THE DEVOLUTION OF HEALTH CARE TO THE SPANISH REGIONS REACHES THE END POINT

THE DEVELOPMENT OF NEW REGIONAL HEALTH POLICIES AND THE NEED FOR COORDINATION: THE CASE OF THE PHARMACEUTICAL MARKET

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SUMMARY(*)

I try to offer in this paper some general comments on the new scenarios for the Spanish Health Policy once decentralisation of health spending has been extended to all the Spanish regions. Once the devolution of health care seems to have then reached the end point, I wonder whether we should expect for the next future a renewed effort from the State for re-centralisation (given some foreseeable difficulties in regional coordination), or is now the time to expect what the Autonomous Communities can manage health care on new grounds and safer financial arenas, and then improve the Spanish Health System on the whole.

After some basic explanation of the new regional financial setting, I argue on advantages and limitations of different strategies for coordination of health policies. I finally apply some of the reflections of the arguments for the new decentralised policies on pharmaceuticals. I examine the role of the regions in the fields of: licensing, pricing, reimbursement and prescription at the medical and at the dispenser level.

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A final appendix offers 'food for thought' on regional/ state drug policies in the cases of Canada, Belgium, Germany and USA.

I.- INTRODUCTION

Even the most optimistic among us did not believe that a Conservative Spanish Government would decentralise health services management to all of the Spanish regions (Autonomous Communities, AC from now on). Nevertheless, the central Government led by the Popular Party surprised everyone in past July 2001 by reaching a new fiscal agreement with the AC (some of them represented by socialist regional Governments) which included placing health care under regional responsibility for them all.

The completeness and speed of the transfer came as a surprise firstly, because past decentralisation (of seven regions accounting for 60% of the overall expenditure) was argued by some to have eroded social cohesion. This view was even supported by some central trade unions in a recent Spanish Social and Economic Council publication. Secondly, the opposition party was divided in its views, representing on the one hand a regional partisan view and on the other the view of an alternative central Government keen not to weaken central powers. Thirdly, the speed of implementation was a surprise because some areas still lacked detailed agreement, notably on finance (for instance, on costing services and redistribution parameters) and the basic central regulation of health planning and co-ordination. The latter is not a trivial issue given that in Spain 10 AC have a population less than two million.

Why then has this happened? A political interpretation is that politicians may think that health care is unmanageable in public hands (because of complaints, demands for extra resources, resistance to administrative change etc) and that decentralisation is a first step towards privatisation. Additionally, by limiting central finance commitments the central Government may protect its own purse while leaving the political costs to be faced by the regions. However, there exists some caveats on this interpretation, as the Conservative Party is involved in a number of regional Governments – Madrid, Galícia, Castilla–Leon and Cantabria – and there is only anecdotal evidence so far to support the view that the Conservatives favour privatisation of public facilities and finance. It may be the case that at present financial arrangements other than complete

devolution looked extremely complex. For example, organising health care for 40% of the population, with high disparities between the INSALUD centrally managed regions (because of the impact of the generous treatment of the Madrid AC) by consortia agreements, regulated cross boundary flows and other mechanisms proved to be very complicated. In addition, there was an expectation on the part of partisan politicians that transfer of health powers would change political powers both between Nationalist/Socialist and Conservative administrations and even within Conservative areas of influence.

A further consideration is that the extension of devolution has been a way of weakening the search for a differential power position by the more nationalistic AC (Catalonia, Basque country and Navarre) in favour of the so called "café para todos" (coffee for all). Having said this, in my opinion, it is likely that if the process had not started already, decentralisation would not have been started by the Conservative Party, but given its progress any movement back to centralisation looked worse than further devolution.

II.- THE NEW FISCAL AGREEMENT

Some key features of the new arrangements are summarised below:

1. For the first time, regional health care finance is included into the general financial AC agreements. Up to this moment, health finance was decided in a separate negotiation framework between the Minister of Health and their corresponding Regional Ministers. Given the importance of the health care budgets (around 40% of regional expenses), the results of this bargaining might seriously affect regional finance. Now it is not going to be determined by political bargaining between the central and the regional Departments of Health, but between Finance Ministers first and secondly, at the regional internal level, between the regional expenditure ministers within each AC. The regional parliaments will now have a more decisive ultimate word on heath policy issues.

2. The bottom line of health expenditure is estimated as a minimum amount to be spent. For this, (i) the effective cost at the moment of the transfer or (ii) the share of the overall central expenditure funds according to population (weighted by 75%), age structure (by 24.5%) and the 'insularity factor' (just for the Balearic and Canary Islands, at 0.5%), are on the table. If the former is above the latter, the central government is committed for three years only to maintain finance for the basic figures increased by the GDP growth in nominal terms and at

factor costs. However, above the basic amounts, each AC will be able in the future to spend whatever it wishes if financed by its own budgets.

3. Since 2002, general revenues for the regions to finance all the AC services (not just health) will come out of revenue sharing Personal Income Tax (at 33%), VAT (35%), Petrol, Tobacco and Alcohol Taxes (40%), and 100% of the revenues collected in the region of some other minor taxes (car registration, energy tax, inherited and donated dwellings, property transfer, gambling...). Initially, everything, including the equalisation central transfer, will be computed in order to guarantee that all the basic needs (health, estimated as described, and education – in per capita terms) will be covered. Similarly for some pre-set increases over time. But if revenue sharing capability increases, due for instance to the fact regional consumption indicators increase in percentage terms, or that a surcharge on personal income tax is applied ($^{+}$/- 20%), no restriction will apply to this additional expenditure.

