiums paid by over 70% of both employers and employees. However, the premiums were not enough to finance the system when retirement payments and unemployment compensations in the 1970s started to grow rapidly and to compete with public health expenses owing to demographic and industrial crisis factors. Hence, a solution had to be implemented to avoid shortages and the health-care funding began to be supplemented with income from the general taxation or from the general budget of the nation. This income—external Spanish Social Security—increased over the years until 2000, when health care became almost fully paid by the general taxation of 97.4%; the remainder came from different services supplied through private insurance—such as car accident insurance—and from other funds as summarized in the National Health System Budget of each year.

Spanish Social Security still owns and controls the property of health centers and also hires the personnel under a special employment regime; it also maintains some control of legal aspects, such as membership cards for the insured. In addition to this major funding shift, Spain initiated a large-scale decentralization process in the 1970s, transferring to the regional governments the management and funding of different departments such as public works, health care, education, and others. By 2000, 54% of public health expenditures were budgeted by the regions under this administrative power. In January 2002, this decentralization process was completed, and the regions were given full funding for health care as well as regulatory and management power over regional health-care delivery systems. The public health-care expenditure per capita in the year 2000 stood at €740.

The public health-care expenditure as a share of the GDP was 5.3% in 1999, lower than the average

in the EU, followed only by Greece (4.7%), Portugal (5.1%), and Ireland (5.1%), and was lower than in the first two countries of this “league”—Germany (7.8%) and France (7.3%). In per-capita terms, a similar rank is obtained, and Spain, at €716, is one of the three countries with the lowest budgets. However, when drug expenditure is considered, Spain has one of the highest rates—about 1.25% of the GDP: only Portugal (1.3%) is greater and this is well above most of the EU countries within the range 0.7% to 1.0%. In per-capita terms, the figure of 192 euros is closer to the average of the EU expenditure (210 euros). The drug expenditure represents a high proportion of the public health budget in Spain and Portugal.

Based on OECD figures of the past decade, the evolution of the Spanish health sector as a share of the GDP has a profile that starts below the shares registered in other countries; the rate of growth of the health-care expenditure is monotonic in time. However, the public expenditure as a percentage of the total health expenditure does not show a clear trend; it is rather stable and in some years, such as in 1997, the proportion is lower. In any case, at the end of the past decade, the public health expenditure as a share of GNP was one of the lowest in Europe (5.4%) compared to 6.6% on average, in 1999. In per-capita terms this expenditure stood at €716, compared to €1600 on average in the EU. As for the rate of increase of public health expenditure, Spain has had a permanent and high rate of increase, well above the growth rate of GDP and justified on some occasions as converging to the EU average. Usually, this annual rate has been approximately 6% to 8% during the past decade. The proportion of public health-care expenditure of total health spending has been stable during the past decade, at approximately 78%.

According to the WHO data for Europe measured in US dollar purchasing power parity, in 1997, the average health-care expenditure in the EU stood at \$1771. This expenditure was of the order of \$1183 (purchase power parity corrected) in Spain, followed only by Portugal (\$1148) within the EU countries, and was much lower than in Germany (\$2364). Health-care expenditure can also be classified according to the types of services provided. Categorized this way, specialized care, both outpatient and inpatient, accounts for about 62% of the total public budget, and primary care—including prescribed drugs—accounts for the remaining 38%. Moreover, despite the relatively low prices of drugs in Spain, prescribed drugs represent about 55% of the primary care budget, which is a high rate com-

pared to other EU countries. Prescriptions have a share of 22% in the health-care budget, again a high share compared to other EU countries.

