Pharmacy

Support for pharmaceutical costs is a basic element of health care both because of its effect on patients' health and because of the importance that this cost has in the overall budget of the health services. The regulation of this sector aims to maximize the positive effects, limiting the spending on pharmaceutical products at the same time.

Given the dynamic nature of the sector, in which companies make enormous investments to create innovative products that improve the health of the population and their own finances, public expenditure must walk a fine line between maintaining the financial sustainability of the health system and the access of the citizens to a high quality pharmaceutical service.

Besides which, the last decade has seen the cost of pharmaceuticals (not including hospital costs) rise in relative importance within the context of the total spending on health in most of the countries of the OECD (Organisation for Economic Co-operation and Development).

Table XIV shows this development. In 1995, Spain belonged to the group of countries (Portugal, Italy and Spain) in which spending on pharmaceuticals represented an important part of overall health spending.

Table XIV: Evolution of pharmaceutical spending as a percentage of total health spending between 1995 and 2005

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Germany	12.9	13.0	13.1	13.6	13.5	13.6	14.2	14.4	14.5	14.0	15.2
Canada	13.8	14.0	14.7	15.1	15.5	15.9	16.2	16.7	17.0	17.3	17.7
Denmark	9.1	8.9	9.0	9.0	8.7	8.8	9.2	9.8	9.3	9.0	8.9
Spain	19.2	19.8	20.8	21.0	21.5	21.3	21.1	21.8	22.9	22.8	22.9
United States	8.9	9.3	9.8	10.3	11.2	11.7	12.0	12.4	12.5	12.5	12.4
Finland	14.1	14.4	14.8	14.6	15.0	15.5	15.8	16.0	16.0	16.3	16.3
France	16.0	16.0	16.4	16.9	17.7	18.2	18.8	18.7	16.5	16.6	16.4
Ireland	10.5	10.4	10.0	10.2	10.4	10.6	10.6	11.1	11.6	11.8	10.9
Iceland	13.4	14.0	15.1	14.3	13.7	14.6	14.1	14.1	14.6	14.4	13.3
Italy	20.7	21.1	21.2	21.5	22.1	22.0	22.5	22.5	21.8	21.2	20.1
Norway	9.0	9.1	9.1	8.9	8.9	9.5	9.3	9.4	9.2	9.4	9.1
Portugal	23.6	23.8	23.8	23.4	-	22.4	23.0	23.3	21.4	22.3	21.9
Sweden	12.3	13.6	12.4	13.6	13.9	13.8	13.2	13.0	12.6	12.5	12.0
Switzerland	10.0	10.0	10.3	10.2	10.5	10.7	10.6	10.3	10.5	10.4	10.4

OECD Health Data, 2007.

In Spain the amount was 19.2%. The following ten years saw this figure rise in proportion compared with total health spending, while Portugal and Italy both saw this figure fall in relative value. Therefore, in 2003, Spain was the country in which pharmaceutical costs reached their highest level, and in 2005 this cost represented 22.9% of the total. Meanwhile, in other countries, including Canada, Finland, France and Germany, pharmaceutical spending is intermediate, situated between 15 % and 17 %, and with moderate growth in the last ten years, while countries such as Denmark, Ireland, Norway, Iceland, Sweden, Switzerland and the United States have a successively lower proportion of pharmaceutical spending, ranging from 8 to 13%. Spending on pharmaceuticals therefore emerges not only as one of the basic services provided as part of health care in different countries, but also, due to its relative weight, in one of the most important factors in health spending, and which justify the efforts made by regulators to increase the beneficial effects of medicines while at the same time controlling the spending on them.

2006 saw the passing of a new general law regulating the use of medicines: the Guarantees and Rational Use of Medicines and Medical Products Act 29/2006, of the 26th of July. This is a general law which establishes the exclusive authority of the state not only in matters of legislation concerning pharmaceutical products, but also in the legal bases and general health coordination. Although it is basically concerned with the legislation of pharmaceutical products, it also regulates the bases of other aspects related with the organization of pharmaceuticals (such as the distribution of medicines, prescriptions, hospital pharmacies, pharmaceutical offices, handling of information accompanying prescriptions, etc.).