4- However, in order to preserve cohesion by avoiding 'excessive' deviation in per capita health spending amongst regions, central transfers will help those AC that shows increases in public health coverage (say due to legal immigration) three points above the Spanish average. In addition, as commented, all the AC will have to finance at least some (increased) basic health care. However, no maximum is defined and then a mobile average according to the effective regional revenue raising capacity may result. The chances of devoting larger amounts to health care may come out of the open possibility to impose a petrol tax at the final retail level (as a surcharge) just to finance health care. This is not however a real earmarked tax, but a way to build a more politically acceptable tax on the former premises. So far, the Central Administration has also approved a central tax on petrol to finance health expenses already committed. AC strongly complain that this makes more difficult to impose their own taxes as stated on the fiscal aggreements.

5- A Cohesion Fund to be funded by the central budget will devote resources to compensate for cross boundary flows of patients amongst regions. The central state is proposing to create an homogeneous information system and a close to DRG type of billing, which needs, however, to be negotiated with the regional health authorities. Some regions seem to be prepared to co-ordinate themselves to avoid those adjustments without central intervention, as, for instance, in the case of the extended central (Madrid and both Castillas) health region. Some caveats exist on how the central state will compensate for new central regulations or pricing policies (new

drugs to be reimbursed, centrally authorised new health technologies...)that affect regional expenses. Without compensation, regional acceptance is less likely.

6- A defined basic entitlement package will become a necessity if patients are not to exploit differences. Diversity itself should not be a cause for concern (so legal precedent suggests) provided the basic minimum package is covered and any additions are financed from regional sources. Handling other variations in policy, such as those applied to drugs, may not be straightforward. Although regions will not negotiate drug prices themselves, they may well influence the prescribing habits of their professionals. This will pose new challenges to the marketing departments of drug companies.

As a result, the integration of health care finance under the general financing system for all the AC for an indefinite period should end a political process that has been very contentious. The present system has promoted little consensus amongst health authorities, with the only point of commonality being the claim of more resources from central Government. There have been endless disputes on the shares each region should have relative to the rest and as a result all health problems have been presented as due to lack of resources, with little discussion of evidence based new policies.

Under the new arrangement complaints about central under finance of regional health care will have to cease. This is appropriate because, despite common perception, Spain is not an unequal country in terms of health delivery and finance. This is borne out by a recent study (BBVA Foundation and the Institute of AC Studies, 2001) that evaluated the impact of regional health policies since the first health transfers for Catalonia in 1981. Indeed the coefficient of variation in regional health care finance per capita is one of the lowest amongst health care systems for which territorial health care expenditure may be identified. By contrast, France and England are among those countries which have most uneven distribution of health care resources. This probably reflects the fact that in those countries health regions are a geographical artefact with no parallel in regional Government. Therefore, these differences are not readily translated into the political arena as happens in Spain or Italy. This means that the central Government is under little political pressure to justify the differences that exist.

Additionally, the differences that are observed between regions in Spain relate to relatively few programs that have little practical relevance to health status. For example, Andalusia finances from the public purse certain low therapeutic value drugs which are exempted in most of the other

regions; only a few regions will finance sex change operations or the “morning after” contraceptive pill.

These differences should cause little concern in equity terms as they reflect different political views on public preferences. They should be self financed as there seems little basis for interregional transfers to support them. Indeed, where conducted, regional opinion polls seem to favour keeping such decisions close to the citizenry affected.

Having said this, we should also recognise that we know relatively little about health differences which derive from variations in quality of care and variations in clinical practice. It is probably not the case that there is a fundamental regional pattern in such disparities. The main equity concern probably relates to intra regional differences rather than interregional differences. Those who have spoken loudest against the dangers of interterritorial inequities have not usually made most effort to redress imbalances between local areas within the regions.

III.- THE PRESENT SCENARIO: MORE AUTONOMY AND GREATER FISCAL ACCOUNTABILITY. BUT THE COORDINATION ISSUE STANDS STILL

For most of the Spanish citizens, the fact that an important area of social policy such as health care has been decentralised to 17 AA.CC., ranging from less than three hundred thousand up to more than seven million people, make for the need of coordination. Common sense dictates that not all the regions have the same management capabilities or even perhaps the required aim for self-governance in order to take the risks that are intrinsic to the exercise of power. Coordination may be then needed. However, it could be very tempting for the central State to adopt the view of the less capable region to manage in a fully autonomous way, in order to limit the variation of health policies for the rest. This may help to keep a more 'cohesionned' country, at the cost, however, of frustrating the whole purpose of the devolution of central powers to the regions.

There is not a clear reason for impelling coordination now, and not before, other perhaps than a better marketing for re-centralisation. Indeed, most of the alleged problems from a potential lack of coordination refer to public health issues. Responsibilities on them were indeed transferred to the regions in 1986 without any claim (given, we have to say, their lower impact on finance). Now is different: more than 35 thousand millions € are at stake and the medical profession, pharmaceutical companies and the health input supplies industries are facing a new political setting: new opportunities for some, life more difficult for others.

The issue of central coordination can be dealt with from different perspectives. One consists of searching for formal procedures in shaping regional policies. This can be done by (i) subtracting from the regional choice (*strategy of 'less-favourable output avoidance'*) those areas that 'a priori' can complicate the achievement of some superior goals of the health system, or by (ii) building networks (*strategy of 'more-favourable input promotion'*), based on new Institutions with regional participation for eliciting common policies on some previously determined fields , to make sure, for instance, that all the legitimate views of agents on issues (jurisdictional externalities, large extent evidence based policies, managerial scale economies, etc.) are well taken. This would require the development of sectorial tables or specific committees –say linked to the Interterritorial Council or similar-, on pre-established better information systems, new regimes for desision-making and settings for anticipating coordination problems or for reacting to them in a 'non discretional central' way. A second view (*the 'preservation of outcomes' strategy*) can be based on accepting full regional autonomy, but holding the Central State some paramount constitutional principles, by re-defining in a more precise way basic notions such as 'portability' of the entitlement of the health rights across the regions, the principle of no discrimination, etc, and leaving threafter the discussion of their fulfilment to the Constitutional Court.