Health care is mainly delivered in public centers. Primary care is well developed and covers the whole population on an equitable basis—short distances even for rural areas, absence of waiting lists, emergency visits to general practitioners always possible during the day, and laboratory samples picked up every day. The public primary health-care network is now well established after the reform of the 1980s. Nonetheless, it has attracted strong criticism, such as the lack of freedom of the patients to choose a physician, the lack of incentives for doctors to perform efficiently, and the abuse of drug prescriptions. Over 50% of the primary health-care budget is devoted to drug expenditure, because a culture exists where patients consider it a right to receive prescriptions in each medical visit. However, this type of health care actually meets the demands of the Spanish population. There are also some private centers that offer primary health care to patients. They usually have a private insurance that pays the doctors and also have a system of copayment. In Spain, approximately 10% of the population has this kind of private insurance. Depending on the sources consulted, the private insurance accounts for between 3 and 10% of the total health expenditure [1,2]. As most of the population is also covered by the public insurance, much of this 10% represents duplicate coverage. Interestingly, civil service workers can choose between Spanish Social Security insurance or private insurance, although the latter is directly paid by the administration, and generally they prefer private companies. For the sake of completeness, it is necessary to mention that in the presence of major health problems, even a civil service worker who that initially chose a private insurance would enter the public system, where the technologies and centers are better than average across the country.

In Spain, a variety of entities own the acute care hospitals, totaling 798: Social Security (128), Ministry of Education (33), regional governments (91), municipalities (69), charity foundations and the Catholic Church (142), the Army (15), and the Red Cross, private insurance companies, and private companies (297) and so on. Most of the acute hospitals belong to Spanish Social Security and are larger, usually over 500 beds. The total number of hospital beds was 162,608 in the year 1999, that is, 4 per 1000 people. Because in its own centers, Spanish Social Security cannot provide specialized care to the insured population, several agreements with

other institutions have been signed. Traditionally, the costs were reimbursed on a per diem basis, but nowadays other instruments such as case mix correction and prospective contracts to pass the insurance risk to other centers have been implemented. Diagnosis-related group (DRG) and other calculations based on analytical accounting criteria were developed during the 1990s, and today there are more common information criteria.

The profile of the Spanish health-care personnel is quite striking compared to other EU countries. Table 3 shows the long-term trends in the supply of the main health professions. There has been a big change in the past 3 decades, passing from 1.34 active physicians per 1000 people to 4.2 in the year 2000, totaling about 171,500 physicians. The number of nurses also increased from 0.84 in 1975 to 5.0 (about 203,000 physicians), and the number of pharmacists more than doubled in that period, from 0.47 in 1970 to 1.15 in 2000 (or 47,000 physicians). This structure of the health personnel is unbalanced: there are too many physicians and fewer nurses than recommended by international organizations. The Spanish ratio of almost 1 physician to 1 nurse is not a guarantee of efficiency of the health-care system. The distribution of the public sector physicians and nurses per 1000 people in 1998 was 0.6 for each professional in primary care and 1.1 for physicians and 1.9 for nurses in specialized care.

When the Spanish figures of human health resources are compared to the European ones, only Italy is above Spain at the head of the “league” of physicians per 1000 people (5.5 and 4.6, respectively); however, Spain is located in the lower part when this “league” represents nurses—far below Norway and Finland (above 18) and other western European countries (about 8).

The use of health services is mainly recorded in databases on specialized care and hospitalizations. Spain has a low rate of inpatient admissions (11.4% per year in terms of total population), much lower than other countries, which have double this rate. The Spanish average length of stay is 10 days,

Table 3 Health-care personnel, 1970–1997

Per 1000 population	1970	1975	1980	1985	1990	1995	1997
Active physicians	1.34	1.56	2.30	3.30	3.82	4.15	4.2
Nurses	—	0.84	3.16	3.73	4.09	4.40	4.6
Pharmacists	0.47	0.53	0.62	0.80	0.94	1.06	1.12

Source: WHO Regional Office for Europe: Health for All Databases.

similar to the figure in other EU countries. The proportion of inpatient occupancy rate is also similar to that in other countries. The number of available beds is, however, quite variable in the EU. Spain has one of the lowest rates, 3.9 beds per 1000 inhabitants, but other countries have over 10 (Italy and Ireland) [1].

