

Economic considerations regarding pharmaceutical expenditure in Spain and its financing

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Introduction

This paper seeks to provide some reflections on the behaviour of health expenditure and the evolution of public health financing, with particular attention to spending on pharmaceuticals. The first part attempts to lay the foundations for a series of considerations on the effects of policies aimed at restraining public health expenditure, in particular drug expenditure. In the second part we offer the reader some reflections on what could constitute an alternative framework which would help to rationalise decision-making processes on pharmaceutical financing and spending.

The problems involved in financing health care

For some years now, the sustainability of the social protection systems that have shaped what we call the welfare state has been a recurring theme in the European political and economic debate. In this debate, the future of the financing of public health care has been one of the most controversial issues, for at least two reasons: because health spending is one of the items that receives most attention from citizens, and because this spending has risen significantly (the proportion of Spain's income spent on public health care has risen nearly 25% in the last decade). Furthermore, the factors that contribute to this growth do not appear to be abating, thus raising doubts as to the financial sustainability of the system.

Spain undoubtedly constitutes an atypical case in the context of the European Union (EU) as regards the growth of public health expenditure within health expenditure as a whole. A cursory look at the figures reveals that the percentage of public spending within overall health expenditure remains very stable (if anything, showing an upward trend) throughout the period considered. This means that the pressure of increases in health spending, in a period of relative growth in income (between 1980 and 2000 the income gap between the Spanish figure and the average for the European Union shrank by 15 points, up to the 85% level at present), was directed just as much at public as at private financing, if not more. Income elasticity (the extent to which a good is considered a "luxury") has proved no different for public and private provision. This observation is contrary to what we would expect (beyond a certain threshold, "normal" social

development substitutes public spending with private spending), although perfectly explicable from the perspective of politics and social choice (in the disjunctive between funding at the expense of the taxpayer and at the expense of the user, ultimately the former weighs more heavily!).

Neither does cross-national comparison of the Spanish health spending yield straightforward conclusions. Although it is true that aggregate data on Spanish public health expenditure show a major difference (some 25%) from the average for many advanced countries, it is important to understand that the comparison is misleading, as it fails to take into account either the different development levels of different countries or the inordinate weight of countries with a tradition of insurance (whether social as in Germany, the Netherlands and France or private, as in the USA) in the OECD sample. Thus, using this benchmark is tantamount to accepting that Spain should increase its expenditure to match that of these countries (a move that we doubt is shared by some of those who propose changes to the system), and that we do not consider the concept of income elasticity in the growth of this social expenditure (which contradicts their own arguments). Both extremes strike us as erroneous.

Therefore, if we take into account the income gap and/or limit the comparison to European countries with public health systems similar to those established by the Spanish General Law on Health, or alternatively, if we look into how much these countries spent – in the past, because they have a lead over Spain – when they had the same level of income as Spain has now, we find that Spain's expenditure is as it should be for its level of development and not less. The overall valuation is, therefore: *a*) if Spain has the right level of health expenditure, why are mistaken arguments for increases in public health spending wielded for the (indiscriminate?) satisfaction of various pressure groups or lobbies (trade unions, the industry) without any point of reference as regards coordinated actions for health improvement? *b*) as the relative income of the Spanish population increases, it seems likely that the growth in health expenditure will likewise do so, the evolution of its distribution (between public and private health spending, i.e., at the expense of either the user or the taxpayer) being at any rate, a crucial endogenous decision for health policy.

In effect, there is an additional error in the conventional argument in favour of new (an indiscriminate) increases in spending: not only is the destination not selected, but there is not even any self-interrogation as to how it would be financed. In practice this means ignoring the need to balance the budget (nothing is free in this world: so what taxes are to be increased? Indirect regressive taxes?), or even opting to return to public deficit (as if debt did not have perverse intergenerational redistribution effects): how can we be concerned about the environmental legacy we leave to our children but not the financial burden of debt?.

Common sense thus requires us to shun fundamentalist approaches and pay more attention to the details of public spending policies, i.e., what Atkinson calls the "subtle" structure of welfare programmes (type of spending, aims, institutional aspects, profit regulation, conditions of access, selection of beneficiaries, method of financing, etc.). In short, it is not true that "all's fair".

To sum up, the question that should concern decision-makers now is not so much whether Spain's current level of expenditure can be put on a par with that attained by its neighbouring countries, but rather to what extent current growth rates of public health spending are compatible with the income scenarios fixed by the Spanish public sector in the process of European convergence and its frameworks of stability.

Prognosis

However, in order to voice an opinion on this issue, it is first necessary to gain an understanding of the behaviour of expenditure and the factors that do most to stimulate its growth.