From a technical point of view it could be argued however, that most of the coordination arena on social welfare spending should be interesectorial, interdepartmental,..; this is, out of the Department of Health, in following a more integrated public policy: ie. say, amongst food and consumption branches of health, transport, education, etc. Even it may be the case that differences in health care policies show a more reduced range of regional variation than most of the related policies[1]. In this sense, coordination of health policies should focus more on public health issues and less on expenditure and health care delivery. And on the redistribution side of expenditure, perhaps internal regional equity access problems need to gain weight above some other less relevant interterritorial ones. The same applies to the 'within-regional' concern to address clinical effectivity. On geographical bases, minima requirements rather than averages levels of basic entitlements are probably better justified in this field too. This is due to the fact that central regulation does not seem to be required for explicit priorisation of some target groups. This may better approached through the internal design of health policies, by informing guidelines of clinical practices and not at a general abstract level.

[1] - See Foundation Encuentro (2002) on the State of the Autonomies.

Finally, a word of caution on the issue of building 'central institutions for coordination'. For instance, the audit and monitoring of the evolution of the Spanish Health System may not justify the creation of new central Agencies of the Observatory type. A major role for contracted-out professional and academic institutions may add better value to the otherwise, truly or not, politically suspicious contaminated works.

An overall assessment of the issue of the new coordination policies may be, finally, the reintroduction of assimmetries in finance and management: in a first step through some re-centralisation, 'advocating' part of the devolution trend through some of the three former strategies already commented, and second, through a sequential process of delegation, but this time, in a more selective way, in favour only of those AA.CC. more able to overtake some managerial capability constraints, by the resumption of some powers. This is an argument with more technical than political grounds, although the outcome it helps the second more than the first.

On the whole, it is likely that this delegation offers a more limited content fore the autonomous exercise at the regional level of health policies. But some AC will be able to run the services to the basic procedures required at the central State level, adding their own concerns to support autonomous policies.

The final outcome may be unfortunate, since it might be read as the result of a central Administration recentralisation. This is, a State that recovers powers from the regions at a time that European Union starts to promote better-grounded policies for deal common issues at the European rather than State level.

In the final sections of this paper I will comment on a particular field in which decentralisation appears to be more problematic, but a field that at the same time, shadows re-centralisation with important caveats too: the pharmaceuticals policy. Indeed, we may wonder here whether the absence of a single central policy in licensing, pricing and reimbursing drugs is compatible with a single national health system. But at the same time, we may question if the success in containing the drugs bill cannot be better result from new regional health strategies: Is just social responsibility what the largest drug companies show when they complaint against the risks of decentralising the drugs market? Is not monopsony worse than competition for the oligopoly industry, as the economic theory shows? Will decentralisation split lobbies and logrolling in the health care market inputs? Are cost savings from the emulation of best practices a benefit worthwhile to pursue in order to incur on some new financial risks? Can AC go ahead with a system where they fully pay the bill of the centrally licensed and priced drugs? Is the provincial Canadian system the way ahead

(in splitting licensing and maximum prices from reimbursement decided at the provincial level)? Is the German system better? (See Appendix 1)

Should AC play the role of pharmaceutical benefit management companies as in USA, searching for rebates and lower prices at the local market level, implementing formularies, treatment profiles and clinical guides of practice, in response to the size and dynamics of the drugs bill? Is arbitraging (vote by the feet) a real thread for regional pharmaceutical provision? May different co-payments o reference pricing systems be made compatible with a central positive or negative list of reimbursed drugs? Can AC affect the dispensing pharmaceutical margins without breaking the 'unity of the market'? Should the pharmaceutical agreement be extended at the regional level, given the fact that they hold any difference in unit costs of the prescription? Is double-checking and validation at the regional level a pharmaceutical management problem or a way of implementing a second licensing system? Does it make sense, finally, for different AC to pursue different policies; say, with reference pricing strongly linked to the development of a markets for generics, or, say, on financing the cheapest brand product out of a chemical entity identification?

IV.- A FORECASTING EXERCISE: THE SPANISH PHARMACEUTICAL POLICY IN A FULLY DECENTRALISED HEALTH CARE SYSTEM

Pharmaceutical's policy in Spain during the last nineties has been primarily concerned on cost containment. This is much unlucky since important issues are at stake other than just looking at the size of the drugs expenditure bills. As a matter of fact, by all means, Spain has a large share of total public health expenditure on drugs. However, this may offer basis for the wrong prognosis. Indeed, pharmaceutical expenditure is not so out of pattern if we account for drugs spending on total health expenditure and on GDP. At any rate, pharmaceutical expenditure is even much more lower on a per capita basis, below the European average.