Key Processes: Incentives and Reforms

Competition and Incentives

The public health insurance through compulsory Spanish Social Security guarantees the coverage of the medical treatments as well as many preventive policies to the Spanish population. The health-care provision occurs in different ways although the most common source is through Spanish Social Security centers by personnel hired by these institutions. The reimbursement to Spanish Social Security centers is retrospective; that is, the deviations from the initial budget are fully covered without major penalties within the system. This also applies to most public hospitals as well as to nonprofit hospitals. However, during the last half of the 1990s some new ideas and incentives began to be applied. Prospective payments were introduced in specialized care settings and a small competition among centers—only in big cities having several hospitals—was introduced [3]. There is a stakeholder—the buyer—different from the payer or funder, and also different from the provider, that creates a sort of internal market that in theory it will improve efficiency. Frequently however, the same institution, Spanish Social Security, or the regional governments responsible for the health management, employ these three stakeholders, and that masks the potential virtues of this competition because at the end of the day they must submit their results to the same director.

In terms of the overall budgeting process, the general flow of money is as follows: 1) the national parliament passes the public health-care budget for the country; 2) then some money is accordingly transferred to every region, with the legal power to manage health institutions (the decentralization process that began in 1980 ended in December 2001); (3) the regional parliaments pass a new health budget that can be equal to or larger than the amounts received from the central government; and 4) finally, the money is paid to the hospitals and primary care centers to pay their staff, investments, and current operating expenditures depending on the region-specific reimbursement schemes (i.e., retrospective, per capita, per diem, per activity, per

DRG). The incentives for the personnel and the centers to perform efficiently depend on several factors, with the reimbursement system being the most important [4].

Primary care doctors of the public system are paid on a salaried basis. Their monthly payment includes several items: basic salary, approximately €14,000 per year, which is almost the same nationwide compensation for the days on duty, approximately €10; productivity, a kind of per-capita payment based on the number of patients covered by that doctor, amounting to approximately €12,000 per year for a typical doctor caring for 2,000 typical patients; and the other complements for being civil servants, approximately another €14,000 per year. Furthermore, primary care doctors may receive two additional annual payments: one related to the fulfillment of some targets, generic prescriptions, filling medical histories, smoking cessation advice, and so on, which sums to about €2,000 per year; and the other related to prescribing generics up to a given proportion of a doctor's total prescriptions, to the sum of about €1,000 per year. These quantities add up to about €40,000 to €50,000 of gross salary per year, with the incentives related to drug prescription being approximately a modest 2%. These amounts can vary across regions, but so far there are 40% of the doctors under this regime; those belonging to the regions that received the health management control in January 2002. The other regions have a different combination of incentives, but they do not represent a much larger proportion of the annual gross salary [5].

Health Reforms

All national health systems seem to engage in a process of perpetual reform as a result of their particular struggle to address the tradeoff between efficiency and equity. During the past 15 years, the Spanish health system has undergone several major reforms. The General Health Law (1986) established health care as a universal right, and it opened the door to the universal coverage of health care for all citizens regardless of their employment status, unlike the prior pure Spanish Social Security system. First, this law backed the new funding of the system that was already receiving an increasingly proportion of resources from general taxation and reducing the share of the Spanish Social Security premiums, which formerly constituted the main income of the health system; in fact, after 1999, general taxation fully financed the National Health System. Second, the law established principles of equity to apply across Spanish regions. Third, it

generalized the transference of health management to regional governments. Fourth, it encouraged reforms in primary care, specifically, by integrating general practitioners in outpatient centers together with nurses and other health professionals such as psychologists. and finally, the law set the basis for the new drug law (1990) that changed the principles for registration, price approval, and reimbursement authorization. In addition to these legal changes, it is interesting to note that this decentralization process implicitly transfers sovereignty from central to regional governments. Importantly, this means that organizational changes and the creation of new agencies can take place in some regions and not in others. This opens the door to alternative approaches to managing pharmaceutical spending and use.