As we have stated elsewhere (López-Casasnovas¹), there is ample reason to believe that the rise in health spending in Spain can be traced to the diagnostic and therapeutic content of average health provision, for which the forecasts to date predict an increase in use as a consequence of the ageing of the population.

Although it is true to say that health care prices are to a large extent endogenous in the public sector (doctor's salaries, at least in the short term) and demographic change is predictable, the evolution of average real provision depends to a lesser degree on governmental decisions.

In fact, the evolution of the factor utilisation depends on a series of variables (the system's ability to solve problems using lower-cost alternative treatment, frequency of service use and the evolution of the intensity of care and/or the degree of "intensity" of technology per care episode), the control of which by the authorities is complicated at best. If the technological frontier is being moved up rapidly in the health sector (combinations of drugs in the treatment of AIDS as the main challenge), new drugs such as statins, antiasthmatics, antipsychotics and antidepressants are appearing (adding rather than substituting existing ones), the population is ageing, life expectancy is increasing (although some unknown quantities remain in the association between ageing, average functional disability and morbidity) and we aspire to improvements in the quality of life (thus blurring the dividing line between health expenditure and social expenditure). Indeed everything is pointing in the direction of new rises in spending due to the diagnostic and therapeutic content of average real health provision.

If this is the case, the relevant question is not whether health expenditure will increase or not (in our opinion it will undoubtedly increase) but rather how its financing will evolve: will both curing and caring be provided through public funds?. Note that this question is easier to answer if the variation in average real health provision occurs mainly in terms of effectiveness, in which case it is possible to discuss its cost-effectiveness ratio as regards public financing. It is much less so, however, when the evolution of the provision incorporates elements of utility or welfare. Although the line between "curing" and "caring" is not always easy to draw, it would seem logical for "exchange value" components (e.g., utility derived from freedom of choice) to have a financial treatment that is closer to the individual user than to the joint or collective user, considering the

greater importance of subjective (and as such less definable) judgements in the former than in the latter.

Thus, in the absence of a general process of rationalisation of decision-making in the health sector, social pressure on public health expenditure can put its financing in a very complex situation. The influence of an increasingly “medicalised” society that expects the health care system to be able to solve practically all its health problems on the rise of new technologies (personalised treatments) and in the face of new diseases, forces authorities to practise a very cruel prioritisation: the possibilities that health science opens up are global, but the resources available for applying it are local. Hence, any rationing is seen largely as a frustration of collective welfare, and political confrontation can yield major electoral rewards.

A minimum of realism in the definition of health policies would thus advise governments to start drawing up alternative scenarios in order to direct all the foreseeable pressure that will be generated by the growth in health expenditure along channels other than those that at present affect the public financing of this expenditure. In the coming context, perhaps the optimal approach would be to concentrate this financing selectively, on provision that passes cost-effectiveness criteria, thus “decompressing” the general tax burden. This is the case not so much because of the level this burden has reached again in Spain (the ratio between compulsory government receipts and GDP lies in the low bracket in cross-national comparisons) as because of the difficulty of introducing new tax increases when rates are strait-jacketed by the fierce competition in international trade.

Pharmaceutical expenditure within health expenditure as a whole

Let us now go on to take a look at some aspects of the role played by medicines within average real health provision (i.e., that of the growth of pharmaceutical spending within health spending). This implies a return to the view that drugs constitute an element of the overall combination of functional expenditure for health production and not an isolated input. Under this approach, and as mentioned above, the expectations of a medicalised society regarding the ability of modern medicine to cure and care, together with the appearance of new lifestyle drugs (drugs against depression or obesity, Viagra®, etc.), all contribute to raising the pharmaceutical bill (see Table 9-1).

Table 9-1. Distribution by categories of the 50 top-selling drugs in the world. Years: 1988-2002 (estimate) (number of products)

Category	1988	1993	1998	2002
Elderly	27	28	22	25
All ages	21	15	18	15
Lifestyle ^a	2	7	10	10

^a Defined as drugs that make one feel better rather than just well, for example, drugs for treating impotence, high lipids or menopause symptoms, and contraceptives.

Source: *The Economist, Special Supplement on Drugs, 2000.*

The realities concealed by the figures are, however, far more complex than a straightforward reading would imply. Although it is true from a temporal perspective that Spain went from spending 14.9% of its overall public health expenditure on pharmaceuticals in 1987 to figures in the region of 23% – not including hospital pharmacy – in 2003 (as opposed to the European average of around 13%), the figures for spending in terms of population are far less anomalous. Pharmaceutical expenditure per capita paints a very different picture, actually showing lower levels for Spain than for the average of Western countries. For the purpose of these comparisons, the inferences vary according to whether the yardstick is captitative (populational) or based on the GDP (income), and whether we consider pharmaceutical spending as a proportion of overall or public health expenditure. Therefore, simply contemplating the multifaceted nature of the problem enables us to reach diagnoses that come closer to reality, as we will explain in the sections below.