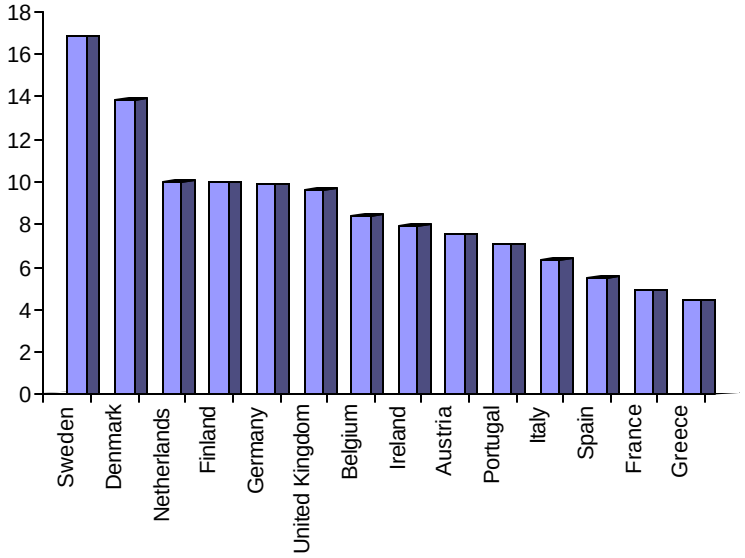
In any case, public health authorities' concern on pharmaceutical expenditure in Spain can be well understood on the fact that this is financed on a very large extent (up to 93%) by the public revenues with one of the smallest co-payment share in EU[2].

Finally in completing the overall picture of the pharmaceutical policy in Spain, we should remark that despite a relatively low average price level (see figure 1) quantities show relatively high figures (the per capita prescriptions factor). This creates an extra cause of concern, since inadequate

[2] - As it is known, the Spanish National Health Service provides free-off -charge universal health care coverage with the exception of prescribed drugs sold in pharmacies, which are subject to cost sharing. From 1980 onwards, the co-payment rate is of a 40%, except for pensioners who are exempt from charges and chronically ill consumers who pay a 10% of price up to a price cap of 2.2 euros.

consumption is not just a problem of a lack of cost effective prescription on the physicians' side, but a patient education problem too, with wasted drugs. At last, Spain as some other countries, has not yet achieved an optimal integration between pharmaceuticals and the rest of health inputs and throughputs, and on the whole, Spain has probably missed a more clever discussion on the interrelationship of national (European) industrial policy and community health interests in general.

Figure 1. Average price of pharmaceuticals in the EU in year 2000



Source: Farmaindustria, 2001.

TABLE 1 Some data on pharmaceutical expenditure

% Increase in public finance of pharmaceutical expenditure											
1991	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2202(*)**
17,03	14,93	7,85	5,63	11,54	12,90	5,82	10,57	9,96	7,52	7,9	13,21

(*) January-February
Source: Ministerio de Sanidad y Departamentos autonómicos de Sanidad.

To improve the present state of affairs, Public health authorities have pursued several and not always well connected pharmaceutical policies. They include negative lists of excluded drugs (1993, 1998), rebates (1994, 1997, 1999) and changes in the linear dispensers margins (2000), some tentative changes in licensing pharmacies (1996, 1997, 2000), repayments from pharmaceutical companies (1996, 1998 and 2001) and more recently, the implementation of a Reference Pricing System (December 2000) and some efforts for promoting of the use of generic drugs through several prescription agreements with primary physicians (Lopez Casasnovas and Puig[3]). As a result a full bunch of policies seem to be simultaneously in place regarding the supply side of the market[4],[5]. At the same time that all the former initiatives show a legitimate concern on the rising pharmaceutical spending, it shows too a certain lack of focus and loss of control.

The former described state of affairs is today under new foreseeable changes. Since January 2002, indeed, some of those policies are under the devolved responsibility of 17 regional health systems[6]. In fact, Regional Health Care Services are taking care of the prescription policies. Licensing new drugs and pricing for reimbursement purposes are under the central Departmental Health responsibilities, but AC have started to manage prescription and stated some pharmaceutical guidelines on the grounds of regional information systems, with carrot and stick type of incentives. In addition, given the way that AC are financed, Regional Health Authorities claim for being heard whenever new drugs are approved or prices are decided, since they will have to hold the bill!. Despite this, it is not clear at this time which role AC will have in the process, since a new Law for central health coordination, as commented, is being expected.

In the following sections I intend to discuss, on the basis of current empirical evidence, future prospects for the Spanish pharmaceutical policies. I plan to explore how they can be influenced by the new regional health authorities, by focussing mainly on the Reference Pricing strategies and the effort of building a market for generics, in the context of the new Stability Agreement with the Pharmaceutical Companies.

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[3] - 'Review of the Literature on Reference Pricing' *Health Policy* 54 (2000) 87-123.

[4] Dispensing medicines are being affected by a bunch of incentives (larger margins) to promote pharmacist's generic substitution and especially, to influence the role of pharmacists as providers of pharmaceutical advice that might show a educational effects on consumers behaviour.

[5] However, copayments, on the demand side, despite much talks, are unchanged.

[6] - A description of the new arrangements can be found in G.López-Casasnovas 'The devolution of health care to the Spanish regions reaches the end point' *Eurohealth* (forthcoming)

For the above mentioned aim, I explore some basic aggregate regional data, their rate of growth and the regional cost of the average precription. In addition, I offer some primary evidence on regional differences in the use of generics across the Spanish Health Regions.

Table 2. Prescription costs per Autonomous Communities (euros)

Galicia	Basque C	Navarra	Catalonia	Valencia	Total NHS
12,68	12'57	12,05	11,88	11,72	11,67
Canarias	**Insalud**	**Andalucía**			
11,60	11,54	11,10			

Fuente: Ministerio de Sanidad y Departamentos autonómicos de Sanidad.

