VI European Research Framework Project

HEALTH BASKET PROJECT

SPANISH HEALTH CARE BENEFITS REPORT

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Table of Contents

PART I. Overall description of the Spanish Health Care System and its Benefits package

Spain has one of the highest life expectancies among OECD countries. However, health expenditure remained at a relatively moderate level. Publicly financed health services are for the most part also publicly provided, with some contracting-out arrangements with private and local public institutions. The Spanish health system is largely based on public financing, with public production also playing a prominent role. Although the Spanish health care system appears to perform quite well in terms of aggregate financing and overall traditional health indicators, health care reform ranks very high on the Spanish political agenda.

The beginning of the process of reform of the Spanish health care system can be traced to the passing of the General Health Act (*Ley General de Sanidad/LGS*) in 1986, although some components and relevant pieces of legislation were established earlier. The main provisions of this law were to achieve universal coverage, to move from payroll to general taxes as the main source of finance and to gradually devolve public management responsibilities to the regional governments. At the beginning of the 1980s the focus of the reform was on the move from a social security type of system to a National Health Service (NHS) type, with universal coverage and financed from general taxation. The concern for equity and the reduction of inequalities were among the main stated priorities. In the late 1980s and especially in the 1990s cost containment became the first priority and the focus of the reform shifted towards changes in the financing, organisational and management models. The key concepts would now be efficiency, incentives, the separation of financing and provision, risk sharing, and so on.

The reform of the health care system has been going on together with a political process of decentralisation of the state, which has markedly affected health reform. The Spanish health care system of the 1970s was a very centralised one. Since then it has undergone several types of decentralisation processes. The most important of these was probably the transfer of the responsibility of managing health services from the INSALUD (the social security agency formerly responsible for the financing and delivery of health services) to the autonomous communities (AC), which followed the political decentralisation of the state into

autonomous communities according to the Constitution of 1978. Some of the initial objectives of the reform, such as universalisation and tax-based financing, have almost been accomplished.

The financing system was not transferred straightforward from the Social Insurance to the general taxation and it was not until 1999 when the system was consolidated with the overall financing coming from the new sources.

The General Health Care Act (1986) and the Organic Law on special procedures in Public Health (1986) were created according to the main following objectives:

- Promotion and prevention of illnesses,
- Public Health Care service to all population,
- Access and service on effective equality, and
- Health policy oriented to overcome social and territorial differences

Universal access, equity, solidarity and an important devolution process of health care to the Spanish regions - Autonomous Communities (AC from now on) - are the main features of this new public health system. Although universal access to health care to all Spanish citizens was formally defined in the 1978 Constitution and articulated in the 1986 General Health Care Act, it was not until 1999 that general taxation finance ultimately substituted payroll taxes. Since 1981, a gradual process of asymmetric health care devolution took place up until January 2002.

The process of transferring Health Care management to Autonomous Communities (AC) was initiated in 1981 with the transfer to Catalonia, followed by Andalusia (1984), Basque Country and Valencia (1987), Galicia and Navarre (1990), and the Canary Islands (1994), the remaining AC received the transference in year 2002. Thus, currently the health system qualifies as a system of regional health services, often named as National Health System (NHS).

The first of January of 2002 the process of transferring competences from INSALUD to AC finished. Since then all AC have their own Health Care Service. Present duties of INSALUD are coordination, management of former INSALUD and the provision of health care assistance to Autonomous Communities of Ceuta and Melilla.

Prior to these events, the major attempt to create a Social Insurance System was done by the Basic Social Security Act of 1967, which initiated the expansion of coverage to self-employed professionals and qualified civil servants. The Spanish Constitution in 1978, had also implied the creation of the National Institute of Health (INSALUD) –from 2003 called INGESA (National Institute of Health Management) by Royal Decree 1087- and the transference of the Public Health responsibilities to some Autonomous Communities (Basque Country and Catalonia).

Some considerations must be taken into account when discussing about whom is entitled and from which law gets this right. At the beginning of the 1940s, health care coverage was provided by the Social Security (SS) Health Service, i.e. Compulsory Sickness Insurance for workers in the lowest income bracket. Since then, population coverage and healthcare network have grown continuously. The 1978 Spanish democratic Constitution is the starting point for the public health care becoming independent from Social Security System, as both matters were developed in separate articles. This remark was reflected immediately in the statutes of autonomy of all the Autonomous Communities, which assumed the competences of health care and social security separately. With the General Health Law and subsequently, the Royal Decree 63/1995 on the organization of health services provided by the NHS, health care assistance is clearly integrated in Health System (Beltrán Aguirre, 2002). This process was culminated in 2000, when this health care began to be financed by general taxation. However, in 1997 was passed a law (24/1997, on consolidation and rationalization of the Social Security System) as a result of Toledo Agreement, which on the contrary of the described evolution, includes inside Social Security coverage some cases of health assistance, such as maternity, common or professional illness and accidents (both labour related or not).

Despite all this discussion, health care was considered already in the Constitution as a universal right. This means that health care coverage must not distinguish in terms of quality among different conditions of people (citizen, worker, resident, etc.). We can then identify both systems and regulations (health care and Social Security) in order to consider all collectives of society entitled to health care.

Hereafter follows a brief description of the Actual health care system and its evolution.

Structure of the health care system

Despite health coverage is defined by Constitution as a “fundamental right”, it is difficult to find the precise content of the health care entitlement as well as an explicit definition of NHS goals, both at the state and at the regional level. As stated in the 1986 General Health Care Act, the NHS is expected to work towards both health promotion and illness prevention, by providing health care to all residents in Spain, and achieving equality of access as well as to help to overcome social and geographical differences.

Health care is currently the foremost policy responsibility of the AC – jointly with education accounts for 60-70% of total funds managed by AC. The so called-Cohesion and Quality Law, passed by in 2003, states the need of strengthening geographical equality of health protection as well as quality of care. This is a particular concern since AC are quite heterogeneous in size, which ranges from less than three hundred thousand million inhabitants up to over nine millions inhabitants.

The central government has exclusive competences on external health (quarantine, vaccination programmes), basic general health, coordination, guaranteeing equity and pharmaceutical legislation (mainly licensing of medicines) (art. 149.1.16º Constitution). While basic legislation is in principle issued by the central state, certain common decisions draw upon the input of the Inter-Territorial Council of the NHS -an advisory committee comprising representatives from the central and regional governments- where coordination, as legally defined, must take place. The Ministry of Health (MoH) takes the central governance of the NHS, although in some critical domains the Ministry of Social Security - still the owner of the buildings- and the Ministry of Finance exercise remarkable responsibilities (for example, in evaluating the economic impact of new benefits).

One would expect from any decentralised NHS should define the “minimum” set of benefits and enable regions to develop additional coverage at the expense of their own fiscal effort, thus transferring risk management to regions. Heterogeneous health expenditure might then result only from differences in clinical practices and central priorities in health care allocation from the past. However, in the new Spanish health System regions might decide to top up expenditure redistributing their budget allocations, therefore taking the risk of a

growing heterogeneity in per capita health care expenditure across the territory even higher than the health status heterogeneity.

1. Health care funding and expenditure

Health care expenditure accounts for 7.6 per cent of the GDP in year 2002 with approximately three quarters (5.4 per cent) corresponding to public expenditure and a quarter (2.2 per cent) to private expenditure. Individuals can supplement the NHS by purchasing private health insurance (PHI), covering mainly primary care and hospital amenities on fixed providers' list.

Input prices in the health sector have been growing at a slightly higher rate than those in the rest of the economy, although the differential is not increasingly wide, mainly due to wage deflation of health professionals. Therefore, other determinants are behind the health expenditure rise: such as health care coverage, the ageing process and especially significant changes in utilisation patterns.

Alongside public expenditure, the composition of private health care expenditure has significantly shifted from 1980 to 1995. Dental care, mostly not covered by the NHS, accounted for 17% of private expenditure in 1980, and from 1990 it has been stable around 30% of total private expenditure. In contrast, the progressive reduction in pharmaceutical co-payments (effective co-payment rate was about 18% in 1980, and declined to 7% in 2003) leaded to out-of-pocket drugs expenditure to decline its share of private health expenditure. Private health care plays a complementary role for the NHS when it does not provide coverage for certain services (e.g., dental care), fulfils the demand for quality of care (non-clinical facilities and waiting list avoidance in primary care). Private provision is substituting NHS coverage, financed by public funds, for some civil servants (MUFACE system, developed later on in the text), at no additional cost.

2. Resource allocation

Spain is divided into seventeen regions, called autonomous communities (ACs), with regional governments that were created following the guidelines established in the democratic Constitution ratified in 1978. There are two completely different systems of decentralisation, the foral regime, instituted only for the Basque Country and Navarre, and the common regime, for the other fifteen regions.