During the 1990s, other health system changes focused on various initiatives: 1) greater evaluation of new health technologies; 2) new methods of hospital reimbursement; 3) the introduction of analytical accounting principles to obtain more accurate information on hospital activity and costs; 4) the creation of the new hospital managers with overall accountability to third parties, such as their own public health insurance, the staff, and the patients, as well as responsibility for coordinating the medical director, nurse director, and administrative director; and 5) the introduction of new training programs for the new staff. These training programs created a small revolution. New technologies such as computers came to be widely used throughout the system during the 1990s; also, quality assessment units spread out all over the country. Primary care pharmacists began to give advice on costs and therapeutic effects to primary care doctors. The application of economic evaluation criteria began to be applied on a voluntary basis for planning and decision-making processes. Several centers began to perform transplants, and the list goes on. In summary, a major modernization of the Spanish health-care system occurred during this period, and it is very likely that during the next few years we will witness the consolidation of these changes, unless new reforms overtake them, which is common in many health systems.

Health-Care Financing and Budgeting

Financing

Since 1999 health care in Spain has been financed by general taxation; before this, financing was a combination of work-related Spanish Social Security premiums, which decreased their proportion

progressively over time, and general taxes. Out-of-pocket spending for health care is due mainly to copayments for drugs, private visits to physicians, and private insurance premiums that people buy on a voluntary basis to obtain, for example, a private hospital room and shorter waiting time for a specialist. Copayments for drugs, 40% for the general, active population, are not directly related to income level, but there are some alternative levels for special groups: zero for retired citizens, 10% for chronic treatment in active population, and a fixed 30% copayment for both active and retired public workers. As was mentioned above, the proportion of public expenses of the total health sector costs is approximately 76%. Copayments account for a low proportion of the health system funding, approximately 7% on average, of the public expenditure of prescribed drugs, and are questioned by several authors [6,7].

National-to-Regional Budgeting Process

The national and regional health budgets are approved by the Spanish parliament. Spain is the most decentralized country in Europe and very likely in the world. The decentralization process has transferred to the regions the funding and management of health-care services, including pharmaceuticals. The culmination to this process was in 2002 when the new financial agreement between the central government and the 17 regional governments placing the management of all public services in the hands of the regions. This financial agreement has three components—one of which is related to health care. To summarize this process, the central government computes aggregate national health budget as the sum of the final public regional expenses in the year 1999 adjusted upward by an annual rate of increase. This total amount can be divided into three funds: general, specific, and a fund to guarantee at least the amount available in 1999 for each region. The funds are also adjusted using a formula based on the population of the region, weighted depending on the proportion of people aged over and below 65 years. The specific funds promote a greater health cohesion across the regions and aim to avoid some frauds detected in the past around the use of sick leave. The monies are not directly transferred to regions from the central government, but are raised by taxes whose revenues are now part of the new incomes of the regions. That is, a significant proportion of these funds are directly collected by the regions instead of received from the centralized budget. Regional parliaments must pass their own

health budget; however, they are not totally free to determine the amount of this particular expense because in the new agreement there is a constraint: the resulting amount after the application of the formula for each region can be supplemented with other funds but cannot be decreased or used for other purposes. In the new agreement, there is a dynamic rule to increase the aggregate national funds for health based on the growth of GDP and of some revenues arising from several taxes of central and regional governments [8].

Regional Health Budgets

Regional health budgets are planned by regional health authorities working with their respective departments of economic affairs that have different names depending on the region. Health budgets are frequently based on the previous budget plus a percentage increase; budgets also include new investments (i.e., not only operating costs) that can be independent from the previous and new budget. In general, the new budget limit is frequently based on the public finance approach of “budget incrementalism,” which increases in a more or less constant proportion (e.g., 4%) to last year’s budget. Also, regional health budgets are divided broadly into primary care and specialized care. Within the primary care budget, drug spending is a very important component, usually greater than 50%. The overall specialized care budget does not, however, have a similar, specific line item for drugs. This regionally approved general health budget care is distributed among centers—mainly hospitals and primary care centers. Hospital managers propose their own institutional budget, probably with at least one line item for drugs, and they are committed to control it. Something similar applies to primary care centers although the budget control—for the sake of the information systems efficiency—is usually more centralized. That is, the director of each primary care center receives the lists of his or her physicians and their corresponding aggregate expenditure figures of the drugs prescribed during each month from the regional health authority so that a more direct control can be achieved at the primary care center level.