NHS public pharmaceutical expenditure across regional health systems
(in thousand pesetas)

	Acum. 2002 (Ene-Feb)	Acumulated 2001	% Change
Navarra	17.869.737,63	15.189.435,61	17,65
Galicia	99.650.238,29	84.948.127,12	17,31
Murcia	39.364.755,14	33.787.879,34	16,51
Aragón	42.056.653,26	36.344.149,52	15,72
Ceuta	1.497.704,52	1.297.759,74	15,41
La Rioja	8.652.363,91	7.508.560,70	15,23
Castilla y León	75.041.780,76	65.132.186,44	15,21
Basque Country	67.743.844,84	58.803.035,98	15,20
Asturias	37.803.378,92	32.945.339,19	14,75
Madrid	134.241643,75	117.015.143,09	14,72
Extremadura	36.033.906,53	31.516.770,78	14,33

Castilla-La Mancha	59.658.076,93	52.461.225,78	13,72
Melilla	1.097.193,48	971.879,97	12,89
Catalonia	217.172.400,20	193.774.455,52	12,07
Valencia	159.395.590,96	142.339.949,87	11,98
Baleares	21.488.087,64	19.280.015,73	11,45
Canarias	51.179.082,81	46.291.721,66	10,56
Cantabria	16.019.638,19	14.496.406,77	10,51
Andalucía	225.770.242,18	204.508.420,39	10,40
TOTAL	1.311.736.319,98	1.158.612.463,14	13,21

Fuente: Ministerio de Sanidad, 2002

Table 3. Generic drugs consumed in the Spanish regional health systems

	% Población	% EFG 1999	% EFG Feb 2001
Insalud	38,0	59,5	47,8
Catalonia	15,7	20,0	22,0
Navarra	1,3	1,4	1,2
Basque Country	5,6	3,7	3,4
Andalucía	18,0	9,2	12,5
Canary Islandss	3,9	1,7	3,3
Valencia	10,0	3,1	6,8
Galicia	7,0	1,4	2,9

***Source*:.IMS 2001. Quoted by M. Almirall Anuario Farmacéutico 2001-2002.**

As commented earlier on, Reference Pricing System was implemented in December 2000. This is applied to off patent drugs in groups with identical active ingredients (López-Casasnovas and Puig, op. cit)[7]. At least one of them in the group has to be a generic product, in an effort to see the generic

[7] -It can be argued that Spain is not the most suitable country where to implement a RP system. Countries that have implemented reference price systems share some basic prior features as innovation being relatively strong, prices remarkably high and a large and competitive market for generic drugs.
The Spanish scenario in the last decade was far from being similar to other countries where RP were implemented. In the year 2000, when the system was implemented prices were 28% lower than the EU average, the EU lowest after France and Greece as Figure 1 shows. Additionally, the RP had strong criticisms from several actors of the pharmaceutical policy process the two years before its implementation

market further developed. A total amount of 114 homogeneous therapeutic groups were designed on the basis of the concept of 'bioequivalence' as defined by the Spanish Office for Pharmaceuticals (Agencia Espanola del Medicamento). 617 homogeneous products (Decembre 2001) were in place. The Reference Price is based on a weighted average, calculated year by year, of a minimum set of drugs that accounts al least a 20% of the group drug market sales. If the difference between the estimated price and the highest priced product is less than 10%, the RP will be the result of applying a 10% reduction on the highest priced product. If the difference between the calculated price and the highest priced product is more than 50%, the RP is estimated as exactly the 50% of the highest priced product[8].

Drugs included in the new system account for the 14.6% of the pharmaceuticals market from which slightly more that half are generics. The market for generics in Spain is quite moderate at an average of 3 to 5%, still far from the EU average being the later 15%.

After one year and half since the implementation of RP we have found small although not negligible effects[9]. At present, prospects are less brilliant since the market for generics is stagnant due to the absence of incentives to producers, prescribers and dispensers to further develop this market[10].

Looking at RP from a decentralised perspective, Insalud[11] and Catalonia proved a better record[12]. In this last case due to an agreement with primary physicians to compensate with an average 10% increase in salaries if they reached a predetermined amount of generics prescribed. Whether this incentive will continue for the future is not however clear. Andalusia, with a worse record in developing the market for generics, but still strongly concerned with pharmaceutical expenditure, has introduced some changes in the way that RP operates, through an agreement (sept 2001) with the Regional Council of Pharmacists. Although reference prices are unique for the whole Spanish State, regional health systems may introduce some differences. The Andalusia government has changed the definition of the product coverage for RP trying to reach the 10 top selling products (at

8 - As a result of the calculation method three results come out. First, the RP will always exceed the one of the generic drug. This is, the RP will be never inferior to the generic with the lowest price. Second, the minimum difference between the RP and the highest priced drug will be of a 10%, guaranteeing in this way at least a 10% saving and, finally the maximum difference with the lowest priced drug will be of a 50% (foregoing in this way further potential savings).

9 - For instance, omeprazol dropped once for all a 40% and on average the affected by RP groups experimented a fall in prices (basically due to the rebates imposed by the pharmaceutical companies) around a 14%.

10 - The promotion of generic products in Spain has been in place since 1997. From then around a thousand specialities have been registered having this market-grown steadily the last five years. Now the market share of generics is slightly higher than a 5%, but is mainly concerted (in a 75%) on four specialities.

11 Up to this year, the centrally managed by the State regional health systems before transfers.

the national level only 2 are affected by RP). This is achieved by considering for RP all those active ingredients with more than two products in the market.[13] This is, all the products with the same active ingredient and presentation form are considered homogeneous and the same RP applies. This allows for a wider coverage than the existing one for Spain (requiring a generic at least on each group). RP is then set at the level of the highest of the two lower priced product for each active ingredient, and pharmacists have agreed to dispense the lowest price product for each active ingredient, independently of its generic status.

However, for this to operate it needs prescriptions to take the active ingredient and not the commercial name of the product. We cannot for the moment to evaluate the effects of this differential strategy (the aggregate data do not seem so far to exhibit lower total increases), but there is no doubts that devolution is not neutral for pharmaceutical policies and more experimentation on prescription policies may appear too in the future. So far, there are important differences in the way drugs are prescribed across regions. Catalonia and the Basque country have developed pharmaceutical guidelines to advise General Practitioners prescription about new commercialised drugs. However, the number of drugs included is still small and consequently, has had no significant effects. Other initiatives have been the Andalucia proposal to follow the WHO recommendations by setting a price cap by active principle that GP´s are supposed to follow when prescribing drugs.