Some more figures and facts

In Spain, pharmaceutical expenditure has recently been subject to all possible cost containment measures (negative lists, reference pricing, price control, generic introduction, transfer of return above an agreed threshold, and price reduction by decree). Nevertheless, it should be stressed that drug prices in Spain appear to be below the European Union average (see Table 9-2), in view of which the problem with pharmaceutical expenditure is above all a problem of overconsumption and dispensing costs. Given the existence of an active parallel trade, control over expenditure entails more factors than one-to-one negotiation with the laboratories directly involved: pharmacies, users and especially prescribers are key, despite which many of the measures used in pharmaceutical cost containment often do not seem to be fully directed at these protagonists.

Table 9-2. Weighted average price of pharmaceuticals in the main European Union countries in 2001 (Spain 100)^a

	Retail price + VAT %
Germany	203
Netherlands	176
UK	186
Belgium	169
Italy	116
Spain	100
France	93

Source: La industria farmacéutica en cifras, Farmaindustria, 2001.

^a A valuation that is properly adjusted to reality ought to consider the weightings of these prices in greater detail (given the diversity in amounts of consumption affected) and their different composition between prices of old and new products (given the effect this can have on their dynamics). Other studies provide a variety of data, quantifying with various weightings and at PPP values, but to date we have not encountered any statistic that offers a synthetic price index that is higher than the European Union average. Obviously, if this were not the case, the well-known problem of parallel trade would not exist.

We would draw attention to some additional information shown in the tables below: Spending on drugs show for Spain *a)* a public pharmaceutical expenditure/GDP ratio 50% higher than the average, *b)* a per capita PPP expenditure much closer (still below) to the average, and *c)* the highest public drug expenditure expressed as a percentage of the total out of all the countries considered (Table 9-3). A good analysis of this can be found in Puig-Junoy².

Table 9-3. Spanish Social Security drug consumption through pharmacies (retail price + VAT) (1988-2001)

Year	Consumption (current million pesetas)	Annual increase (rate)
1988	310,845	16.2
1989	360,363	15.9
1990	413,208	14.7
1991	481,189	16.5
1992	558,534	16.1
1993	600,027	7.4
1994	635,007	5.8
1995	720,949	13.5
1996	800,853	11.1
1997	842,264	5.2
1998	926,262	10.0
1999	1,016,003	9.7
2000	1,097,472	8.0
2001	1,211,582	11.1

Source: *La industria farmacéutica en cifras*, Farmaindustria, 2001.

In this context, Table 9-4 shows a certain amount of convergence in the relative weight of public pharmaceutical expenditure within the GDP. Over the last two decades those countries that started at lower levels have come to have higher rates than those that started at higher levels (Germany, Belgium, France), with the result that the 2000 percentages are closer than those for 1980. Finland and Denmark are extreme cases, considering the constancy of their low ratios in time.

Table 9-4. Public pharmaceutical expenditure as a percentage of GDP

	1980	1985	1990	1995	2000
Austria	0.5	0.5	0.5	0.6	0.8
Belgium	0.7	0.6	0.5	0.6	0.9
Denmark	0.3	0.3	0.2	0.4	0.4
Finland	0.3	0.3	0.4	0.5	0.5
France	0.8	0.9	0.9	1.0	1.2
Germany	0.9	0.9	0.9	0.9	1.1
Ireland	0.5	0.5	0.5	0.6	0.7
Italy	0.7	0.9	1.0	0.5	0.7
Netherlands	0.4	0.4	0.5	0.9	0.9
Portugal	0.8	1.0	1.0	1.3	1.3

Spain	0.8	0.7	0.9	1.1	1.3
Sweden	0.4	0.4	0.5	0.8	0.9
UK	0.5	0.5	0.6	0.7	0.7

Source: OECD
Health Data

Table 5 shows the evolution of public pharmaceutical expenditure as a percentage of total public health spending. Note at this point that the very high Spanish figure rises over time, whereas Germany and Italy seems to stand still. Although they have managed to “anchor” their total spending on drugs at a low percentage of their GDP, the Nordic countries unmistakably register also significant rises in the public pharmaceutical component within public health spending: Sweden doubled their proportion, and Denmark and Finland’s rose by 50% or more.