The primary difference between the two systems is that regions under the foral regime have authority to raise taxes locally, whereas regions under the common regime do not have significant taxing authority. The most recent reform, passed in July 2001 and effective as of 2002 devolved some taxing autonomy to regions under the common regime). In terms of spending, both types of regions have similar responsibilities.

Tax Funds are centrally collected -with the exception of Navarre and the Basque Country and some minor taxes for the remaining regions. Before 2002, the system has operated under a single central transfer. An agreement of the *Consejo de Política Fiscal y Financiera* was reached in November 1997. This agreement established a General Fund for regional Distribution (accounting 98.5% of total resources). In the agreements for the regional allocation of general revenues on year 2001, health care expenditure was included into the general transfer system, expanding the basis for calculation to other factors than population such as isolation, average income and density of population and age. A Cohesion Fund to be funded by the central budget has been developed –so far with a low starting amount- to devote resources to subsidise cross boundary flows of patients amongst regions. A more precisely defined basic entitlement package will become a necessity if patients are not to exploit regional differences.

Public funds have been allocated to the decentralised ACs (the regional level) according to different criteria. The regional financing system for health services introduced in 2002 is characterised by several notable changes. First, health services are integrated under the general regional financing system, which includes all public services (education, health, social services, etc.). However, ACs must devote to health services at least a minimum amount established by the central government (expenditure needs level) that can be raised subject to autonomous decisions with regard to financing sources. This expenditure needs level is calculated as a weighted function of covered population (75%), population over 65 years (24.5%), and insularity (0.5%). Regional variation in the aged population will probably result in greater differences in expenditure per capita than under the old system, in which this factor was not taken into consideration.

The rough capitation criterion employed until 2001 imposed the same expenditure per capita in all decentralised regions. The range of variation in per capita expenditure was very low, around 5%. The coefficient of variation for per capita

expenditure is clearly lower than in many other decentralised countries. Furthermore, even in this case, the differences observed in Spanish health care expenditure per capita at the regional level have very often been an object of political debate on their equity justification. The main reason for this may be the lack of any objective need-based and transparent formula for regional allocation of resources. However, the so-called expenditure needs level formula introduced in 2002 is also the result of a political agreement and has not been based on any available empirical evidence on the relation between resources and needs. Therefore, it is not possible to conclude that the new allocation formula has introduced any needs adjustment.

This expenditure needs level is guaranteed by the government and it will increase annually according to the growth rate in state revenues obtained from partially ceded taxes (ITE), or only during the first three years (until 2004), according to the annual GDP increase if it is higher than the preceding rate. Thus, the integration of regional financing of health services in the overall regional financing system is subject to some unjustified requirements. The minimum health expenditure level imposed on regions appears to be contrary to their right of autonomy. It would be more in accordance with patient rights protection to improve the definition of guaranteed services and access conditions to all Spanish citizens regardless of their region of residence. Not only does the equity criterion thus imposed (the so-called expenditure needs level) in practice fail to meet any usually accepted definition of equity, but furthermore the homogeneous dynamic evolution for all ACs is at odds with heterogeneous evolving needs.

Second, the fiscal accountability of ACs is increased by the extension of ceded taxes to indirect taxation (see above), and by the increase in normative power over direct taxes. The result is a notable reduction in the amount of transfers coming from central government, and an increase in tax revenues (67%). Third, a compensation system (cohesion fund) has to be established by the Ministry of Health and Consumption in order to compensate for the cost of patient flows between ACs. Fourth, a Sufficiency Fund is designed to set up a transfer system ensuring that there is enough fiscal capacity (mainly represented by revenues from ceded taxes) to cover expenditure needs. Fifth and lastly, a Levelling Allocation system is also established that especially affects health services. It is foreseen that a Levelling Allocation financed by central government will be negotiated between the state and an AC if a deviation greater than 3 points in the

regional proportion of covered population is observed when compared with the base year.

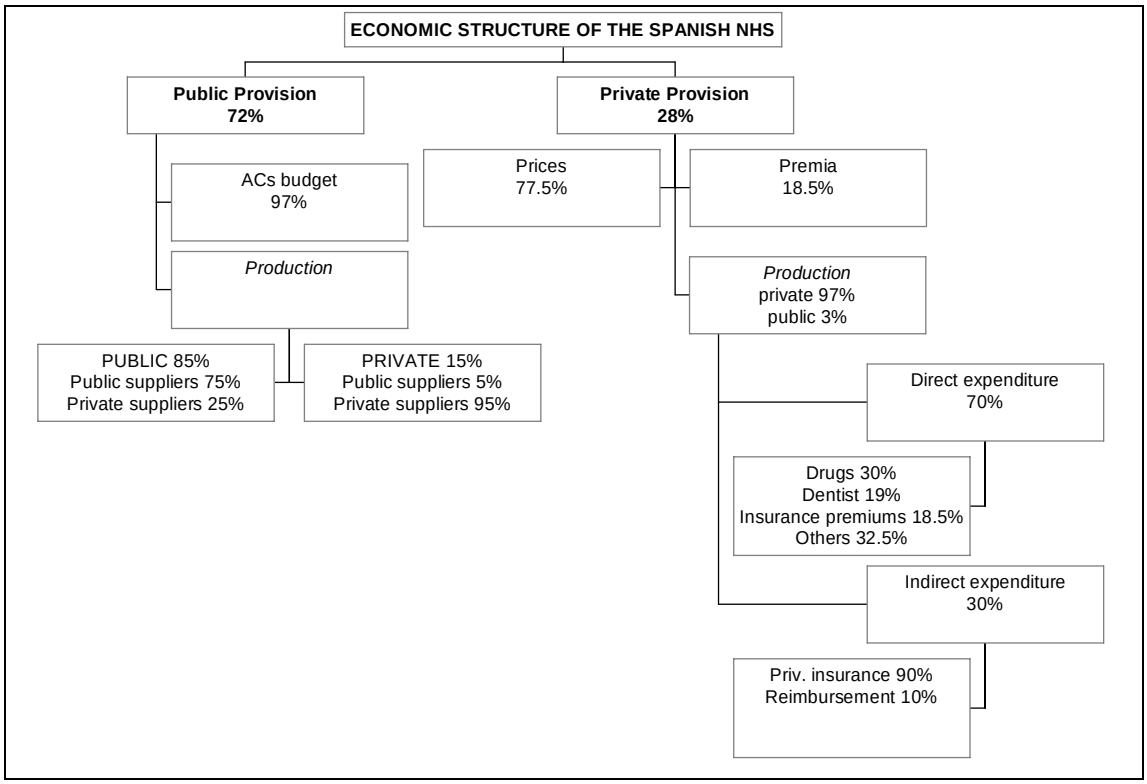
In the new regional financing system set up for 2002, along with completion of the devolution process to all ACs, regional fiscal accountability for increases in health care expenditure is partially devolved to ACs. Regional increases in health care expenditure as an expression of regional preferences may now come from regional decisions concerning the redistribution of funds between competing public services, or a regional growth rate of revenues from ceded taxes that is higher than the ITE growth rate, or alternatively from the use of regional normative tax power.

Nevertheless, some significant problems remain unsolved in the 2002 regional allocation system. First, although ACs' fiscal accountability has greatly increased with the new system, it is far from reaching full fiscal responsibility. The proportion of ceded taxes in total AC revenues has notably increased (more than 80% of total revenues in some ACs), but the normative power over revenues has not increased in the same proportion (normative power applies to less than 20% of ACs' revenues). Second, some specific taxes related to unhealthy consumption (alcohol and tobacco) are lower in Spain than in other European Union (EU) member states. This could have been an argument in favour of allowing ACs some normative power over these taxes, as regional tax powers over these specific taxes could have been an alternative within the context of EU harmonisation criteria. However, ACs are not allowed any normative power over specific taxes.

Third, fiscal powers increase efficiency incentives of ACs, but potential regional inequalities in health services financing may become more visible and vulnerable to the political debate on inequity. Attention has repeatedly been drawn to the likelihood that this move will encourage political controversy about the trade-off between efficiency and equity stemming from the extension of regional fiscal powers. Regional differences in per capita level according to the expenditure needs level fixed for 2002 will be smaller than they were before completion of the devolution process, and can be partially explained by an apparently need-related factor (ageing). Regional expenditure above this guaranteed regional level would be the result of a higher additional fiscal effort and judgements require more caution in this case. In fact, transparency and more evidence-based criteria in the regional allocation system and clarification of equity objectives will be needed to

introduce a more informed political debate. One critical question is to define the guaranteed level of service coverage common to all regions, and also the maximum level of divergence in regional coverage given that regional differences are the expected result of the devolution process.

Table 1. Economic structure of flows in the Spanish National Health Service.