Some conflicts amongst the Department of Health and the full group of Regional Health Authorities have risen from the way that Farmaindustria, the corporate association grouping most of the Drug Companies, have bargained and signed different agreements with the Department of Health. Repayments from Farmaindustria to the Health Authority are not by any means new. In 1996 it was agreed a 4% rebate on laboratory prices plus discounts if additional sales (publicly financed) over-exceed a predetermined amount. Similarly in 1998 and more recently in 2001. The present agreement states a repayment of 60 million euros for 2002 and 2003, and half of this amount for 2004 in order to fund a public research program. This fixed contribution corresponds for the a publicly financed drug sales increase one point above the GDP nominal increase. Thereafter, for each point above that accepted amount, contributions from Farmaindustria will increase 33 millions additional euros up to a maximum of 100 million euros (for 3 points above the stated criteria).

[12] - I acknowledge comments and information for this section from Joan Costa and Jaume Puig.
[13] - This makes for over 240 active ingredients with 590 homogeneous products and 2900 products which sales account for 35% of the market.

However, in 2002, differently of what happened in the past, the Regional Health Authorities claim the right to participate on this extra finance either with the creation of a regional fund or by sharing decisions on how these central funds are applied in a less discretional way, since again they argue to hold the bills.

The disagreements in guiding pharmaceutical strategies between a common Spanish health policy and the new regionally financed and managed health systems are now more evident. Indeed, Regional Health Care Services will need to care of pharmaceutical policies, given its impact on total regional finance. For this, licensing new drugs and pricing for reimbursement purposes despite the fact that they continue under the central Departmental Health responsibility, will require with a more or less extent, the AC consensus. This has to be the case given the way that AC are financed. Regional Health Authorities will have to be heard whenever new drugs are approved or prices are decided, since they will have to hold, partly or totally, the resulting bill. Despite this, it is not clear so far the exact role of the AC in the process, since a new bill for central health coordination has not been yet approved.

In any case, it seems clear that the State is willing to keep a strong control of pricing and licensing drugs in order to avoid internal arbitrage on the basis of the safety and market disruption. However, the exact defintion of an identical entitlement of drugs for all the Spanish citizens cannot be guaranteed anymore, neither on the consumption access (the application for instance of the negative lists, nor in the copayment side (reference pricing when differently applied creates different effective copayments)[14].

The effort to hold drug legislation under a more strict central State responsibility explains probably that pharmaceuticals (and by extension, health care delivery in general) is still considered by the present Spanish legislation a part of the Social Security system. This is due to the fact that the Spanish Constitution does not allow for decentralisation on the Social Security arena. Indeed, this seems to be the case, despite this running against the common sense that Spain has an universal health care system not related anymore (since 1986) to social security contributions. This has also side- effects on the issue of who controls health care expenditure (at present, the Social Security Department with its own auditing office) and who owns the physical assets and the health sector facilities (at present, again, the central social security Fund). This is unfortunate since reposition

[14] Different parts of the paper, and this section in particular has benefited from the comments of Dr. R. Meneu.

and expenditure on new capital assets are financed by general revenues, tax funded and under regional responsibilities).

Although licensing and pricing for reimbursement purposes will probably remain under the responsibility of the central Administration, not likely the prescription policies (the mix and quantity factors). In fact, once health care delivery has been transferred to all the Spanish Autonomous Communities, and the pharmaceutical bill starts being paid by them, AC will naturally aim for a better integration of pharmaceuticals with the whole set of health care delivery. This is in itself a legitimate aim, since this is an important input for a rational health care delivery, and a straight forward and perhaps the simplest approach (other than freezing wages!) to expenditure control[15].

As a result, and as commented, without splitting the licensing and financing regime (in our view the way forward in changing the present state of affairs) is today difficult to hold the view that the central state should be allowed to approve new drugs and therapies without consulting and/or explicit compensating AC, if they have to pay the bill.

Finally, it seems clear that only one price makes sense in a free movement Spanish internal market (avoiding internal parallel trade and similar). However, it will be more difficult, and perhaps undesirable, to reconcile this with different prescription practices. This may create new concerns for pharmaceutical companies, since this new setting moves the target group for marketing and lobbying on a geographical and on a more diversified political influence, given the different parties in power in the Spanish AC. It is perhaps non sense to expect 17 different prescription policies, but a more competitive (emulating?) framework is undoubtedly today open, with new leadership coming out from 4 or 5 Regional Health Service Authorities..

In this new scenario, given the fact that regional finance departures from close capitation criteria (the existing at the moment of devolution) and that regional responsibilities will focus on the supply prescription side, we should foresee a role for regional health authorities rather similar to that of Pharmaceutical Benefit Management Units (PBM). In fact, they may work for their capitated Health Maintenance Organisations (Regional Services- HMO style, financed by their Finance Ministers) taking care of prescription strategies to improve pharmaceutical expenditure and, in case, keep savings. As in the case of PBM, this requires, on a territorial basis, establishing formularies

[15] Undoubtedly an easy arena than that related to manpower planning or to somephysicians remuneration problems.

and then negotiating rebates on these. From a territorial integrated delivery perspective it might reach positive or negative lists and monitor thereafter pharmaceutical consumption through the development of drug utilisation reviews. Regions may favour incremental therapies using the more expensive drugs at a later stage and to promote and facilitate the use of generics by changing incentives in physician prescribing behaviour better related to local conditions at the market place, and perhaps implementing some restrictive rules regarding refills and requiring additional authorisation procedures.