Table 9-5. Public pharmaceutical expenditure as a percentage of total public health expenditure

	1980	1985	1990	1995	2000
Austria	10.3	10.0	10.3	11.1	14.4
Belgium	11.9	9.8	8.2	8.9	14.9
Denmark	3.7	3.7	3.1	5.5	5.6
Finland	6.3	5.5	5.5	8.6	10.4
France	13.0	13.9	13.6	12.5	17.4
Germany	12.5	12.8	13.6	11.4	11.6
Ireland	7.1	7.9	10.4	10.8	13.0
Italy	12.1	15.7	15.6	10.2	12.2
Netherlands	7.0	7.5	8.8	12.7	17.2
Portugal	21.2	30.1	23.7	26.3	22.8
Spain	16.8	15.7	16.2	18.7	23.7
Sweden	5.0	5.4	6.4	10.6	11.7
UK	9.3	10.5	10.9	12.0	14.3

Source: OECD
Health Data

Table 9-6. Some other (financing) pharmaceutical indicators. 2000

	Public /total Pharmac. Costs	Public Pharmac exp/ Public pharmac.costs	Patient copay/ public pharmac. costs
Austria	90.3	85.9	14.1
Belgium	69.8	82.9	17.1
Denmark	79.7	54.2	45.8
Finland	66.6	61.7	38.3
France	83.0	76.4	23.6
Germany	79.0	92.6	7.4
Greece	53.9	82.0	18.0
Ireland	78.1	91.3	8.7

Italy	50.3	90.7	9.3
Netherlands	100.0	93.9	6.1
Portugal	69.4	76.0	24.0
Spain	78.0	93.3	6.7
Sweden	92.6	63.6	22.4
UK	83.4	95.1	4.9

Source: OECD Health Data

An initial reading of the evolution of pharmaceutical consumption within the Spanish Social Security system enables us to conclude, albeit in isolation and tentatively, that in per capita terms drug consumption has grown more than the nominal GDP, but that it has maintained its position within public health expenditure as a whole. Therefore, in terms of evolution, rising consumption does not represent a differential feature within the general growth in health spending.

Lastly, Tables 9-7 to 9-10 provide various additional data.

Table 9-7. Total drug consumption in the European Union in euros per person per year 2000

Austria	234
Belgium	388
Denmark	287
Finland	318
France	470
Germany	373
Greece	245
Ireland	253
Italy	283
Netherlands	254
Portugal	290
Spain	265
Sweden	334
UK	238
EU total	325

Source: La industria farmacéutica en cifras, Farmaindustria, 2002.

Table 9-8. Pharmaceutical consumption and expenditure in Spanish Social Security prescriptions per insured person per year (1995-2001) in pesetas/year

Pharmaceutical consumption	1995	1997	1999	2001
Pharmaceutical consumption ^a	21,552	25,036	30,035	33,724
Consumption of products	19,406	22,588	27,156	30,647
Pharmaceutical expenditure by the Social Security ^a	19,645	22,978	27,825	31,379
Beneficiary's contribution ^a	1,908	2,059	2,210	2,358
Number of prescriptions ^a	14.1	15.1	15.2	15.7

^a Includes consumption of products, formulas, effects and accessories, through prescriptions dispensed through pharmacies.

Source: *La industria farmacéutica en cifras*, Farmaindustria, 2002.

Table 9-9. Average sum per prescription of pharmaceutical products in the Spanish Social Security market (retail price + VAT) 1992-2001

Year	Current pesetas	Variation (%)
1992	1,133	14.7
1993	1,227	10.2
1994	1,330	8.4
1995	1,419	6.7
1996	1,500	5.7
1997	1,547	3.1
1998	1,703	10.1
1999	1,837	7.9
2000	1,901	3.0
2001	2,014	6.0

Source: *La industria farmacéutica en cifras*, Farmaindustria, 2002.

Table 9-10. Pharmaceutical expenditure in Europe by categories in 1999 (in million US\$)

	France	Germany	Italy	Spain	UK
Cardiovascular	3706	3802	2140	1219	1740
Alimentary/metabolism	2144	2558	1363	843	1501
CNS	2009	1920	1054	862	1463
Anti-infective	1584	1381	1207	538	455
Respiratory	1327	1481	775	577	1230
Urogenital	878	956	504	223	477
Musculoskeletal	688	697	506	252	448
Skin care	528	656	310	202	388
Cytostatic	233	712	495	245	234
Blood agents	307	361	343	142	72
Sensory organs	265	235	185	100	143
Mixture	90	218	33	8	37
Hormones	240	339	179	155	96
Diagnostic agents	179	315	99	3	95
Hospital solutions	14	45	29	3	10
Parapsychology	32	24	7	3	37
Total	14224	15700	9229	5375	8426

Source: IMS Health, 2000.