Source: Adapted and updated from Lopez-Casasnovas G and Planas I (2001)

3. Public Health Care benefits package

Health care is free at the point of use to all residents (including illegal immigrants in case of emergency; only Navarre and Valencia offer other health benefits to foreigners in irregular situation) and user co-payments are restricted to pharmaceuticals. Benefits are comprehensive although coverage for some services such as long-term care and dental services is limited and varies according to region-specific political willingness.

The Spanish National Health Service has not defined a basic package of services, however, the Royal Decree 63/1995 established a general framework of benefits and so did the Law 16/2003. The content of these benefits will be developed in

this section. Regional Authorities decide over a range of benefits, being some of them offered at different co-payment levels (such as orthopaedic prosthesis).

The Royal Decree 63/1995 defined benefits on the National Health Service according to each type of service:

(a) Primary Health Care, which covers general medical and paediatric health care in the medical centre's or at patient's home; as well as prevention programs, health promotion, and rehabilitation,
(b) Specialised health care, which covers medical and surgical specialities in acute care, for any inpatient or outpatient,
(c) Complementary benefits, prosthesis, orthopaedic products, wheelchairs, health care transportation, complex diets, home-based oxygen therapy, and children's hearing aids; for certain orthopaedic products and prosthesis some co-payments are required, and
(d) Pharmaceutical benefits, user pays 40% of medicines prices prescribed by out-patient NHS doctors (100% on private prescription drugs), with the exception of some specific groups (retired, handicapped, invalids, and people who suffered occupational accidents), for which there is no co-payment. There is also a reduced co-payment rate applied to drugs for chronic diseases with a maximum amount (500 ptas, 3,01 Euros for year 2000).

After this general definition, the Parliament passed a law (16/2003) that enlarged Spanish Health Care benefits with the purpose of equalisation of benefits among regions (Autonomous Communities). Law 16/2003, on cohesion and quality of the National Health System, has included benefits related to public health, primary care, specialised care, long-term care and pharmaceuticals. This law also guarantees the right of all citizens to have access to a second medical opinion, the right to receive medical assistance in their Autonomous Community of residence in a maximum time and the right to receive by that Health Care Service the medical assistance of the defined benefits of the NHS, with the same conditions and guarantees than the citizens resident in that Autonomous Community. Finally, the law established that Autonomous Communities can approve their respective Health Care Baskets on their competences level. These health care baskets must include at least those benefits defined by the NHS.

Since the content of services has been defined in a generic way sometimes it may not be clear if a service may be included in one of the above groups. The National

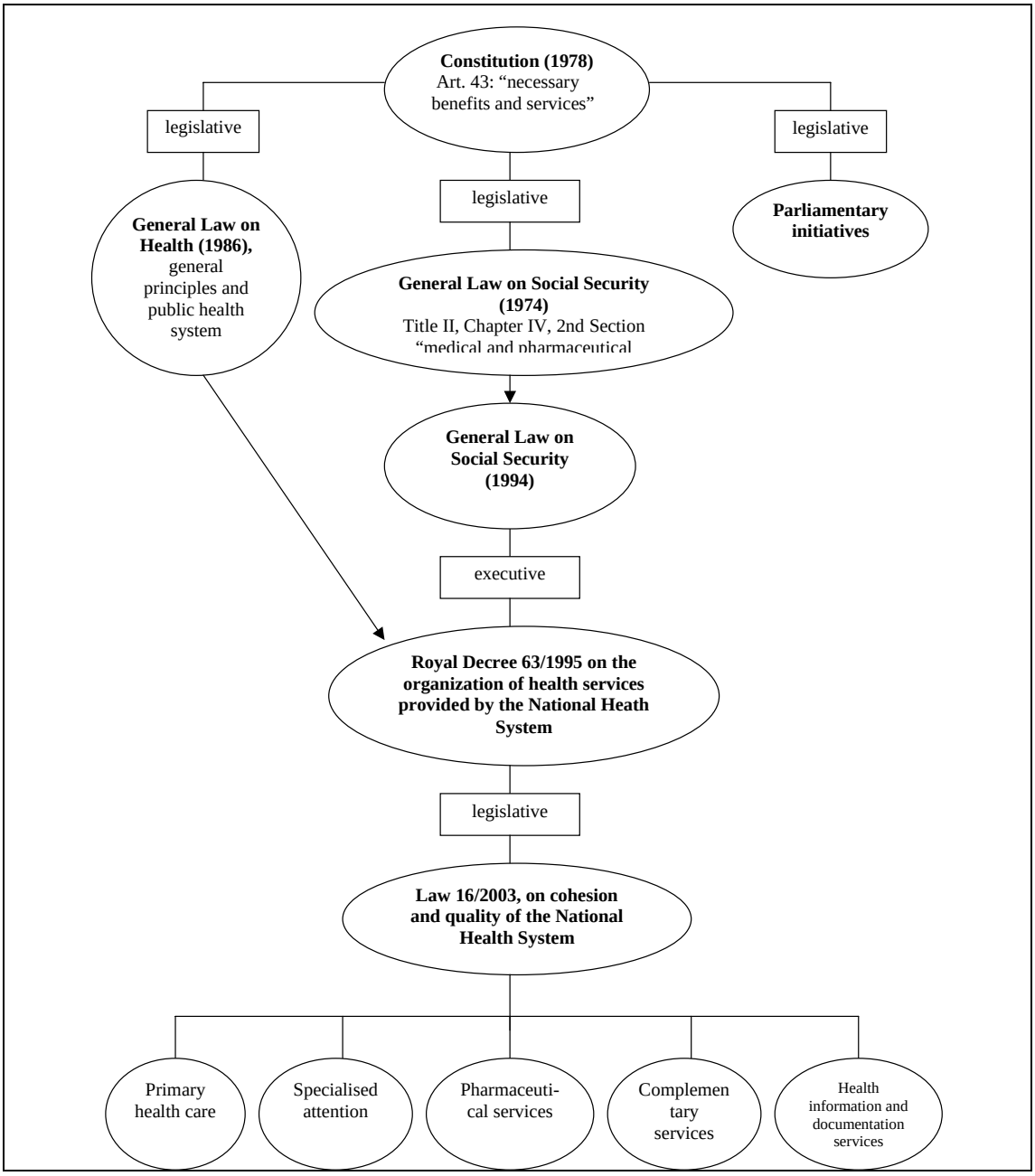
Health Service has explicitly excluded the following benefits: psychoanalysis and hypnosis, sex-change surgery (which is not excluded for some Regional Authorities), spa treatments or rest cures, plastic surgery not related with accidents, disease or congenital malformation, and dental care (only extractions, Health promotion and education, and pregnancy diagnosis services are included).

Unlike most of AC, the Basque Country, Navarre, Extremadura, Castilla la Mancha and Andalusia decided to offer full coverage of child dental care. Since (1990 Basque Country, 1991 Navarre, 2001 Andalusia, 2004 Extremadura and Castilla la Mancha) these Regional Authorities offer these services without any type of co-payment. Although different Spanish legislation introduces these benefits on the public package it has never been implemented so far. Similarly, whereas long-term care is defined as a public responsibility in some regional basic statutory Law (e.g., Cantabria, Castilla-La Mancha), in some other regions it is defined as an individual responsibility publicly supported (e.g., Catalonia).

Social and Community care are also excluded from the NHS benefits because it is part of Regional (Autonomous Communities) and Local Governments (only at citizen's home social care) duties Law 16/2003, on cohesion and quality on the NHS defines social care only in the strict health area. This definition comprises long-term care, convalescence care and rehabilitation in patients with recoverable functional deficit.