In theory and on paper, there is a limit to the aggregate drug expenditure in primary care. However, it is important to note that government budgets are a special case in the sense that they estimate incomes that can be either lower or higher than planned, but limit expenses to the figures approved. Any budget law has two exceptions to this general

rule concerning the limits of the expenses: retirement payments, if retired people live more than planned they receive their payments, and prescribed drug expenses. Even if more people get sick than expected, drug reimbursements are made, or as they operate in Spain, payments are made to pharmacies, no matter how much money is left in the budget, at least within some range of possible fluctuations. So far, health budgets for pharmaceutical expense are not subject to a rigid constraint: patients are not denied drugs when the budget is exhausted, as they are in some systems. The same applies to specialized care where hospital drug bills are paid although the final expenses may be higher than planned. This flexibility is not abused probably owing to the constant monitoring and messages from the health managers and authorities on how the drug expenditure is evolving and that it is higher than planned. Therefore, there is a kind of permanent pressure on practitioners to stay within budget.

In some regions, an incentive system is used to match the planned expenses with the real ones; this system applies to primary health-care centers that receive a new drug budget depending on the compliance of the previous targets. Most of the regions provide some incentives to doctors in the sense that they can receive a lump sum at the end of the year when performance objectives are met, including budget targets as well as other ones, such as generic drug prescription rates, reduction of waiting lists, compliance with hypertension treatment guidelines, use of preventive and obesity programs, and reduction in referral rates of patients to specialized care. Some regions go further and have an incentive system where the achievement of goals related to drug spending yields a reward equally distributed among doctors, nurses, and ancillary staff; in those cases, indirect controls—monitoring and surveillance—of medical decisions by other professionals are often used. This technique is disliked by providers but does give positive results in terms of keeping drug spending within budget.

In specialized care, the individual hospital manager is committed to control the hospital’s drug budget, and when spending deviations from the local budget are detected, the pharmacy department must explain the causes; however, in these settings there are neither positive nor negative incentives for doctors support the achievement of drug budget goals. On some occasions, conflicts of interests occur among doctors, pharmacists, and hospital directors. Usually an agreement is achieved among the parties, and a prescription guideline must then be followed.

Adjustments over time of drug budgets within a region are made according to demographic criteria, for instance, population size if migration takes place, weighted by the age, and also according to the spending results of the previous year. For instance, if the real rate of increase were 10%, it would not be logical to think that in the following year there would be a zero increase. Regional health authorities make these adjustments for their own regions. The drug budget of each primary care center may also be adjusted as a consequence. The specialized care drug budget is adjusted taking into account the activity of the hospitals. For instance, there may be adjustments owing to changing morbidity patterns, technological innovations, administrative changes such as new assignment of population to a hospital, and so on. Patients are referred to specialized care both to outpatient specialists that perform their consultations mainly in hospitals and to get an admission by primary care doctors. Specialists can, of course, recommend a hospital admission as well as the emergency service of a hospital. These issues condition hospital performance and growing budgets and help to explain and understand the continuing rise in drug expenditures.

Pharmaceutical Budgeting and Use

In spite of the Spanish administrative decentralization process, almost fully accomplished in the health-care system, the central government still retains the control of three major policies: authorization, price regulations, and reimbursement. For the authorization, Spain uses the EU criteria of multicountry recognition, centralized procedure, and single country registration. However, for price regulation there exists a norm that must consider several criteria (sales forecast, research and development expenditures for the new drug, production costs, and so on), as well as, if known, the price of that drug in other EU countries. Reimbursement approval is almost automatic once the drug has an authorized price [9]. Only some few drugs either that deal with minor health problems or that have a low efficacy are excluded from this public policy [10].