As Figueras and Saltman note in their report for the WHO³, however, cross-national comparisons prove to be extraordinarily misleading *a)* depending on our choice of benchmarks, and on whether we consider public or overall health spending, or per capita pharmaceutical expenditure, *b)* in view of the fact that final pharmaceutical expenditure includes taxes and intermediaries' markups, when both of these factors vary greatly from country to country, and *c)* given the

variety of combinations of functional expenditure, type of care and regulation of access to health services. Figueras and Saltman show that if we calculate spending using ex-factory prices and applying the same markups to both prescription and non-prescription drugs, the UK (which according to the conventional indicators of the first group is always in the low spending bracket) comes to have the largest percentage of pharmaceutical expenditure as a fraction of overall spending. It even surpasses Germany, which as a gross percentage without accounting for margins had a figure no less than 25% higher, and more than doubled the British one in terms of per capita in US\$.

Having said this, we nevertheless have no answers to many other questions relating to the behaviour of pharmaceutical expenditure. What is the degree of efficiency of Spain's pharmaceutical consumption? Is it high or low? Will a solution be forthcoming with the introduction of a generic market (considering the poor prospects for introducing one), or the liberalisation of markups, or the opening of pharmacies, or the vertical integration of the wholesalers? In short, is pharmaceutical spending excessive in Spain?

Public financing and pharmaceutical policy

Quite apart from the above reflections, it should be stressed that no single approach to the problem can provide an ultimate justification for a general policy of decreasing or increasing this item of expenditure. Pharmaceutical expenditure is really just another input in health production policies, and complementariness or substitutability with other inputs, and cross-effects in general, make it necessary to take an overall approach to any rationalisation process.

Seen from this angle, measures like the “*medicamentazo*” (the popular name given to Spain's first major negative list, passed by governmental decree in 1993), despite their immediate aim of cutting expenditure by discouraging the unnecessary use of medicines, often have a rebound effect on other items of expenditure. Thus, “all's fair” is an unacceptable approach for a health care rationalisation policy. The design and structure of co-payment offers a descriptor of the extent to which the objectives of more funding (without reducing consumption, higher unit prices) and less spending (cost containment by reducing consumption in the face of higher prices) are affected by health care regulation. As a result, only when the measure has a strong effect on the reduction of “unnecessary” drug consumption are we dealing with a case of effective health care prioritisation.

Specifically, Spain's experiences in the selective financing of pharmaceuticals up to 1997 (Order of 6 April 1993, developing Royal Decree 98/93 of 22 January 1993, which regulates the selection of medicines for purposes of financing by the National Health System, BOE No. 88, 13 April 1993, Madrid, *Boletín Oficial del Estado*) lead us to conclude that the effectiveness of these measures has been small as regards their cost containment objectives. The decrees on the selective financing of pharmaceuticals of 1993 and 1997 were aimed at the exclusion of drugs judged to have a low therapeutic value; although empirical studies value this aspect positively, the results in terms of reduction in spending are less

conclusive. Indeed, the recent increase in the market for the prescription of drugs amounts a 9% (2000), 11.3% (2001), 9.9% (2002), up to the 11.7% increase for 2003.

From an overall perspective, everything seems to indicate that on the whole there has been no downward trend to date in pharmaceutical expenditure in Spain, but quite the opposite.

In general, the results confirm the short-term nature of the pharmaceutical cost containment strategy. The trend followed by spending in the long term effectively shows a return to the initial levels prior to the measures.

This has lead some observers to support the introduction of direct measures aimed at containing consumption, such as raising the co-payment rate or the imposition of a general *ticket modérateur* on consumption⁴. In effect, Spain has one of the lowest beneficiary contributions to public pharmaceutical consumption in Europe: 6.7% in 2001 (a third and a sixth of those for Sweden and Denmark, approximately). Intrinsic to this are the growing ranks of pensioners, whose numbers increased by 21.8% over the period 1985-2002, the number of prescriptions per person per year rising steadily (15.7 in 2002). All this leads us to similar conclusions to those seen when analysing the previous issue. These are utilisation factors for which the ceiling is an unknown quantity, with very difficult management measures (as they affect society's expectations of the system), the de-marketing of which is highly problematic. In addition to the liberalisation measures already undertaken and efforts to restrict the profits of the pharmaceutical industry, there seem to be clear indications that it is also advisable to attempt to moderate users' consumption and achieve a better integration for pharmaceutical provision within professional practice. The dissociation between pensioners and the poor should perhaps accompany any new policies undertaken in the future.

Having stated the above, it is absolutely essential to make some comments on the current package of measures regulating the Spanish pharmaceutical market. As we mentioned earlier, the expected effectiveness of tackling the problem of pharmaceutical consumption in a single sphere of intervention (supply, demand or wholesalers) is small. Equally, the study of the impact of any measure of this sort must therefore incorporate an integral approach to the problem (see Table 9-11).