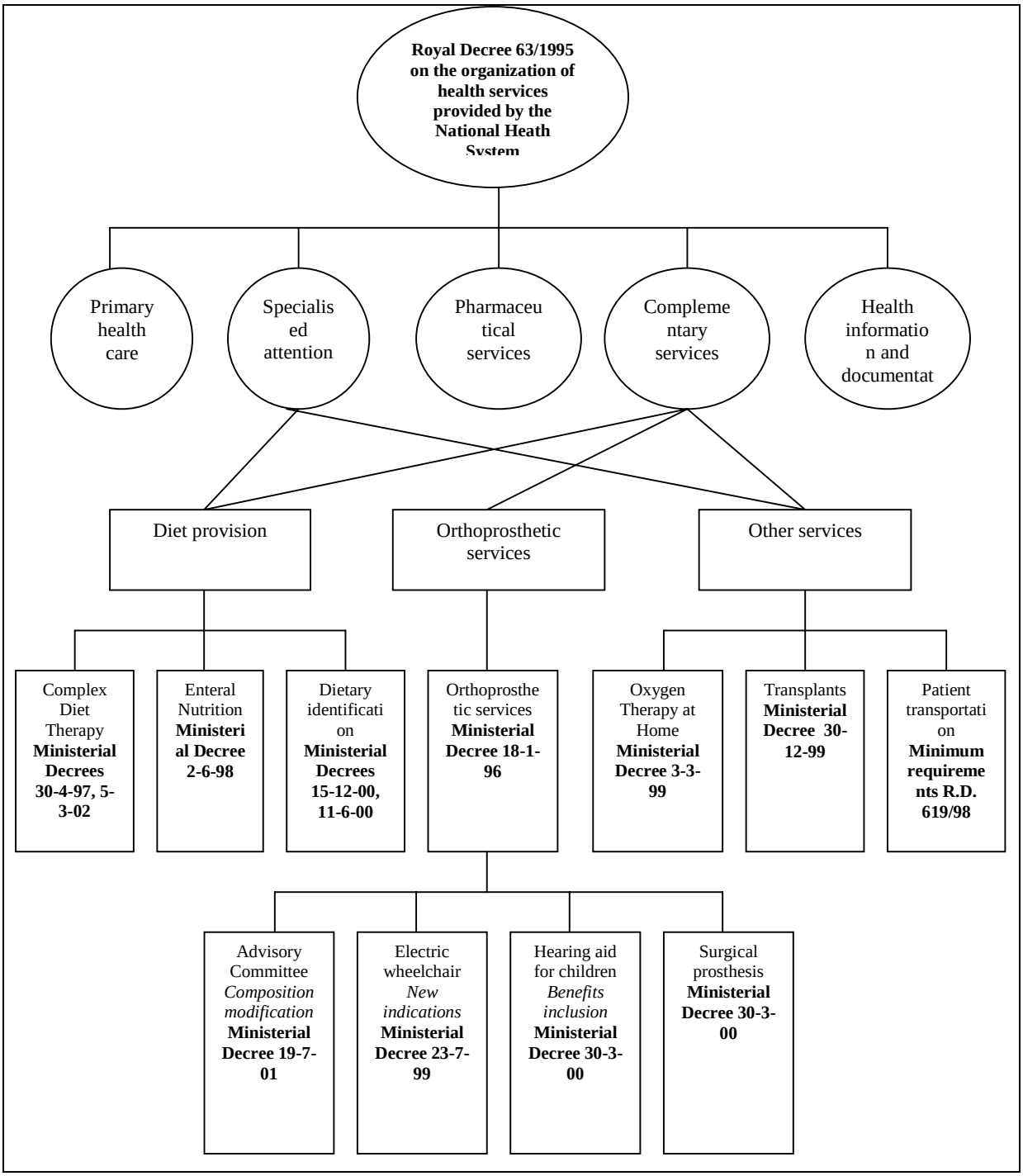
Other arguments that may be used to exclude the provision of services by Spanish public institutions are: (a) lack of scientific evidence on safety of clinical effectiveness, redundancy of interventions with prior treatments, (b) failure to clearly establish that the intervention is effective in the prevention, treatment or cure of the disease; or that it helps in the conservation or improvement of life expectancy, to self-help or elimination or relief of pain (palliative care), (c) in case that the intervention is considered as leisure activity, rest comfort.

Table X. Legislation on Decision-making on benefits in Spain



Source: Own elaboration.

Table X. Legislation on Decision-making on benefits in Spain. (Continued)



Source: Own elaboration.

3.1. Benefits provided by Autonomous Communities.

Since 2002, all Autonomous Communities have health care competences. These competences were recognised in the Spanish Constitution of 1978: article 148.1.20 and 21 allows AC to assume competences related to social assistance, health care and hygiene. This means that they manage their health system and they can legislate on this matter. Before the process of transferring competences was finished some Autonomous Communities (ACs) had regulated the provision of health benefits not included in the National Health System. As time went by, differences among benefits provided by Autonomous Communities increased. At this moment, we may consider in Spain a map with eighteen slightly different health systems. Inequalities among health benefits are subjective and objective. Subjective inequalities are related mainly to recognition of health access rights to foreigners. For instance, Navarre and Valencia recognize, apart from emergency care, other benefits to foreigners. Objective inequalities can be quantitative or qualitative. In the first group we could include different conditions depending on the AC in benefits such as pharmaceuticals, orthoprosthetic services, chronic and acute patients assistance, sex-change surgery, children dental care, morning-after pill, etc. Qualitative inequalities come from different waiting lists, euthanasia regulation, freedom on choosing doctor and centre, etc.

Provider choice has traditionally been conferred a low priority by public authorities. Since 1986, patients have had the right to choose their GP within their health area. Royal Decree 1575/1993 came to recognise to all NHS beneficiaries the right to choose GP and paediatrician in their corresponding health area. Some AC have implemented this right (Andalusia and Catalonia within primary care teams and paediatrician, Navarre allows choice of GP within primary care team, paediatrician and specialist physicians). The possibility of a second specialist advice has been regulated by Navarre, Andalusia and Extremadura and finally by the Law 16/2003, on cohesion and quality, for all the National Health System.

3.2. Civil Servants (MUFACE) scheme

Spanish Civil Servants are included in a special social insurance regime called MUFACE. Once a year each civil servant is asked to choose either continuing on the MUFACE's scheme (choosing any of the several providers of health insurance with which MUFACE has per capita agreements) or to change into the National

Health Service scheme. Main benefit differences are that MUFACE's affiliates pay a 30% of drug's price vs. the 40% for active and 0% for retired in the NHS scheme. Within MUFACE's different providers there are also some *per visit* co-payment.

Another special civil servants scheme is that of the Barcelona's council employees (PAMEM). PAMEM is a *mutulitee cretienne*, which receives a fixed capitation amount from the Catalan Health Service, and manages the health care insurance for its affiliates. Pharmaceutical co-payment is also 30% for both active and pensioners. As in the MUFACE scheme the average pharmaceutical expenditure is lower for PAMEM affiliates than the one for those under the National Health Service coverage. In 1997 average per capita expenditure for MUFACE affiliates was 88 euros versus de 138 euros of the NHS affiliates. Similar schemes exist for the army (ISFAS), sailors (ISMA), and layers (MUGEJU).

3.3. User charges

It appears that the co-payment system, so far only applied to pharmaceuticals and prosthesis, is not intended to be increased nor extended to other health services. However, there is evidence that the level of co-payment is low in comparison with other EU countries, and it also represents a decreasing proportion of the price financed by the patient.

For pharmaceuticals, users pay 40% of the price of medicines prescribed by NHS doctors, with the exception of those aged over 65 and some specific groups (retired, handicapped and people who have suffered occupational accidents) and their dependents, for whom there is no co-payment. Another exception to drug co-payment is the case of chronic diseases. Only 10% co-payment is applied, with a maximum amount (3.01 euros for the year 2000), when NHS doctors prescribe drugs to consumers identified as chronic patients. Another exception to this rule is that applied to civil servants who are under the *Mutualidad de Funcionarios de la Administración Civil del Estado* (MUFACE) insurance system. MUFACE insurers, both employed and pensioners, make a 30% co-payment for all pharmaceutical products.

The 79/1998 and 128/2001 Bills established the present regulation for orthopaedic prosthesis: co-payment stands at 40%, with a minimum of 30 euros, and each regional health service can decide the prices of orthopaedic products for

outpatients. A catalogue establishes the products, the price and the public share (60%), including orthopaedic prosthesis such as wheelchairs for the handicapped and special prosthesis. For inpatient cases in which surgery is needed there is no co-payment for this process.

What do we know about the effects of this co-payment system? First, drug price elasticity is low but not negligible (a 10% increase in the co-payment rate will reduce expenditure by 2.2%). Second, despite invariant normative co-payment rates, effective co-payment rates show a decreasing trend (15% of the consumer price in 1985, 8.9% in 1995, and 7.1% in 2000). This trend can be attributed to the increase in exempted pharmaceutical consumption to a great extent due to population ageing, but it is also attributable to the existence of a notable level of fraud: a high proportion of co-payments are avoided by using elderly members for the family's prescriptions. Third, MUFACE pensioners pay 30% of the consumer price and their per capita expenditure is less than those included in the social security system, which indicates the potential scope for moral hazard. The effective co-payment rate for MUFACE insured population was 21.7 of the consumer price in 1991, and exactly the same rate in 1997. And fourth, current co-payments present a high level of concentration among individuals: 2% of the population concentrates one-third of co-payment revenue. These observations clearly reveal that severe efficiency and even equity problems affect the present system.

Negative lists have excluded some pharmaceuticals from public financing, being equivalent to setting a 100% co-payment rate. The Spanish government used this policy for the first time in 1993 (when the Socialists were in power) and then again in 1998 (with the Popular party in power) to control public pharmaceutical expenditure. These two negative lists led to the exclusion from public funding of 29% of the total pharmaceutical brands registered on the market.