In terms of the specific area of pharmaceutical regulation, there have been changes in the rules applied in the Autonomous Communities.

The Canary Islands[98] and Valencian Community[99] have modified their laws regulating pharmacies administration while Extremadura has passed a new Pharmacy Act[100]. Navarre is also carrying out modifications in the organization of its pharmaceutical service[101].

98 Act 3/2006, of the 20th of March, modifying article 33 of the Act 4/2005, of the 13th of July, of Pharmaceutical Regulations in the Canary Islands; Order of the 15th of May 2006, approving the boundaries of the pharmaceutical regions of the Canary Islands.

99 Act 7/2006, of the 9th of June, modifying Act 6/1998, of the 22nd of June, of Pharmaceutical Regulation of Valencian Community..

100 Act 6/2006, of the 9th of November, of Pharmacy in Extremadura.

101 Foral Decree 72/2006, of the 16th of November, modifying the Foral Decree 197/2001, which set out the guidelines for the development of Act 12/2000, of the 16th of November, of Pharmaceutical Attention concerning Pharmaceutical Offices.

Pharmaceutical spending in Spain associated with the invoicing of prescriptions issued by the National Health Service during 2006 amounted to over 10,799 million euros, spread over 793,015,672 prescriptions. This implies a 4.09% increase in the total number of prescriptions issued by the National Health System, and an increase in the total spending of 5.82% between 2005 and 2006.

This means that the spending per prescription in the National Health System has grown from €13.15 in 2005 to €13.36 in 2006, which represents an annual increase of 1.65 %[102].

The analysis of spending on pharmaceuticals in Spain which is associated with the invoicing of medical prescriptions from the National Health Service during 2006 has been based on five indicators and broken down by Autonomous Communities (table XV). The first two are absolute indicators (total number of prescriptions and total pharmaceutical spending) and reveal which of the Autonomous Communities has greater weight in the market and pharmaceutical spending (Andalusia, Catalonia, Valencia and Madrid), but not the effect of the policies for the rational use of medicines.

The third indicator, the average cost per prescription, gives us the first indication towards the rational use of medicines. Andalusia and Catalonia are the Autonomous Communities which have the lowest cost per prescription in 2006. This indicator has some limitations, however, such as the differences in the prescription guidelines that are followed in different communities (such as a promotion of different generic medicines).

2006 has been a year in which most of the Autonomous Communities have been consolidating previously inaugurated strategies, accompanied by advances or innovations that have been mentioned by several of them. The general framework for the rational use of medicines is a prevailing factor in each of the regions analysed. Several variations can be observed in their interpretations, but there are two primordial features at the root of all of them: first of all, the defence of rational use in pursuit of an improvement in the quality of prescription and the service offered to the user/patient/citizen and, secondly, the idea of this quality in the level of assistance offered being complemented by the support it offers to the financial resources of the health system. All of the regions have manifested their efforts to encourage a rational and efficient use of medicines, although there are variations in the tools employed. This is a logical consequence of the key concepts which each community applies, and which vary according to the medium and long-term strategy which the corresponding health authority has established.

102 The national figures for 2005 were obtained by using provisional data available at the web page of the Ministry of Health and Consumers' Affairs (www.msc.es/profesionales/farmacia/datos/diciembre2006.htm) whereas the data for 2006 was obtained by adding together all the data recently provided by the Autonomous Communities for the Ministry.

Table XV: Homogeneous indicators of pharmaceutical provision in Autonomous Communities, 2006