Table 9-11. Some cost-containment measures in the pharmaceutical sector

- Devolution of the implementation of pharmaceutical legislation to several autonomous communities (Catalonia, Navarre, Canaries, Galicia, and Castile and León)
- Relative deregulation of pharmacies (marginal extension of the number of authorised establishments and opening hours) and continual adjustments to markups (decrees of 1997 and 1999)
- Promotion of generic policy and setting up of the Spanish Pharmaceutical Agency in June 1999, in an attempt to achieve more rational pharmaceutical policies
- The potential effects of the decree passed on 19 June 1999, regulating the reference pricing system, on the financing of pharmaceuticals by Social Security funds. Similarly for 2003 (implemented Jan 2004)
- The move towards selection in the latest decree on public financing of pharmaceuticals (1998) and as a result from a new reference pricing system due to start in 2004.
- Agreements with Farmaindustria for health care cost sharing in 1998, continuing those of 1995 and 1997, and in 2003, with a contribution of 20,000 and 125,000 million respectively for 1998 and 1999.

In addition to the economic objective of savings for public health care funds, the regulation of the Spanish pharmaceutical sector pursues other goals, both economic and social. Thus, from a social welfare viewpoint, it is important to bear in mind the repercussions of regulation on the health status of the population, the equity of the health system either generally or from a more sectoral perspective, and innovation and localisation processes in the pharmaceutical industry as a whole.

We can divide the package of measures regulating the Spanish pharmaceutical market up to 1997 into those that directly affect the supply side and those (such as the *medicamentazo*) that fall on the demand for drug consumption.

Measures affecting the supply side

One of the most important factors on the supply side has been the agreements between the Department of Health and the pharmaceutical industry (Farmaindustria), first for the period 1995-1997, which imposed a ceiling on the pharmaceutical industry rate of return, at 7% in 1996 and 4% in 1997. These agreements established the refunding of the gross margins corresponding to increases in expenditure above the fixed percentage, together with a series of recommendations for pharmacies to offer discounts (up to 2% of the retail price) to the users of the drugs. The contributions of the pharmaceutical industry to the Spanish Social Security as a result of this agreement amounted to Pts 14,173m, 17,909m and 18,043m (Ministry of Health and Consumer Affairs estimate) for 1995, 1996 and 1997 respectively. This sort of agreements was extended up 2003, when the new reference pricing system was approved with the opposition of Farmaindustria.

On a different front, a debate has been initiated on the suitability of single linear markups, alternative proposals being made for differentiated markups according to the services offered, by likewise differentiated sectors or groups.

Indeed, the recent history of the financial regulation of pharmacies provides us with practically the whole range of possibilities: a fixed 25% markup in 1945, subsequently increased to 30% (but with a 6.6% reduction for “Compulsory Insurance” drugs), then progressive markups inversely proportional to the retail price, which were introduced in 1963 and 1964 for those that exceeded a certain amount and then modified in 1977, then the single markup again in 1981, although with modifications to the rate for various reasons in 1985, 1988, 1993 and 1997, and finally a return to special markups (Royal Decree Law 5/2000 on the rationalisation of drug use). This established a maximum markup of 27.9% for drugs with a retail price of up to Pts 20,000, a fixed sum of Pts 5,580 for drugs costing more than this amount, and a markup of 33% for generics. It also

authorises a discount on over-the-counter drugs of up to 10%. On a different note, the decree also regulates the deductions (refunds to the public health system) to be applied as a function of the monthly turnover of drugs dispensed in pharmacies.

The alternatives to this system of remuneration are well known, although their effects on the present status quo appear to be an obstacle to their being applied. For example, one possibility would be to determine a fixed component (for active service or stand-by) or a semi-fixed one (according to the number of pharmacists in service), and a variable component per prescription/package dispensed, a percentage of the price and a fee for special services. There is no need here to enter into the details of the incentive compatibility problems raised by one type of contractual rule or another, whether it is viewed in the context of the agency relationship between health authorities and pharmacist or the more liberal or private one between user and pharmacist (see Cabiedes and Ortún⁵). The actual effects of the markups resulting from the various combinations can be calibrated in relation to their present values, depending on: *a*) the size of the municipality, *b*) sales (and how they are distributed between prescription and over-the-counter drugs), *c*) the evolution predetermined by the fixed component of the formulations (nominal GDP or CPI, basically), and of course *d*) the weight of the amount per prescription versus the markup on the retail price. Simulations and subsequent calibrations have been carried out in Catalonia with real data for the provinces of Girona and Tarragona. An excellent analysis of these changes can be found in Andreu⁶.