Both experiences have shown limited effectiveness of negative lists of drugs in reducing pharmaceutical expenditure. However, in addition to these control purposes, other clinical or epidemiological objectives are often used to argue in their favour. The Spanish 1993 bill was based on two main objectives: (a) to prioritise public financing for those drugs whose need or the severity of the illnesses for which they were used was greater, and (b) to exclude from public financing those drugs with low therapeutic value. Short-term effects showed a reduction in the number of prescriptions in 1994, but a substitution effect is

probably responsible for a subsequent increase in the following years in the number of prescriptions, with a higher average price per prescription.

The government introduced a second list of excluded medicines in 1998 (834 products corresponding to 39 therapeutic groups). The delisting policy was agreed between the Ministry and the industry. Critics argued that cost containment criteria prevailed in the agreement, unlike in the case of the more pharmacologically oriented list introduced in 1993. In the 1998 list not even the short-term impact was observed, given the high rate of increase in public expenditure occurring in this year (above 10%). This second list was fiercely opposed by the Andalusian regional government, which decided to finance the consumption of excluded medicines with funds from its own budget.

The products included in the negative list of 1993 had been on the market for an average of 20.9 years, and those included in the 1998 list had been on the market for 20.1 years. A large number of excluded medicines disappeared from the market in the following years: at the beginning of 2002, 40% of the medicines excluded in 1993 and 25% of those excluded in 1998 were not available on the market.

Spain also operates a positive list –a catalogue of products that are approved for NHS reimbursement. This list is updated monthly. The Royal Decree 83/1993 defines the criteria, based on which a drug is assessed for possible inclusion in the positive list: disease characteristics, characteristics of the patient population, clinical utility, public spending limits, and the existence of alternative therapies. Products that offer only symptomatic relief or that treat relatively minor conditions do not qualify for inclusion in the positive list. Drugs that are not economically justifiable or that are deemed unnecessary are also excluded.

Finally, Social Security General Act of 1974 (articles 68.1 and 2) created some non-profit organizations called Occupational Accidents and Professional Diseases Friendly Societies. These organizations collaborate within Social Security management and finance all the cost of medicines for those workers in provisional disability due to professional diseases and occupational accidents. This would be another exception for drugs co-payment.

The range of co-payments in the Spanish system is therefore comprised by pharmaceutical co-payments, co-payments for complementary benefits

(orthopaedic prosthesis), and Health services excluded from public benefits and financing. Evidence on co-payment effects is very short but it seems to point out that is mostly a way to raise revenue from users of the services rather than from taxpayers, than a system to ration pharmaceutical consumption.

3.4. Reference Pricing - Avoidable Co-payments

In 1996 and 1997 a series of legislative reforms opened the way for the introduction of generic drugs and a reference pricing system in the Spanish pharmaceutical market. Reference pricing (RP) is equivalent to setting a co-payment consisting of a variable amount depending on the price of the selected drug, and which may be avoided if the drug price does not exceed the reference price.

An RP system was effectively introduced in Spain in December 2000. This system is applied to off-patent drugs with the same active ingredient (bio-equivalence). All the pharmaceutical products included in the same homogeneous group (identical RP) are bio-equivalent, and at least one of them has to be a generic product.

For each homogeneous set of products a reference price is calculated on the basis of the weighted average (year on year) of the lowest-priced products that account for at least 20% of the market sales. If the difference between this calculated price and the highest price in the group is less than 15%, the reference price will be the result of applying a 10% reduction to the highest price (this achieving at least a 10% saving). If the difference between the calculated price and the highest-priced product is more than 50%, the reference price is recalculated as exactly 50% of the highest-priced product (some potential savings thus being foregone). In no case will the reference price be lower than the generic with the lowest price.

The RP system was applied to 114 homogeneous groups in December 2000. These groups totalled 590 products, which accounted for 10% of public pharmaceutical expenditure. The RP system was updated and extended to another 28 homogeneous groups, comprising 113 products, in April 2002.

The regional devolution of health services management to the autonomous communities (ACs) completed in January 2002 allowed all these regional

authorities to introduce their own procurement mechanisms. In September 2001 the regional government of Andalusia introduced a new pharmaceutical procurement mechanism based on RP, which competes with the RP system applied by the central government. In this regional RP system, product coverage is defined by all those active ingredients with more than two products on the market, which are being sold at different consumer prices. This regional RP system covers 239 active ingredients with 591 homogeneous groups (2,900 products), sales of which account for 35% of the prescription market. Under this RP system all products with the same active ingredient and presentation are considered homogeneous and the same reference price will be applied to them. Potential product coverage of RP as applied in Andalusia is wider than in the Spanish RP system; however, the main problem of this regional RP system is that it requires prescriptions to be made out using the name of the active ingredient and not the commercial name of the product. In June 2002, 9% of prescriptions in Andalusia were made out using the name of the active ingredient.

In Andalusia the reference price level is set at the level of the higher price of the two lowest-priced products for each active ingredient. Reference prices are updated every six months or automatically if the price of the reference product is modified. This regional government agreed with the pharmacies to dispense the lowest-priced product for each active ingredient, independently of its generic status. Since its initial introduction in Andalusia, regional reference pricing systems have also been introduced in Extremadura, Madrid, Aragón and Castilla-La Mancha.

A radical change in this generic reference pricing system was approved under the Cohesion and Quality of the National Health System Act (Act 16/2003, 28th May). Implementation details of the new approach introduced by these Act were actively debated in the Spanish health policy arena until de final approval of their legal development by the Minister of Health and Consumption in October 2003 (Order SCO/2958/2003, 23rd October).

The approval of these pieces of legislation during this period has implied an important change in the framework of public financing of old and out-of-patent medicines. The main changes introduced in the Spanish generic reference pricing system by the preceding regulation were the following: less restrictive equivalence criteria for the medicines under the reference pricing system, a different calculation method for the reference price level for each group of

medicines, when prescription price is higher than the reference price and there are other generic products in the same "group", the pharmacist has to dispense the lowest price generic in the same "group", and additional generic price regulation.

This reform of the reference pricing system has transformed the reference price into a sort of maximum price in order not to be excluded from the public financing list of medicines. Patient choice has been reduced if the avoidable co-payment for a medicine price above the reference level is removed by compulsory pharmacist substitution for the lowest priced generic.

Waiting lists

Problems of transparency and comparability of data are the most important on designing a quality indicator for waiting lists to health care access. In year 1996 there was a Waiting Times for Surgery Interventions Reduction Plan started by INSALUD pursuing a continued reduction in waiting lists specially for those interventions which could be done with ambulatory surgery (cataracts, varicose veins). In 2000 there was an increase especially strong in the "more than 6 months" list for heart surgery, and that obliged INSALUD to undertake another Strategic Plan in year 2000, which just in 3 months officially reduced the list from 602 patients to 28, fixing the waiting time in this speciality in 30 days.

Waiting lists are a decisive factor of the access to health benefits. The central Government guarantees a maximum waiting time and then AC can introduce additional rules improving these periods and establishing the access to other medical centres. Seven AC have regulated maximum-waiting times so far: Valencia[3] (90 days), Andalusia[4] and Navarre[5] (180 days), Castille la Mancha[6] (Specialist visits 40 days, Diagnostic procedures 20 days, Surgical interventions 120 days), Aragon[7] (30-180 days depending on prognostic), Canary Islands[8] (150 days) and Catalonia[9].

3 Further information: Decree 97/1996, May 21st.
4 Further information: Law 2/1998, June 15th, and Decree 209/2001, September 18th.
5 Further information: Foral Law 12/1999, April 6th.
6 Further information: Law 24/2002 on Guarantees in Specialized Health Care and, Decree 9/2003 and Decree 1/2004
7 Further information: Decree 83 dated 29.04.2003.
8 Further information: Order 202 dated 15/05/2003.
9 Further information: Decree 418/2000, December 5th, and Decree 354/2002, December 24th.

In year 2000 the Inter-territorial Board of the NHS agreed to review the situation of surgery organization in Spanish Hospitals, main measures proposed were: to increase ambulatory interventions, increase activity by extending intervention hours (top afternoon timetable), standardization of waiting times records and protocols.

4. Health care delivery

Health care delivery is mainly undertaken through a network of publicly owned, staffed and operated inpatient and outpatient centres, with significant geographical differences in the way services are contracted out to the private sector. Non-transparent waiting lists counterbalance tight NHS budgets, playing the role of actual 'implicit prices'.

Catalonia and the Basque country first instituted a sort of independent public body to coordinate the public coverage function while decentralising the purchasing at health care areas.