Despite an unique pricing reimbursement system defined at the central level, some margins may come out from selecting the licensed price according to the therapeutic value of the drug with regard to best practices from cross-regional comparisons.

This may help to reformulate the purchasing function of drugs in a closer protecting patient interests. In order to stimulate efficiency, more than a single monopsonist in a diversified (regional) risk-holding agencies[16], may be useful. They may bargain with the providers 'ex ante' on the grounds of pre-set prices, advocating different rebates -given the type of drugs and the supplier- and a narrow monitoring, for a more cost effective prescription and a better patient educated demand. This may decrease the actual spending trend and at the same time reduce waste in the consumption of drugs.

[16] - Some caveats may exist on whether financial control may be loosed by the decentralisation of the monopsony. It may be the case however that a better identifiable responsibility and risk-holding may press changes in physicians prescribing behaviour and a larger effort to keep regional finance in balance.

APPENDIX: SOME CROSS-COUNTRY COMPARISONS ON DECENTRALISED PHARMACEUTICAL POLICIES

Although the nature of the institutions of the fiscal federalism are not probably the only factor (the character of the health system in itself is relevant too) there exist few doubts about the point that decentralisation make for different health care policies. We summarise in the following section the case of USA States in public programs, German Länders, Canadian Provinces and Belgium Communities.

USA

Nearly half of the States in USA run pharmaceutical assistance programs in an independent separate way, and many other are developing new programs (see Ventimiglia S.C. for the Hearing on Prescription Drugs, National Governors Association, July 2001). They try to improve benefits through direct subsidies or discounts. Public involvement in Medicare and Medicaid reflects on several pharmaceutical policies, based on:

1- Different cost-sharing strategies and then different state senior citizens' co-payments. States use a variety of them, including annual enrolment fees, annual or monthly deductibles, co-payments and different strategies in relation to dispensing fees.

2- Eligibility differs too amongst States. For instance on age, disability, means test... or by the existence of an income cap (from 100 to 200 % of the federal poverty level amongst different States) and annual limits on benefits.

3- Differences in the type of drugs being covered (prescribed/ non-prescribed; for some treatments for specific illnesses.

4- The type of revenues to fund their pharmaceutical programs: from general funs to other earmarked revenues, including tobacco settlement funds, local foundation support, excise on tobacco products, sales tax on construction materials, lottery and casino revenues.

5- Several cost management tools, typically used by pharmacy benefit managers to contain pharmaceutical program expenditures, implemented by themselves or by subcontracting them out to Pharmaceutical Benefit management Companies: program enrolment, eligibility determination, outreach, claim processing reimbursement and drug utilisation review.

6- Some other management tools being implemented in a different level by the States are: group formularies; generic substitution, prior authorization; multi-tiered co-payment structures and negotiated manufacturer rebates and drug discounts.

For a further details, it can be seen 'State-Based Pharmaceutical assistance Programs: Temporary Fix or Lessons for Medicare' *National Health Policy Forum. Issue Brief*. no 762. The George Washington University.

Germany

The structure of the pharmaceutical market in Germany is seen by the pharmaceutical industry and the physicians' association as 'beneficial for the 'therapeutic freedom' of the medical profession. Not surprisingly, drugs without any or clear evidence of therapeutic effectiveness are amongst the most widely sold pharmaceuticals. German legislation has been mainly concentrated on cost-containment.

The Pharmaceutical policy in Germany is weakly dependent on administrative rules, since more of the relevant decisions are taken by scientific, consultancy work such as, among others, 'The Paul Ehrlich Institute (for blood sera and vaccines) and The Federal Institute for Pharmaceutical and Medical devices are in charge of licensing human drugs, safety being their most important concern. Only a marginal benefit effect of a new drug needs to be demonstrated with an small sample in order for it to be sufficient to fulfil the efficacy (not a cost-effectiveness) criteria (see *Health Care Systems in Transition. Germany* European Observatory on Health Care Systems, 2000).

On the whole, regulations concerning the pharmaceutical market offers to extreme cases. On the one hand, regulations concerning the distribution of drugs through wholesalers and pharmacies and their respective surcharges on ex-factory prices are established in great detail. Market admission is otherwise not linked to an obligatory comprehensive and systematic surveillance system. On the other hand, regulations concerning the pharmaceutical industry's pricing and the need to prove efficacy are remarkably liberal. The growing realization that a significant share of the prescribed drugs have a level of unapproved effectiveness, led to the introduction of the mandate for drug licensing in 1976. Before that, products only had to be registered, once a minor examination concerning possible toxic effects was passed. Also the new regulation affects only newly developed pharmaceuticals because the 1994 Act extended the deadline for licensing pharmaceuticals already in the market to the year 2005.

The fact that the federal administration involvement is rather low and that the 453 insurance companies have the final word on reimbursement and coverage of drugs may explain the lack of a Land involvement in pharmaceutical policies, limited at the regional level to the issues related to supervision of pharmacists and their pharmaceutical professional institutions. For instance, the most important body for the joint negotiation between sickness funds and physicians concerning the scope of benefits is the national-federal committee of Physicians and Sickness Funds, established in 1923. Amongst other responsibilities, the Committee issues guidelines to regulate the prescription of pharmaceuticals and medical aids.

Up to 1998 regional spending caps existed for pharmaceutical expenditure as a whole. Since this year, they were replaced by practice-specific soft targets on a regional level to exclude both certain types of drugs and drugs for patients under certain indications. Over-prescription sanctions do not seem to have been very effective in the past.