The central government is also concerned with budget control, although one could think that after transferring the health management to the regions this will not be a meaningful issue. In fact, in 2001 a general agreement on stability, called “El Pacto de Estabilidad,” was signed by the central government

and *Farmaindustria*, the Spanish association representing the pharmaceutical industry. This agreement fixed the limits to the annual growth of drug expenditures that will be globally reimbursed. If they surpass the limits a general discount should be applied by the industry in the sense that some funds from *Farmaindustria* will be sent to the public administration to finance some research activities related to health. Nonell and Borrell [11] give a description of the relationships between government and the drug industry.

The regional drug budget is not divided in advance by either disease or therapeutic subgroup. However, there is an a posteriori classification of drug expenses according to therapeutic groups to understand how it was in fact distributed as well as to examine the variation of morbidity on prescription habits.

The outcomes of the budgeting process are the result of many forces—and politics is not a marginal one. Regional health budgets do not compete directly with other expenses because the fund is linked to health services and because adjustments to this amount are covered by the general agreement on regional funding. However, the increases in that amount might conflict with other departments and the solution to that problem is, hence, political. An efficiency criterion such as “let us expend on those public services that have a higher return rate” is not used, probably owing to the difficulties of knowing or estimating the monetary value of the benefits of health care as well as the value obtained from other public services. Therefore, budget incrementalism with adjustments for various specific criteria—population, innovation, tax revenues, and GDP values—is the most common solution used in this public budgeting process. Medical decisions are taken according to efficacy, safety, and budget availability. This means that short-term budget constraints override considerations of efficiency, which usually require a longer time horizon to study both the costs and the effects on health. In this sense, the regional budgeting process in Spain is not using the results of a systemwide evaluation of pharmaceuticals and other health technologies. Clearly, then, this process does not routinely incorporate the efficiency outcomes of different activities in developing spending priorities.

Regional Technology Assessment and Regional Policies on Drug Expense Control

The Spanish central government regularly publishes a bulletin with the therapeutic information for pre-

scribers and pharmacists in the national health system. New drugs are classified according to their quality—mainly efficacy, safety, innovation, and capacity to treat new diseases. Technology assessment is also formalized in several regions and, in the near future, all the regions will have their own units for this purpose. Currently, there are a variety of mechanisms by which the regional health authorities make these assessments.

Some regions have a variety of pharmacoeconomic guidelines or requirements. Examples of this approach include bulletins and Web pages that regularly publish the evaluations of new drugs, describing several parameters, such as relative efficacy and safety versus comparators and the price per defined daily dose. Usually, the presentation of the assessment adopts the form of a classification—a kind of cost-consequences analysis—and sometimes a ranking is established. These assessments do not typically consider the long-run effects of treatments and the possible necessity of specialized care utilization, such as hospital admissions, derived from each option. Patient well-being and quality of life during treatments are frequently secondary elements of these assessments. One reason for this is that many new drugs provide a convenience benefit or higher quality of life during treatment, but have the parameters of efficacy and safety similar to those of other existing drugs but they are traded at a higher price; further, their long-run effects are unknown at the moment of the introduction in the market. Other regions analyze what is called the “intrinsic evidenced value of the drug,” a way of weighing together safety, efficacy, quality of the drug (including ease of administration, adverse effects, and price per defined daily dose) and classify the drug accordingly to inform prescribers. In one region the assessment unit mainly focuses on the newly traded drugs and analyzes their value for health outcomes as well as their price in relative terms with the existing drugs. Because these assessments must guide current medical decisions even when full information is not available, the bulletins often have a short-run focus and are written keeping in mind the relevance of budget control; assessments with these limitations run the risk of presenting a somewhat biased profile of the situation.