Along with primary and inpatient care, the NHS funds 92% of the total pharmaceutical expenditure. Regulation was based on a relatively recent reference pricing system although the weak generics penetration still limits its effectiveness in reducing expenditure (already restricted by the Royal Decree 2402/2004). Other services are long-term care and dental care. Long-term care coverage is limited and mostly means tested, regulated at the AC level and provided at the local level. Public home care is narrowly promoted (4% of total supply) and the involvement of the public sector financing in residential care is about 6.9% of total expenditure. Dental care is mainly provided by the private sector with the exception of some minor procedures (e.g., extractions).

4.1. Ambulatory care

Ambulatory care after the reforms was organised in Health Care Centres, where most of GPs and specialist are working full time with main principles being: preventive care as a driver, and curative care with a global perspective of the population. Health care professionals are under a contract basis with a fixed part based on professional status plus a small variable part based mainly on seniority (nowadays called professional career). Multidisciplinary teams and supporting teams substituted the pyramidal based old system. Primary care in Spain has

progressively moved towards a better-integrated public system, geographically organised in 'health zones' and managed at the level of the 'health area' covering 50-100 thousand inhabitants. The gate keeping system asks patients to pursue GP referral to visit the specialists unless they make use of the emergency care. Freedom of choice of primary care physicians within the same health area and some basic ambulatory specialists is allowed, but no much exercised (Royal Decree 8/1996 for the former INSALUD regions and for the rest of ACs most have regulated in their Health Law).

4.2. Hospitals care

The Spanish hospital network is made up of approximately 800 hospitals largely dispersed among ACs (the number of hospitals is 8 times higher in the better-qualified Autonomous Community than in the worse). With the exception of Catalonia, where just 36% of total beds are provided by public hospitals, the system is predominantly publicly integrated (approximately 68% being publicly owned) although contracting out implies about a 15% of public expenditure. The majority of the staff is salaried employees and hospital payment has moved from retrospective to quite-prospective payment systems.

Hospital care may be accessed directly through emergency services, or with a referral from a GP or specialist. Most of Spanish Hospitals have also outpatient visits, which in most cases implies faster access to hospital facilities than Primary Care Health Centres (theoretically, you would also need a referral to access those outpatient facilities, although in practise the screening system in the hospital can take you there straightforward).

From 1997 some few public hospitals are self-governed and from 1999 some other public hospitals have become independent agencies.

4.3. Long-term care

In Spain there are around six and a half million elderly people. There is a very low level of home care (4% of total offer) and very low public financing of residences (only 40% are publicly financed). According to Casado and López (2001) in 1998 the Health Status situation of elderly, 34.2% of elder people were dependent, 77.9% of them only received informal care, 11.4% privately financed domiciliary care, 4.4% publicly financed domiciliary care, and 2.5% were on

public residences, and 3.8% on private residences. That summarises that only a 6.9% receive care financed through public expenditure.

Long-term care has been transferred to the Autonomous Communities except the domiciliary care, which can be accessed by users through municipalities. Total public financing is less than 30% of long term care expenditure in Spain.

4.4. Pharmaceutical care

Political concern regarding Spanish pharmaceutical expenditure usually arises from the observation of what is interpreted as the high proportion of public health care expenditure devoted to pharmaceuticals. This proportion increased from 16.2% in 1990 to 21.7% in 1999, which represents an increase of 5.5 points in nine years. It is the third highest in the European Union (EU), only Greece and Portugal showing higher levels.

Total pharmaceutical expenditure per capita in Spain was US$ 246 per capita in 1997, a figure that is slightly below the average of the European Union (EU) countries (US$ 260 in 1997). Private expenditure on pharmaceuticals, including co-payments, represented nearly 30% of total private health care expenditure in 1998. Two significant features of Spanish pharmaceutical expenditure should be highlighted from the point of view of public financing.

First, the most important difference between Spanish pharmaceutical expenditure and that of the European Union as a whole is the relatively high and increasing rate of public financing in the former. The proportion of pharmaceutical expenditure that is publicly financed increased from 71.7% in 1990 to 78.1% in 1997 (6.4 points in seven years). This tendency does not only reflect a lower proportion of pharmaceuticals privately financed outside the public system; it was also accompanied by a major decrease in the effective co-payment rate from 11% in 1990 to 7.1% in 2000, which represents a 35.5% decrease in ten years.

Second, average price per prescription has been increasing very fast in recent years, despite the fact that drug prices are under strict price control. Average cost per prescription doubled in current monetary units between 1990 and 2000. Drugs prices in Spain are still among the lowest in the EU and the Spanish market is an important source of parallel trade in the EU. Although regulated market price increases fall short of the inflation rate, the average prescription price has

risen steadily, owing mainly to drugs recently introduced on to the market at high prices.

As a result of these trends, public pharmaceutical expenditure per capita rose from US$ 104 in 1990 to 192 in 1997, by which time it was 18% higher than the average for the EU, despite the fact that Spanish per capita income was 23% lower than the EU average. From the macro perspective, these data clearly indicate that the main difference between Spanish pharmaceutical and that of the EU countries as a whole lies in the level and trend of public financing.

To control the prescription of certain drugs, the government sometimes imposes a prior authorisation ("visado de inspección"). For such drugs to be dispensed at the expense of the NHS, the prescribing general practitioner must justify the prescription and the inspection service must authorise its use. The system aims to improve de use of drugs that are subject to Special Medical Control, to limit the prescription of costly therapies, and to prevent off-label prescribing. Selective cycloxygenase (COX)-2 inhibitors, acetylcholinesterase inhibitors, interferon, and many antimicrobials and vaccines are among the long list of drugs subject to prior authorisation.

The management model of prior authorisation prescription process may be very different in each AC. In some case, the patient has immediate access to the authorisation in the health centre or hospital (Andalusia, Catalonia, Galicia). In other ACs, the first authorisation is provided by the inspection, but the following prescriptions are authorised directly in the pharmacy office through an on-line electronic system (Castilla-La Mancha). In both cases, opportunity cost for the patient in the form of travel, waiting and extra-visits is lower. However, in other AC the access to prescription that require prior authorisation is more complicated because it is the patient who has to make an additional visit to the inspection offices (Asturias and Basque Country).

PART II. Available benefits covered by the Spanish National Health System, at federal and regional government

Along this section the different benefits covered within the Spanish Health Care benefits package are described following a sector-by-sector ordering. For a better understanding, for each category of services there is a description of the basic benefits which all AC should provide, and also within each category by a description of the additional benefits that some AC have included in their own basket.

The following sections are ordered according to the OECD functional categories; nevertheless, main laws regarding the Spanish Health benefits Basket; the Royal Decree 63/1995 on the organization of health services dated January 20 and the Law 16/2003 on Cohesion and Quality of the Health Care System are included in the annex and one could observe the way in which Spanish health care benefits are organised. A brief description has also been provided in part one of this document.

As the Law 16/2003 argues this Health Benefits package should serve as a minimum defined package for all Spanish residents in order to keep equality of access and benefits among them, independently of where they live. Nevertheless, as AC may vary the allocation of their funding, some may decide to offer new benefits or include those that are explicitly excluded by the Royal Decree 63/1995 and the Law 16/2003.

One of the other main problems of this legislation act was that it did not clarified clear whether health care was a “health” or a “social security” matter. The Federal Law 49/1998, dated December 30th, on the 1999 General State Budget, partially regulated this, establishing that no contribution would be made from the Social Security System treasury to the financing of health care expenditure.

A novelty introduced in the Law 16/2003 was the establishment of a general procedure to actualise the content of the health benefit package. To this purpose it regulates two instruments: a) the evaluation of new techniques, technologies or procedures, which will be carried on by the *Agencia de Evaluación de Tecnologías Sanitarias del Instituto de Salud Carlos III* (created by the same law); and b) the “In ward use”, which means that one could use these procedures with the

purpose of determining the level of security, efficacy, effectivity and efficiency in the technique under supervision, before the final adding to the health care benefits package, and that it will be funded by the Health Cohesion Fund (*Fondo de Cohesión Sanitaria*). In both instruments the Inter-territorial Council plays an important role.

In broad terms, main responsibilities assumed by the Central government are: a) general coordination and basic health legislation, b) financing of the system, and regulating the financial aspects of social security, c) definition of a benefits package guaranteed by the National Health System, d) international health, e) pharmaceutical policy; health professionals undergraduate and postgraduate training, and f) civil servant human resource policies.

Different ministries share these responsibilities and therefore affect the Health Benefits package, although the Ministry of Health and Consumer Affairs plays the main role in determining health policies. The social security system and/or the Ministry of Economy and Finance have to authorise many financial aspects, as well as the definition of benefits; and the Ministry of Public Administration deals issues related to personnel. Moreover, the Ministry of Labour and Social Affairs is responsible for social and community care (including nursing and elderly homes), although these responsibilities have been progressively transferred to the regions.