Autonomous community	Total number of prescriptions	Total spending on pharmaceuticals (euros)	Average cost per prescription	Percentage de prescriptions for generic drugs/ total prescriptions	Percentage of cost in generic drugs/total spending on pharmaceuticals
Andalusia	144,212,070	1,739,302,732.00	12.06	22.16	12.23
Aragon	24,400,843	355,473,672.59	14.57	14.62	6.15
Asturias	21,550,618	318,101,562.18	14.76	13.65	6.54
Balearic Islands	13,698,142	194,157,739.83	14.17	21.36	10.12
Canary Islands	33,535,348	462,526,886.83	14.51	9.50	11.00
Cantabria	10,001,198	134,459,207.12	13.79	8.82	4.00
Castile and Leon	44,609,095	643,611,085.53	14.43	18.99	8.28
Castile-La Mancha	37,211,628	505,745,285.00	13.59	17.10	7.91
Catalonia	129,274,450	1,674,288,889.00	12.95	20.28	10.57
Valencian Community	95,285,147	1,414,262,724.00	14.84	11.08	4.73
Extremadura	21,536,048	295,249,107.00	13.71	14.68	7.56
Galicia	54,569,481	781,128,656.16	14.31	7.67	3.63
Madrid	87,740,960	1,148,110,366.96	13.09	22.88	10.57
Murcia	24,857,968	374,083,737.60	15.04	10.38	4.77
Navarre	10,231,203	144,219,881.00	14.10	14.67	7.02
Basque Country	33,217,638	493,181,728.47	14.85	9.71	4.24
Rioja	5,219,282	73,030,452.09	13.99	14.35	5.83
Ingesa (Ceuta y Melilla)	1,864,553	24,172,210.89	12.96	15.34	6.80

Created from information provided by the Autonomous Communities for the National Health Service Annual Report, 2006.

There is also an idea which runs through all of the reports on pharmaceuticals which the different autonomous communities have submitted[103]. The improvement of the information systems is a crucial element which should contribute towards better management of the available resources. This idea is emphasised in every report, and every one of the regional health authorities has made it one of their priorities.

103 When this information becomes available, for example, in 2006, some autonomous communities, such as Murcia and Asturias did not send information referring to significant actions undertaken that year relevant to the analysis of pharmaceutical prescription and policies of rational use. This does not mean that no action was taken, but simply that it was not considered to be a new development, as they may have been doing it for some time.

The Ministry of Health and Consumers' Affairs assigned 105 million euros in 2006 to a battery of measures aimed at promoting a more rational use of medicines, by developing continuous vocational training programmes for doctors in the National Health System, a programme of health education aimed at the general public and policies of cohesion in this health issue.

In relation with the Strategic Plan for Pharmaceutical Policy, the continuous training programme for doctors of the National Health system was established in 2006 with a budget of 70 million euros. It forms part of the commitment which the Ministry of Health and Consumers' Affairs assumed regarding training, and it makes it possible to implement and strengthen the initiatives developed until this time by the Autonomous Communities.

The most important of these initiatives carried out by the Autonomous Communities are listed below, classified into groups according to the measures introduced:

- Policies of prescription by active ingredient and promotion of generic medicines.
- Improvement of information systems:
  - Support for electronic prescription.
  - Electronic prescriptions.
  - Creation and distribution of therapy and pharmacology guides.
  - Training programmes and information aimed at the prescription writers.
  - Informative programmes aimed at users/the general public.
- Improvements in coordination of assistance:
  - Coordination programmes between specialised services and primary health care, in general.
  - Programmes of attention for chronic illnesses and patients with multimorbidity/polymedication.
  - Programmes for pharmaceutical support in health and social centres.
- Programmes of individual incentives for prescription writers.
- Improvements in the purchasing process.
- Others.

This classification has been proposed for functional reasons, and it is clear that this and any alternative method would not be free of difficulties, given the inherently complementary nature of the different actions outlined. For example, it would not be possible to introduce a valid incentive programme for prescription writers without a good information system. Similarly, one of the indicators of quality used to receive this incentive could be compliance with the criteria set out in a pharmacological

guide, or meet a set quota of prescriptions for generic medicines[104]. In this way, the strategies for the rational use of medicines combine the tools mentioned in the previous classification in order to offer a quality service at a cost that the system can afford to pay.

The Royal Decree 1338/2006 was published on the 21st of November, and it develops certain aspects of article 93 of the Act 29/2006, of the 26th of July, on guarantees and rational use of medicines and medical products in the framework of the referenced pricing system. In the same way, the order SCO/3997/2006, of the 28th of December, determines the groups of medicines and their referenced prices, and regulates certain aspects for the application of the contents of the Guarantees and Rational Use of Medicines and Medical Products Act 29/2006, of the 26th of July.

The average consumption of generic medicines in the National Health System during 2006 reached 16.83 % in terms of containers dispensed, with a variation from 16.08% in January until 18.17% in December of the same year, which represents an increase of more than two points.