The coverage of drugs is regulated, as said, in the pharmaceutical guidelines of the Federal Committee of Physicians and Sickness Funds as a part of the contract amongst these two parts at the federal level. These guidelines are legally in force. They attempt to steer the appropriate use of different groups of pharmaceuticals, limiting the prescription of certain drugs to certain indications, specifying in cases that they may only be used after non-pharmaceutical treatments were unsuccessful, and in a few cases, disallow any prescription by the sickness funds (eg. Drugs to quit smooking). However the overall effect of these guidelines are very doubtful (HIT. Germany, 2000). Since 1999, licensing is not anymore a sufficient condition for the coverage by the social health insurance system. This may change a lot the German status quo of the drug policies in future. However, still the cross- Länder nature of most of the sickness funds and the remaining 'technical' non administrative character of drugs licensing and prescription (in hands of some Federal Institutes more than in hands of the central federal powers) seem to justify the weak presence of the regions in the German Drug policy issues

The Canadian Provinces

The federal-provincial discord on pharmaceutical policies in Canada is defined by A. Anis (*CMAJ,* feb 22, 2000) as a sort of 'Dog's Breakfast'. Indeed, prescription drug coverage varies widely across Canada. Provinces have the responsibility and jurisdiction over the funding al all health care services, including pharmaceuticals. The Federal government is responsible for patents and initial approval and labelling of prescription and for ensuring 'overall market

competitiveness'. It is, however, completely insulated from the impact of policies, because it regulates prices but it does not buy any drugs. In contrast, provincial governments have no jurisdiction over pricing yet end up paying for most of the drugs expenditures incurred.
Provinces have then full responsibility for funding, coverage definition and on the effective pricing policies, and other cost containment guidelines, such as drug product substitution laws. More recently, several provinces have mandated that a cost-effectiveness analysis of each new drug be done to help determine if the drug should be added to their formularies (Bacovsky RA: 'Drug submission, review and approval' *Joint Commission Pharmaceutical Industry-Ontario Ministry of Health*, Toronto 1997).

On the whole, provincial regulations highly differ. Despite the fact that the initial pricing of a new drug and any price increase over time is defined at the federal level, cost units effectively differ amongst provinces. This is the result of the provincial powers in defining coverage (by the pharmaco-economics condition), substitution laws (by reference pricing strategies) and the bargaining purchasing capability (discounts and rebates, either explicit or not). All of these affect unit costs and then the provincial drugs bill. In addition, given the need to strength controls on the pharmaceutical costs, provinces now conduct second review programs of each new drug before the drug is included under provincial financial coverage. In this step the new drug is typically compared with other similar drugs, in contrast with the Federal Therapeutics Products Program, at the federal level, which typically compares new drugs with placebo.
At present it seems that the Federation and Provinces follow separate and distant patterns: Federal regulations allow longer patent terms, higher prices and less generic competition. Obviously, the Federation does not face the consequences of its regulations. At the same time, provincial policies are requiring cost-effectiveness justification prior to formulary listing and reference pricing in order to contain higher drug acquisition costs. As a result of the different existing strategies, agreement amongst provinces on the concordance between formulary decisions is so low as 0.21 (kappa statistic, with a pairwise within a range of –0.11 and 0.64). (see Anis , ob .cit.)

In brief, Canadian Health Care is best thought of as a series of provincial health insurance systems operating within broad federal parameters. The Federal legislation (The Canada Health Act) specifies that provinces must respect five principles: universal coverage, they must cover all 'medically necessary' services; they must be publicly administered; coverage must be portable outside the province; and accessibility must no be limited by user fees or extra-billing

by physicians. The nature of these principles allow however for some interpretation and then variation. In addition, out of these principles, differences are legitimate and acceptable as a part of the existing fiscal federalism agreements.

Belgium

Belgium shows the case of the compatibility of a highly centralised system in health care and an effective policy making within the federal government very close to the new Community and the Regional Governments, by an important consultative mechanism of corporative governance.

Indeed, the decision that a drug can be registered is taken by the Ministry of Public Health after consultation with a pharmaceutical committee composed by scientists nad general practitioners) and a 'transparency' committee composed of representatives of insurance companies, universities, pharmacists, general practitioners and pharmaceutical companies. Registration has to be re-obtained every five years. The Ministry of Economic Affairs' Pricing Committee for Pharmaceutical Specialties set the maximum price at which the medicine can be sold at Belgium. After registration and the price known, a pharmaceutical company can apply to the Technical Council for Pharmaceutical Specialties to put a medicine on the positive list in order to be reimbursed by the compulsory health insurance on a national basis. The Council makes a recommendation, which often involves a reduction of the maximum price allowed, so as to make reimbursement feasible, ultimately under the decision of the Minister of Social Affairs. Thereafter, the drug is classified for a given co-insurance level according to the social importance of the drug, pharmaco therapeutical criteria and price parameters. No cost effectiveness procedures are required for the approval and reimbursement.

As explained, regional direct involvement on the whole process is almost nil. However, indirect involvement through concertation is required given the need of consent of federal representatives from both the French and Flemish speaking groups. Despite the fact that they do not have a formal role in the federal legislature, an elaborate set of rules and regulations in the health sector mandate notification and consultation between levels of government. In addition at present, Flemish nationalists are pressing for a larger decentralisation of key elements of social security, including health insurance. So far the Wallonian community has resisted any further decentralisation but the fight is still there.

In brief, the specificity of the policy framework (consultation and concertation of procedures) is in Belgium high, with important interregional financial transfers between existing Communities, and with relatively low interregional differences, so far in the way that the Health Care System is managed. In other words, whenever the technical role of the insurance is larger in a health system (in contraposition to the more central politically administrated Health Services) actually less intervention seems to be claimed by the regions in the context of decentralised political jurisdictions.