Another important agent in the coordination and evaluation of new benefits to be added to the Spanish Health Basket is the Institute of Health Carlos III, which is in charge of promoting and coordinating biomedical research; training of personnel in public health and health services management; services on public health; health information; technology assessment; scientific and technical accreditation; and technical advisory functions. The Institute performs these functions through the Agency for Assessment of Health Technologies, the National School of Public Health, the Health Research Fund, and a set of National Centres, which cover a series of research and service areas (Epidemiology, Clinical Research and Preventive Medicine, Nutrition, Environmental Health, Health Information, Microbiology and Fundamental Biology).

0. User's coverage

Before analysing each category of services we must describe the situation of coverage, who is covered by the Spanish Health Care System and how one can get access to the system.

The Spanish Constitutional Act in the article 43 implies that the condition of Spanish citizen is enough to be entitled for health care benefits. The General Health Law 1986 enlarged this condition to foreigners who had the residence permit, with the same access rights and conditions. Nevertheless, this law didn't separate the health benefits of the social security system, obliging some people to pay as private users those treatments received in the public system. The Royal Decree 1088/1989, dated September 8th extended health benefits to low income people, thus remaining outside of the coverage only those individuals in special regimes of the social security system (mainly self-managed professionals). The Parliament agreement of December 18th, 1997 was the final legal decision for the definitive universal extension of health benefits rights to the overall population.

Main differences among ACs are related to foreigners (specially depending on their legal situation). We can find 3 different groups (in brackets specific regulation on coverage enlargement): a) Same coverage as that provided by the state regulation and emergency care for foreigners: Andalusia (Decree 66/1990), Aragón, Asturias, Cantabria, Castilla-La-Mancha, Canary Islands, Galicia (extra benefits to the Decree 63/1995 only for residents) and La Rioja; b) All care for residents and non residents, independently of their legal or administrative situation: Balearic Islands, Castilla León, Madrid, Basque Country (Decree 26/1988 and Order 28.6.1982) c) All care for residents, independently of their legal or administrative situation: Murcia, Extremadura, Navarra (Foral Decrees 71/1991 and 640/1996), Catalonia (Decrees 55/1990 and 178/1991), d) Special case: Valencia, coverage of health care but also of long-term care for all citizens in the AC (Decree 88/1989 and Order 16.10.1989).

The 12TH of April of this year (2005) the European Court of Justice condemned Spain to reimburse the medical expenses generated in a third country. The court dictated a sentence in which it forces the Spanish institution of Social Security to directly reimburse the cost of the assistance of Mrs. Keller in Switzerland to her heirs, since she passed away during the treatment. With this sentence, the Court of Justice takes a step forwards in its jurisprudence forcing a State member,

Spain in this case, to reimburse the expenses caused in a country that is no member of the European Union.

1. Services of curative care

1.1. In-patient curative care.

Understanding as inpatient curative care the specialised health care in the hospitalisation regime including: acute somatic inpatient care, acute intensive inpatient care, transplantation, and acute mental inpatient care, this category of care is regulated at both national, and regional levels. From all this categories, the acute somatic inpatient care is not explicitly mentioned in any benefit package in Spain.

Main regulation affecting these areas is: the Royal Decree 63/1995, and the Law 16/2003[10]. This regulation defines as benefits covered by the National Health Services, which ought to be provided by all ACs, as the following service groups:

- Specialised health care in the hospitalisation regimen, which includes medical attention, surgery, obstetric and paediatric services for acute processes, worsening of chronic processes or delivery of recommended diagnostic treatments or procedures.
- Organs, tissues and cells of human origin transplants according to the special legislation on this matter as long as they show checked therapeutic effectiveness. (Royal Decree 2070/1999 on transplants, which modifies Royal Decree 63/1995).
- Palliative care to terminal patients (*).
- Mental health care and psychiatric assistance, which include clinical diagnosis and follow-up and the prescribed group of family psychotherapy if it implies hospitalisation when required. Hospitalisation in units of short or medium stay takes place at the psychiatric department of the general hospital. It can also be partial (open regime) or total hospitalisation. Inpatient mental long-term care services take place at psychiatric hospitals, which are included in the long-term care network.

[10] Whenever this law introduces a change in what the Royal Decree 63/1995 includes, it is marked by a "*" symbol.

Generally, access to specialised health assistance in hospitalisation regimen will be provided by a referral of the medical specialist or through the emergency services when the patient needs foreseeable special and continuous care, which cannot be provided at out-patient clinics or at home. Access to referral hospital services will be provided upon instructions of the other specialised services according to the procedures set by the health services, but taking into consideration the provisions contained in article 15.2 of the General Law on Health. All these services are free of any payment.

The responsible actors are the Central (Federal) Government, which has defined this level of benefits by a Royal Decree. After this general definition, the Parliament has passed by a law (16/2003) which enlarges Spanish Health Care benefits with the purpose of equalisation (using the word equity in Spanish, although in practice used as equality) of benefits among regions (Autonomous Communities).

Since 2002 responsibilities on planning, financing and providing health care services to the population have been decentralised the Autonomous Communities. Therefore, although they do not have real competences in regulating or developing new benefits packages for their population, they may enlarge the benefits package through provision and financing of new benefits.

The Interregional Council (defined above) is responsible for granting equality of benefits and access among regions. Definitions are not uniform for all payers and there is a need to look for regional differences (AC) even within definitions of service parameters. Main exclusion of benefits within this category of services are: mental inpatient care, which is only included “when required”, which means that a referral is needed, and the special legislation on transplants excludes: hair, nails and placenta (Royal Decree 2070/1999 on transplants, which modifies Royal Decree 63/1995).

About enlargements of the basic Health Benefits package in this category we find the sex/gender change surgery intervention, which is explicitly excluded in the Royal Decree 63/1995, and that Andalusia is offering. That was approved by a non-law order of the Andalusian Parliament on February 11th, 1999. Andalusia also offers epidural anaesthetics during birth.

The other main enlargement is related with Euthanasia. Catalonia (Law 21/2000, dated December 29th), Galicia (Law 3/2001, dated may 28th 2001), Extremadura (Law 10/2001, June 28th) have regulated and included the vital testament as a benefit.

Mental Health Care

We have separately developed this category since it has its own specific characteristics. Such as a huge variability of infrastructure along the territory, and differences in the organisation among ACs (such as some programs depending on different departments, department of health or department of Social Affairs).

This area was traditionally a very bad organised area with many agents involved in its provision with shared responsibilities and a total lack of coordination. A Ministerial Commission for Psychiatric Reform was set up in 1983, which drafted a document laying down the framework and broad criteria for reform of psychiatric services. The General Health Act (1986) went on to confirm that mental patients were to be treated as users of equal worth and made provision for the integration of mental health within the general health care system.

The Mental Health Report is the better compilation of situation in each AC and was written by the Observatory of Health of the Spanish Health and Consumption Department by order of Benefits Commission of the same Department in October 2002, with the collaboration of at least one expert from each AC. This report describes Mental Health Services as follows:

- Mental Health Care and Psychiatric assistance:
- Relapse prevention programmes.
- Relative interventions.
- Social reinsertion.
- Treatments guided to prevent complications and decrease the risk.
- Therapeutic Communities for giving up bad habits.
- Maintenance Services.
- Complementary Services for helping smokers.

About how explicit is the definition we have to distinguish between the government level, at which parameters deciding service level are rather vague,

i.e. they only mention a group of services such as “medical attention”, “clinical diagnosis”, etc; and at the regional (AC) level: any of the Autonomous Communities (AC) have developed or established more detailed descriptions of mental care health services. Some of them have indirectly defined those services through a Mental Health Plan that, in any case, only establishes de targets towards which the regional government should work to achieve. For instance, Catalonia is in the process of developing a general Health Services Basket for mental health. Valencia is also developing it, but confining this basket only to primary health care. It is expected Asturias to create also its own. Navarre has already established one but restricted to internal relationships within the health care organization. Balearic Islands, Castilla y León and Basque Country have determined a partial Health Services Basket, limited to certain assistance programmes. Finally, Castilla y León is including these services in Functioning Guidelines by devices.

1.2. Day cases of curative care

Following the OECD categorisation we have included in these categories the specialist outpatient care and day surgery (in OECD: “ambulatory surgery”= HC.1.2 but “out-patient surgery”= HC.1.3.3), and haemodialysis.

These entitlements are regulated at National level by the Royal Decree 63/1995, and also in the Law 16/2003 (which does not change the benefit characteristics). These two laws define the service groups included in the Spanish Benefits package as:

- The specialised ambulatory health care consultations that could include minor surgical procedures;
- The specialised ambulatory health care delivered in “day-hospitals” for those patients in need of continuous specialised care, physician’s or nursing services, including major surgery as long as it does not require hospitalisation; and,
- Haemotherapy.

Generally, access to specialised ambulatory health assistance will be provided by a referral from the primary care physician, a way to escape this gatekeeping instrument is to access specialised care centres through the urgency unit. They are all free of charge.