As regards the percentage of generic prescriptions as a proportion of total prescriptions, there are notable variations between communities. Madrid is the community with the greatest relative weight, at 22.9%, followed by Andalusia (22.2%), the Balearic Islands (21.4%) and Catalonia (20.3%). At the opposite end of the scale, Galicia is the community with the lowest proportion of generics compared with all prescriptions, at 7.7%, followed by Valencian Community with 11.1% and Asturias with 13.7%.

Most of the Autonomous Communities place emphasis on their efforts to promote prescription by active ingredient and the prescription of generic medicines. In Andalusia, for example, 70% of all prescriptions are dispensed by their active ingredient.

The manner of promotion varies. For example, some communities have chosen to include indicators related to prescription by active ingredient or to a certain quota of generic medicines prescribed among their criteria for quality. Others include these indicators in their programmes of individual incentives for prescription writers as an alternative, or even as a complement to the above. At the same time, the creation and adoption of pharmaceutical guidelines, and their distribution among prescription writers, training programmes and information about generic medicines or prescription by active ingredient, and the efforts of primary care and hospital pharmacists

104 The description "generic pharmaceutical speciality" (especialidad farmacéutica genérica) is defined in article 8 section 6 A of the previous Medicine Act 25/1990, of the 20th of December. At present, article 8 of the Act 29/2006 establishes the definition of "generic medicine". Further on, in article 14 (identification guarantees) the aspects dealing with the naming of medicines are regulated, determining in point 2 that generic medicines will be identified by the letters EFG.

all have an influence on the prescription writers who are responsible for meeting the objectives outlined above.

Another interesting measure mentioned is the signing of agreements between the health authorities of several regions and the official schools of pharmacists on the maximum price of prescriptions by active ingredient, and the prescription of generic medicines.

The group of measures adopted with the aim of seeking improvements in the information systems were also underlined. This improvement in information systems is not an end in itself, but different health agencies coincide in affirming that it is an essential factor in the optimisation of resource management.

It follows that making better and more complete information available is a key factor in the rational use of medicines, thereby providing the patients with better quality health care. This element is therefore present to a greater or lesser degree in nearly all the actions presented by the Autonomous Communities.

The pursuit of improvements in the information handling systems can be transferred to different scenarios. In any case, the final beneficiary of these improvements should always be the patient. However, it is worth recalling that the asymmetric relationship in the health sector regarding information generates a relationship where the principal (the patient) entrusts his or her decision to an agent (the professional) with greater technical understanding of the problem in hand (his or her health). This leads to a second relationship between these professionals and the regional health service, wherein the latter employ the former and can condition the contract or part of its payment to the achievement of certain goals. Finally, there is the relation between the public and the financial administration of the health services (regional government and health services) in which the former choose the representatives of these organizations, and expect, in their role as taxpayers, that the resources are handled efficiently and, in their role as patients, that the service provided meet demanding standards of quality. The figure of the health manager has to reconcile these two objectives.

Therefore, although the patients are the final beneficiaries of the improvements in the health service, they are not always the final recipients of improvements in information handling.

2006 saw the Directorate General of Pharmacy and Medical Products working on an improvement in the information system for the pharmaceutical service with a new software application for handling the names of pharmaceutical products, their manufacturing date and consumption via prescriptions. This improvement in the application aims to make it possible to interrelate the information systems of the autonomous communities and the Ministry of Health and Consumers' Affairs, leading to more efficient use.

The development and introduction of an information system for medicines based on prescriptions has been mentioned as a relevant point by several communities. Such a system can support other measures in meeting their objectives, such as the prescription by active ingredient and the promotion of prescription of generic medicines, or to alert the prescription writer of possible incompatibilities between prescribed medicines. The combination of the electronic prescription system with the digital clinical history has created synergies by improving prescription information on the previous experiences of the patient and the pharmaceutical possibilities available.

The steps taken by several communities towards the introduction of an electronic prescription system are worth mentioning. Electronic prescription "is a technological process which allows us to develop the professional functions by which medicines can be prescribed automatically, and the instructions for treatment stored in a database accessed from the dispensing point where the medicine is given to the patient"[105].