In some regions, health authorities evaluate drug therapies for specific diseases, and then they recommend a prioritization of the therapies with budget control being a crucial criterion. Other regions review major therapeutic areas and select the most effective drugs in each one. Then health

authorities require manufacturers to provide their whole set of drugs at prices lower than the maximum authorized prices of the central government. If prices are considered by the health authority to be low enough, then that manufacturer can provide the drug to the hospitals located in that region. Otherwise, they may not be permitted to sell them in the region concerned. In a further step, each particular hospital can negotiate an additional discount with each manufacturer. Thus, there could be two discounts from the maximum central government price.

Other regional policies that would possibly be applied in several regions in the near future are related to what is called “maximum pricing.” In Spain, the central government is entitled to fix the price and the reimbursing conditions of drugs. That price is considered as the upper threshold of the price and manufacturers usually trade their products at that price. This applies to prescribed drugs in primary care. When drugs are sold to hospitals, there are often special agreements based on total sales, and discounts are commonly applied. Since 1999, a reference pricing scheme has also been introduced at the same time as the increase of new generic drugs in the market. However, in Andalusia, an additional step in reference pricing is operating. Under this maximum pricing policy, the two lowest prices of each drug in Spain are taken, and the price of the second lowest is considered as the maximum price that would be reimbursed by the regional government to the pharmacies. Hence, pharmacists provide patients with one of these drugs that doctors prescribed under their generic name. Incentives for doctors are related to the rate of prescribed drugs under their generic name; patients will save the proportion of the copayment of a cheaper drug, and pharmacists will keep lower stocks of many drugs and will focus on the two of lowest price of each active ingredient. Further, an information system was designed so that when doctors prescribe a drug whose price is higher than the maximum, a warning signal appears on their terminals. Health authorities then will have an easier budget control. Patient well-being will probably be lower because of the fact they get lower quality drugs, for instance, with different administration paths and dosages, and on some occasions more laboratory tests are needed because cheaper drugs require a closer follow-up; the same applies to the visits to the physician. Thus, the attempt to control the drug budget can lead to unanticipated increased resource use in other health sector components.

Economic Implications of the Budgeting and Allocation Process

General Process and Incentives

The budget process, as has been described here, has three main steps: 1) the general funding of the health system through general taxes that provides care on an universal coverage basis; 2) the distribution of the funds to the regions based on population size and economic criteria; and 3) the allocation of the regional health budget among the different components. The first two steps are neutral with respect to the utilization of pharmaceuticals as well as other health services; however, the distribution of funds among the health services can be used to pursue alternative drug spending policies. In this sense, the budget can be a powerful tool to promulgate health policies, by redistributing the supply of funds it will condition and induce the demand for each type of care. In the case of drugs, the initial allocation of budgets together with the incentives created by regional policies create alternative options to control the total expense and define the “rules of the game” between health-care providers and patients.

The stated national policy position aims to guarantee that patients receive the right amount of drugs as well as have access to the right types of drugs. But usually the policies are oriented to encourage the selection of the “most adequate active ingredient” (a difficult-to-define concept) with a lower cost per daily dose. As is common in public health systems, the socioeconomic circumstances of patients should be independent of the application of that general policy.

Budget impact analysis is probably the type of study most frequently implemented; many decisions on drug policy are taken based on the results of this kind of analysis. As is well known, the utilization of the information provided by a budget impact analysis is not necessarily sufficient to improve the efficiency of the system, but is rather just a budgetary control. More studies on the efficiency of drugs should be promoted by both the industry and the public health system; these kinds of studies assess health outcomes and costs, and the resulting information could help lead the system toward efficiency. In the Spanish system, this third step of the budget allocation is the logical place to establish incentives for efficient prescription and not just on cost containment. Nevertheless, studies on the efficiency of health technologies are difficult to develop, but one cannot deem a budget system to be totally ineffi-

cient just because there are not enough studies for all resource allocation decisions. Both incentives and information are important.