Some of the above changes have been proposed as a reaction to the incipient introduction of a generic market in Spain⁷. However, taking into consideration that this market barely accounts for 3% of total prescription costs, together with the scant development of European regulation as regards patents in the pharmaceutical sector (and the little impact of the progress made in this direction in Spain) we can forecast that the effect on pharmaceutical expenditure will be small. This may take the form of a mere “exchange of copies”, which represent 30% of the country’s prescriptions. The OECD recommendations for the future that are being introduced into several works hinge on the need to carry out a thorough evaluation of variations in prescription patterns within and between countries, and to advance towards selective deregulation of the retail market.

Measures affecting the demand side

As regards distribution, there is a clear need for a broader structural reform than the political situation sometimes allows, although the law passed by the autonomous community of Navarre (Statutory Law 12/2000 on Pharmaceutical Care) seems to have opened up something of a breach in this respect. In our opinion the necessary reform, which affects both organisational and financial aspects, requires a coherent strategy centred on a new regulatory arrangement for pharmacies.

This could be based around the following points:

1. A minimum coverage health plan could be established that would guarantee one pharmacy for a certain number of inhabitants and/or a certain distance to travel to one. For example, one pharmacy for a town with 800 inhabitants and/or at a distance of no more than 250 metres (the Statutory Law in Navarre mentioned above attaches each pharmacy to a Basic Health Zone, moreover adding that unless this coverage is guaranteed no new pharmacies will be authorised to open anywhere in Navarre, as in this respect the public interest predominates over business initiative). If to this end it is necessary to invite inverse tenders (public non-private financial compensation for sharing capital gains derived from the barriers to competition thus generated) the previous thresholds should be guaranteed.
2. Once this minimum pharmaceutical care is covered, pharmacists would be free to set up any other initiative. The erosion of earning power that this might spell for existing pharmacies could be offset by means of minimum market protection periods and by prohibiting chains of pharmacies without a single owner per pharmacy.
3. Initially the system of public grants for pharmacists and would only affect pharmacies that correspond to planned authorisation. The initial realistic approach would require the maintenance of the grants with existing pharmacies, although the system of allocating the best clause tendered (possibly guaranteeing the established minimums) could be imposed. This would be particularly plausible after an initial period (e.g., three years) before the pharmacies broaden their range of pharmaceutical care services to raise the initial requirements of the health authorities for public pharmaceutical care. In this way, the awards could be made by invitation to tender (even with different levels: basic, and complementary with pilot programmes) to a given number of pharmacies, at least equivalent to the number planned according to population size and not necessarily coinciding with the number that had previously enjoyed public grants.

It would be desirable for the above process to result in the future pharmaceutical grants taking in the entirety of pharmaceutical services. Possible lines of implementation would be: *a)* the definition of the range of services offered by each pharmacy, *b)* the purchase of these services from each pharmacy by the corresponding health services, *c)* selective grants depending on the services offered, and *d)* changes in the dispenser's remuneration system to bring it more in line with priority pharmaceutical care activities.

This strategy might help to generate a level of professional competition between pharmacies that would encourage them to perform pharmaceutical care activities with the ultimate goal of improving the quality of the care received by citizens. This would include aspects such as the management of the product (as regards guaranteeing the accessibility of the drug: availability, product quality and dispensing), clinical management (appropriate use of the drug by the patient, including evaluation of the outcome of pharmaceutical intervention, treatment monitoring, observance, information, detection of therapeutic problems, etc.) and a series of preventive activities (e.g., health promotion in primary pharmacy, and screening in specialised pharmacy).

Summary

To sum up, the diagnosis derived from the foregoing aggregate analysis shows that:

1. The problem of Spain's pharmaceutical expenditure appears to lie in its growth rate over the last two decades. But this cannot be judged without considering the point of departure: its share in terms of GDP was already high in 1980 and has remained high to the present. The international price convergence is behind its dynamics but it does not fully explain the values. In most countries the diagnosis is the opposite: it is primarily a problem of growth rate already from a high spending level.
2. The problem of Spain's pharmaceutical expenditure does not lie in its absolute level but in the large proportion financed publicly (74.4% of the total, whereas the European average is 58.3%). The absence of significant co-payments for the population as a whole and little screening in the type of drugs financed may explain this.
3. In spending per capita, Spain also stands above average, although less strikingly so. But contrary to what we find in many neighbouring countries, in Spain the problem has more to do with excess consumption than with relative prices. Thus, for example, more than half the growth in spending between 1995 and 2002 can be explained by the number of prescriptions per capita. The effect of prices is especially strong on the component (which stands at around 15% of the total) of consumption of new products (those that have been on the market for less than five years), as they more than double the prices of old products (those marketed for 10 to 15 years). Indeed, over the period 1980-1996 the price of new products had an average impact on the upward trend in health expenditure of 442%⁸.