Following on from the Individual Health Card and the conversion of patients' clinical registers (to digital clinical history), the introduction of the electronic prescription is one of the key areas for action in the Quality Plan for the National Health System as regards the use of information technology.

2006 also saw actions by the Directorate General of Pharmacy and Medical Products on the project of the Royal Decree of medical prescriptions and orders for hospital dispensaries.

As regards electronic prescriptions, it establishes, among other things, that the aspects bearing on the criteria for offering the pharmaceutical services of the National Health System, the guarantee of its application in the Autonomous Communities and the setting up of basic criteria on the design and use of electronic prescriptions will all be regulated.

Among the objectives which the introduction of electronic prescription aims to achieve are those of "guaranteeing that the public can receive their prescribed medicines from any pharmacy in the country without a paper prescription; freeing the medical profession from the administrative and accountancy aspect of prescription writing; encouraging programmes for the rational use of medicines, and advance towards the introduction of information systems which allow the Autonomous Communities to be informed about the transactions taking place".

105 From the Ministry of Health and Consumers' Affairs Quality Plan of the National Health System. Use of Information Technology to improve attention offered to patients. Strategy 11. Online health. October 2006.

Some communities had already started in 2006 to introduce an electronic prescription service, or indicated that such a measure was in the pipeline (Andalusia, the Balearic Islands, Catalonia, Valencian Community, Galicia, Basque Country and Rioja), and it was an aim explicitly mentioned by others.

In preparation for this future development of medical prescriptions, several communities have already introduced electronic authorisation. In these cases, agreements have been signed between the official schools of pharmacists in the respective communities so that the application of this authorisation can be handled quickly in the pharmaceutical offices.

The introduction of *therapy and pharmacology guides* in support of prescription in another element mentioned by several communities We can distinguish several variations: some communities have adopted a therapy guide for primary care published by SemFYC (Spanish Family and Community Medicine Society), and others have chosen to create their own guides, employing experts and prescription writers from their own health services. The information in the guides is supplemented by regular publications in pharmaceutical bulletins and clinical test results of newly commercialised active ingredients.

Two more activities which support those already mentioned are the reinforcement of the role in the rational use of medicines played by the pharmaceutical and therapeutic committees in hospitals, and the incorporation of pharmacologists as support for the management teams of primary care. These pharmacologists can fill a support role of or provide training. A number of the communities underline their actions in training prescription writers.

The programme of continuous training for National Health System doctors responds to its need to articulate a comprehensive training strategy which will ensure the development of training activities on the subject of medicines for its doctors. This training strategy has to be stable and permanent over time so as to ensure that the state of knowledge regarding pharmaceutical therapy, which is continually advancing, is maintained up to date.

The training programme is to be managed by the Autonomous Communities. The distribution of funding decided by the Interterritorial Council of the National Health System was settled with a fixed amount of 100,000 euros for each community, with the remainder distributed in accordance with population criteria. The distribution of this fund is as follows: Andalusia (12,219,000 euros), Aragon (2,070,000), Asturias (1,793,000), the Balearic Islands (1,606,000), the Canary Islands (3,120,000), Cantabria (975,000), Castile and Leon (4,032,000), Castile-La Mancha (3,015,000), Catalonia (10,841,000), Valencian Community (7,262,000), Extremadura (1,795,000), Galicia (4,437,000), Madrid (9,251,000), Murcia (2,141,000), Navarre (1,022,000), Basque Country (3,435,000), Rioja (563,000), Ceuta (218,000) and Melilla (207,000).

These training activities are destined for the benefit of the doctors of the National Health System. The group of MIR deserve special consideration as they are at the stage where they are learning what are to be their guidelines for prescription in the future.

The selection of training activities is the responsibility of the communities. The programmes are oriented towards four preferential training areas: updating clinical and therapeutic information on the most common pathologies in Spain, introducing new active ingredients to the pharmaceutical service of the National Health System, encouraging generic medicine and actions related to drug-related illnesses.

Together with the support and training offered to the prescription writers, it has been useful to address information to the patients (in campaigns on the rational use of antibiotics and information on generic medicines supported by the Ministry of Health and Consumers' Affairs, and regional campaigns) The primary care provider and the pharmaceutical offices have been the preferred means to reach the patients.