Some Examples and Their Implications

Many Spanish regions distribute their regional primary care budget among several primary health-care centers. Some regions have a budget process designed in such a way that proportionally lower funds are assigned to the centers with a higher per-capita expense in the previous year. Doctors working in those centers have an incentive to redistribute their prescriptions in the way that would tend to introduce a lower proportion of new drugs, usually at higher prices than the older ones, compared to regions without this process [12]. Consequently, the utilization of generics is reinforced in centers with severe budget constraints as an easy way of meeting budget targets and the diffusion of new drugs is slowed down.

In some Spanish regions, health budgets are allocated to primary care centers depending on performance in relation to a group of targets agreed between each center and the regional health authorities. They sign what is called a “contract-program.” One of the common provisions of this contract is that the prescription of pharmaceuticals must increasingly be based on generics and also keep the budget under control; however, if drugs are first prescribed by a specialist, then those drug expenses are excluded from the objectives of this primary care contract. This combination of incentives may ultimately result in the referral of patients to specialized care because the specialists initially prescribe a more innovative therapy and also are more expensive. While the contract targets would be met, this activity places an additional burden on patients, who must wait for the visit and travel twice, and on specialists, who then have a heavier work load. This can increase costs overall.

Options for Reform and Improvement

National Drug Policies

For the past few decades many health reforms in Spain have focused on drugs. During the past 7 years the introduction of generics has become a reality (approximately 6% of the prescribed drugs in 2001 were generic), currently with an increasing trend, although still lower than the average proportion of the EU countries [13]. and since 1999 a reference price system began to operate with some groups of pharmaceuticals, initially 114, and in

2002 about 200, where there exists a generic drug that is already traded.

The Spanish central government has retained control of three major drug policies: authorization, price regulation, and reimbursement. The 17 Spanish regions must manage their own health budgets, and they complain that it is impossible to fully manage a process when a third party—the central government—takes key decisions that affect regional budgets. Hence, the new Minister of Health has recently proposed to integrate the regional health authorities in these three policies. Also the regions, as some have already done, will have some capacity to set maximum pricing policies that will not conflict either with the reference pricing scheme or with the reimbursement policy that is very similar throughout the whole country, although the Andalusian government reimburses some drugs that have 100% copayment elsewhere.

In September, 2002, the new Minister of Health also announced that the new drug policies will need to take into account the efficiency criterion, but she was not more precise; therefore, it is still unknown which policies, price and/or reimbursement, will be affected and what weight studies of efficiency will have in the final decisions. Something similar already applies to regions where some health authorities have incorporated this concept in their programs and public declarations.

The new Minister also aims that the reimbursement policy, which currently includes almost all new drugs, will change and will only finance new drugs that can prove a significant improvement compared to the existing ones.

Price and Substitution Policies

Other centralized policies also announced by the Ministry of Health will further promote generic drugs and will oblige the pharmacists to deliver the cheapest generics with the same therapeutic outcome. In the medium run, all manufacturers with drugs in the same homogeneous set with a common reference price should equalize the price. The reimbursement policy that currently almost includes each new drug will change, and it will only finance new drugs that can prove a significant improvement compared to the existing ones.

Parallel trade will be reduced; there is a new royal decree under preparation in the sense that the distributors of drugs should be able to trace their sales and then, de facto, the parallel trade will not be able to operate; this royal decree would theoretically eliminate the necessity of pricing drugs in the

same rank of values of other EU countries, generally too high for the Spanish purchasing power [14]. This may help to avoid or slow the rate of increase in drug spending.

Organizational Changes

Each region could develop its own health policy and establish incentives on different issues, such as the evaluation and use of drugs; some of these policies could use the drug budget as a vehicle but others could add information campaigns based on efficiency analysis. In fact, new regional agencies or units for the evaluation of health technologies are starting to work and to produce their first documents.

Primary care pharmacists—a new kind of staff in some health-care centers and in the primary health-care authorities—will increase their activities advising on the rational use of drugs to physicians and study the prescription habits to develop further policies. Several prescription guidelines have been developed by regional health authorities, and there are more under study.

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