Final considerations

It is extremely difficult to forecast what the Spanish health system of even the near future will be like, particularly if it continues to be "anchored" in the dynamics offered today by national health services: "services" as if they were just another administrative service, "national" implying a strong tendency towards uniformity, and "health" denoting an intention that is not always translated into the best integration (for instance, between ultimate objectives and the provision of services, or between health sector policies and all the other economic and social sector policies).

It seems likely that in the future we will need to tackle health problems from an angle that has more in common with the idea of a social insurance system. "System" for a better interlocking of ultimate objectives and health care services between public and private actors, and between different public actors, all politically legitimated throughout the territory, and for their better coordination, crucial for the success of any health policy. "Insurance" because of the inescapable nature of the idea of specifying levels of health care coverage and selective limitation of provision. "Social" because of the foreseeable continuity of the implicit objective of solidarity in its system of financing, protection through

the coverage of all or part of the population, and a closer integration of the social health needs of the population.

As we mentioned above, the health sector may easily remain stuck in the present status quo, and as such incapable of responding to the new needs of society. This can be attributed, among other reasons, to the very roots of universalism (benefits that tend to be presented as “necessary” for all), the short-term approach of health policies (which works against major changes), the customary corporatism of today’s prevalent interests, and the frequent use of health care as a political weapon in elections.

Thus, reorientation towards a new social insurance system may take a very long time to impregnate the health care of the future. This would come to replace the British model of the NHS (imported for the Spanish General Law on Health, more than 50 years too late), a service that was, after all, created under very different circumstances from the present (in a postwar period of extreme poverty with “compassionate” Conservative governments and a strong predominance of social over individual responsibility). It is difficult to see this instrument, which was so successful in the past in improving the welfare of the population, as being extrapolable today in the face of a future marked by hitherto barely imaginable possibilities such as the appearance of genetic testing and personalised treatments, the irruption of new and costly “lifestyle” drugs, technological capabilities in which “caring” is of greater value than “curing”, and strong expectations to introduce elements of individual welfare – not only clinical effectiveness – into health care provision. And of course, in consonance with all this, greater acceptance within society of shifts of responsibility from collective state action to the individual sphere.

Between the “old” that puts off its death and the “new” that puts off its birth, doubts are rife, but discussion on the subject is invaluable.

In this context, and in the specific case of pharmaceutical provision, the prognosis provided by the series of considerations raised in this chapter leads us to emphasise the following points.

First of all, if, as we have seen, the problem is one of overconsumption first and cost level (including dispensing costs) second. Therefore, it should be the former and not the latter that dominates policy agendas.

Despite this fact, beyond the pressure exerted on the laboratories, almost none of the measures that have been implemented in Spain (negative lists, reference pricing, control of authorised prices, generic introduction, transfer of return above an agreed threshold, and price or markup reduction by decree) have any direct influence on the day-to-day development of expenditure and its key protagonists: users, pharmacies and above all prescribers.

As we understand it, only combined action involving the participation of decisive parties, and a return to the view that drugs constitute an element of the overall combination of functional expenditure for health production (and not an isolated

input), can lead to the creation of a stable framework for the sector, thus pointing it in the right direction to face the future challenges of the Spanish health system.

Second, there is every reason to believe that the externalities that pharmaceutical development has in technological innovation, the industrial policy of a country and patients' welfare require a more stable framework than is the case at present. In this regard, we would stress that general public regulation should be sufficiently broad and long-term to be able to guide the sector through short-term upheaval in the financing of expenditure. Most of the utilities in any country (electricity, gas, telecommunications) enjoy a stable "legal" framework that enables the parties to know where they stand, according to a semicontractual arrangement with obligations and duties for both parties. The constraint of discretionality is particularly necessary for those economic sectors that require long-term investments entailing major fixed costs (research and development) that are often irrecoverable. Although this demands a more thorough public regulation study than is possible here, it strikes us that pre-fixing a particular line to follow according to variables such as the evolution of the GDP, plus an additional index for diagnostic and therapeutic value (similar to that developed by Berndt and others⁹) provides a better formula than sporadic adjustments made to variables that fail to discriminate sufficiently between either industries or products or turnover (volumes versus margins).

This may encompass the substitution of drugs with greater therapeutic value (economy clause), levels of advancement in selective financing (favourable evolution of private financing in the joint financing of the expenditure), positive adjustment for convergence of prices in the single world market (against parallel trade) and other factors concerning industrial economic policy (weight of R&D spending over the total for the sector in relation to volume of business).

We consider that working towards a stable framework for the sector in Spain is one of the main challenges for the evolution of public financing of health expenditure. The necessary consensus to achieve this could be built on the discussion already formalised in parliament around a broad agreement for the pharmaceutical sector, although we are very much afraid that in the end electoral issues will outweigh what is advisable and rational.

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