The programme for informing professionals and the general public, funded with 15 million euros, has been used to set up informative actions in favour of the rational and responsible use of medicines.

The National Health System aims to guarantee by these means to provide medical professionals with permanent access to independent information on medicines. This scientifically valid information will be updated and made available free of charge and password protected for all doctors and pharmacists in Spain via the internet.

The information system for medicines will also regularly make reports considered clinically relevant available for professional users. It will also include the therapy guides for primary and specialised care, which will be made available for professionals free of charge.

Campaigns aimed at the general public will make the users of the system better informed concerning medicines and the negative consequences that they can have on health (adverse effects).

Some communities already provide a pharmaceutical therapy guide, not only for the medical professionals, but also for their patients. Finally, one of the communities (the Balearic Islands) has encouraged efficient use of medication by using new technologies (SMS to remind patient to take medicine). Several communities have developed programmes to provide orientation to improve the pharmaceutical treatment for specific types of patient.

Several communities (the Balearics, Cantabria, Catalonia, Extremadura, Valencian Community and Rioja) have promoted activities to link up the *medicines from public health and social centres* with the pharmaceutical services of primary care and hospital pharmacies (Castile and Leon) In Extremadura,

a guide for pharmaceutical therapy of the elderly was approved in November 2006, in collaboration with the medical service of the Social Services Council and the doctors of the most important private residential homes.

One aspect which is particularly relevant is the introduction of individual incentives which tie health professionals with the efficient use of medicines. This is clear in the fact that more autonomous communities are adding this to the working conditions of their health workers.

Some communities have their centre of operations set the level of these indicators after consulting experts. Others reach agreements with the prescription writers themselves (or their representatives), and it is the qualified staff that are the principal contributors to the pharmaceutical therapy guides, which they must later abide by in order to meet the quality targets set.

Another measure which was commonly referred to by the health representatives of the communities was the advance that has been made in the *rational management of purchasing.*

As part of the rational use of medicine policies, some autonomous communities have given great importance to the systems of pharmacological vigilance. In Spain, the adoption of the *Therapy Guide for Primary Care* published by SemFYC (Spanish Society of Family and Community Medicine) on the part of several regional authorities has been notable, while others have written their own guides, using experts and prescription writers from their own services.

A third group of measures refer to the coordination of health care. Improvements in the information system can permit better coordination between primary and specialised care, although the communities remark that it is important that initiatives focused on specific goals are encouraged. Examples include a unique digital clinical record shared between primary care and specialists, introducing a prescription module with recommendations from a shared therapy guide. Common protocols of intervention developed and a single management body suggested, along with the establishment of corporate standards and indicators, to be shared between primary specialised care. Commissions formed for the rational use of medicines and pharmacy in which experts and professionals from both areas of assistance contribute.

Hospital pharmacies are specially interesting because of their increasing spending, but also because of the previously mentioned process of coordination between different levels of assistance, and the restructuring that hospital dispensaries have experienced in recent years, with a higher profile in the safe, efficient and effective use of medicine in hospitals, providing guidance for the professionals in their consultations with outpatients and contributing to the reduction of medical errors due to inadequate medication.

In conclusion, and with a view to the future, the evolution of pharmaceutical services in the Spanish National Health System in the first

years of the 21st century is marked by three fundamental elements: the conclusion of the process of transferring responsibilities for health issues to the autonomous communities which have not already adopted them, with the accompanying new system of financing, which became law on the 1st of January 2002; the Strategic Plan for Pharmaceutical Policy for the Spanish National Health System, which was drawn up by the Ministry of Health and Consumers' Affairs and published in November 2004, and finally, the passing of the Guarantees and Rational Use of Medicines and Medical Products Act in July 2006.

It only remains to mention that the Directorate General of Pharmacy of the Ministry of Health and Consumers' Affairs has proposed that independent clinical trials be prepared and carried out as part of the programme for the development of policies of cohesion in health matters, which has been endowed with 20 million euros, and that the members of the ethical committees on clinical trials be selected in collaboration, and activities carried out to improve the quality of pharmaceutical care.