The responsible is the Central (Federal) Government, which has defined this level of benefits by a Royal Decree. After this general definition, the Parliament has passed a law (16/2003) which enlarges Spanish Health Care benefits with the purpose of equalisation of benefits among regions (Autonomous Communities). Autonomous Communities are responsible for planning, financing and providing health care services to its population. The Definition on the level regarding the benefits catalogue is rather vague as it doesn't define minor and major surgery categories, which makes it difficult to differentiate them according to the specialists' opinion. Some other questions are also not answered such as: who determines the need of continuous specialised care, physician's or nursing services?; who determines when major surgery does not require hospitalisation? Which procedures and services include the haemotherapy?

Definitions may vary depending on the different payers (AC) even within definitions of service parameters.

The following services are explicitly excluded not differentiating between in-patient or out-patient categories: plastic surgery when it is not related to accidents, disease or congenital malformation; sex change surgery, except for those cases in which it is necessary to repair pathological intersexual conditions. About the latest, in January 2005, Andalusia has approved a parliamentary initiative to finance sex change surgery at its hospitals, although prior to this law, some hospitals in Andalusia have been offering those services (free of charge, paid by the regional authority) at least during the last two years.

1.3. Out-patient care

The OECD categories included in this section are: HC.1.3.1 Basic medical and diagnostic services (curative) primary care, HC.1.3.2 Out-patient dental care, Dental prophylaxis, care, surgery, HC.1.3.3 All other specialised health care, Specialist out-patient care–somatic, Specialist out-patient care- mental; special area: psychoanalysis, therapy, and HC.1.3.4 All other out-patient curative care, Ambulatory services by other professionals: physiotherapy, ergotherapy, speech therapy, chiropody, podiatry, dietetics, optometry,…, Alternative & complementary medicine – services (TCM, acupuncture, spa therapy,…)

Outpatient care is generally provided in Primary Care Centres or Specialist Care Centres (Outpatient Clinics). There is a large disparity in the number and use of the latest among AC. These categories of care are regulated both at National, but also at the AC level. The different regulations affecting this area are the Royal Decree 63/1995, the Law 16/2003, Ministerial Decree 30-04-1997, Ministerial Decree 05-03-2002, and the Ministerial Decree 15-12-2000 at the national level. And at the level of each AC we can find several legislation acts which will are described below.

Service Groups defined by the Royal Decree 63/1995, and the Law 16/2003 are as follows, all free of charge:

- Health assistance for health consultations services and centres. Including basic medical and diagnostic services (curative) primary care.
- Health services provided at home.
- Indication or prescription and the compliance, in relevant cases, with examinations and basic diagnostic measures as indicated by the primary care physician.
- The administration of parenteral treatments, cures and minor surgery.
- Initial mental assistance is provided in Mental Health Centres, where patients are evaluated, assisted or referred to other assistance services. Benefits provided are: pharmacological and psychotherapy treatments, crisis interventions, etc. Mental emergencies can also be treated at the Hospital Emergency Services (*Informe de Salud Mental).* In Spain, it doesn't exist any Mental Health Plan at national level.
- Emergency primary health care will be provided to people of any age and delivered in a continuous fashion during twenty-four hours a day, through medical and nursing services, on an outpatient basis or at the domicile of the patient if the situation so requires.
- The primary dental health care provided shall comprise the following
    - Dental health and hygiene information and education[11].
    - Preventive and assistance measures: application of topical fluoride, obstructions, sealing of fissures or other services for the infant population according to the annual financial budget and special programmes for dental health[11].
    - Treatment of acute orthodontic problems including dental extractions.

11 These three benefits will also be included in the Prevention and public health services, but we also included them in this one since this is the order in which they are included in the Royal Decree 63/1995).

- Preventive exploration of the oral cavity in pregnant women.[11]

- Renal lithotripsy, interventionist radiology and radiotherapy.

The next lists of services includes all those that are not free of charge but not explicitly excluded from the Spanish Health Care Benefits package:

- Complex diet therapy, which includes the diet therapy treatments indicated by a medical specialist for those who suffer certain congenital metabolic carbohydrate (inherited lactose intolerance and/or galactosaemia and temporary situations of lactose intolerance in the nursing baby) or aminoacid syndromes.

The regulation of this group of services was made by: a) Ministerial Decree 30-04-1997, on complex diet therapies, b) Ministerial Decree 5-03-2002, which brings up to date the previous rule, c) Ministerial Decree 15-12-2000, on identification conditions for food allocation to medical purposes available for public financing, d) Interterritorial Council agreement, which established coordination procedures in diet treatments to temporary displaced patients in a Health Service different from the one of residence, e) Agreement on data that must be recorded in the clinical report so that Health Services can determine the authorisation of diet treatments in the exceptional cases of allergy or diagnosed intolerance to cow milk protein in children older than two.

These rules put in a precise form the list of congenital metabolic disorders and the diet to follow in each case. Likewise, they point out that specialist of hospital units have to clearly authorise them for this purpose, and therefore recommend the treatment.

There are maximum prices covered by public funding for diet products, which are detailed in the law 53/2002, art. 123 and 124.

The responsible actor is the Central (Federal) Government, which has defined this level of benefits by the Royal Decree. After this general definition, the Parliament has passed a law (16/2003) which enlarged Spanish Health Care benefits with the purpose of equalisation of benefits among regions (Autonomous Communities). Since 2002 the Autonomous Communities have been decentralised the competences in planning, financing and providing health care services to its population. Therefore, although they do not have real competences in regulating

or developing new benefits packages for their population, they may enlarge the benefits package through provision and financing of new benefits. The Interregional Council is responsible for granting equality of benefits and access among regions.

Main exclusions are: Spa treatments and rest cures, and psychoanalysis and hypnosis are the excluded benefits in this area by the Decree 63/1995. The diet therapy treatments are not explicitly defined although they are included if a specialist prescribes them.

Enlargement of benefits by the ACs in this category of care is quite broad, by sublevels of care is as follows:

- Primary care:

The Basque Country Decree 118/1990, the Decree 195/2004 in Extremadura, the Decree 273/2004 in Castilla La Mancha, and finally, the Catalonian Autonomous Decree SLT/213/2004.

- Specialised out-patient care:

Navarra offers obstetrics and gynaecologist and family planning such as menopause care (Foral Decree 259/97 and Foral Order 1661/97).

Valencia offers in diabetics provision of reactive strips for the determination of glucose in blood an urine.

- Dental care:

Orthodontic services included in primary health care are rather vague defined by the Royal Decree, however the different AC which have included these services in their benefits package have a very accurate list of these services. There are six Autonomous Communities that have regulated free dental care for their children: the Basque Country, Navarra, Andalusia, Extremadura, Cantabria, Galicia, Castilla Leon, Castilla la Mancha and Catalonia.

The Basque Country has regulated it by the Decree 118/1990. It offers for their resident children between seven and fifteen years old an annual revision,

emergency services, medical examinations and diagnostic tests, special treatments due to malformations, traumatisms of the incise-canine tooth and pathologies in milk tooth with serious repercussion in the permanent tooth. Moreover, it offers free dental care to special cases of disabled children. Orthodontics treatments are excluded.

Under the Decree 281/2001 Andalusia established, that the Andalusian Department of health will offer for their resident children between six and fifteen years old an annual revision, teeth repairing, sealed of fissures or graves in the permanent pieces in certain cases, clogging, pulpy treatments and extraction of permanent pieces, extraction of temporary pieces, emergency services, medical examinations and diagnostic tests, tartrectomy (supra-gingival tartar removal), special treatments such ace of the incise-canine group due to malformations and/or traumatic injury. Moreover, it offers free dental care to special cases of disabled children. The following services are those that are excluded: special treatments such ace of the interjection-canine group because of traumatic injury when it exists someone obliged by law to pay for this treatment (that is mainly when it is a result of a traffic accident, or when a court is involved), orthodontics treatments and repairing treatments for temporal teeth.

Extremadura has also included extra dental care services by Decree 195/2004. It offers for their resident children between six and fifteen years old an annual revision, emergency services, basic assistance treatments (sealed of fissures, topical fluorine treatment, clogging of permanent molars, extraction of temporary and permanent pieces, tartrectomy (supra-gingival tartar removal) in permanent teeth, extraction of erupted supernumeraries and re-evaluation and follow up of decay, periodontal disease, malocclusion as well as of patients medically weak or in a special risk), special treatments (those related to problems of the incise-canine group, including splint on basic the care treatments, reconstruction, high reconstruction, intrarradicular prefabricated bolt, tooth re-implant, soft weave suture, pulpy treatment of permanent pieces that includes *apicoformación* (root stimulation mechanism), direct pulpy covering and endodontic procedures. Next services are excluded: temporary teeth replacement treatments, orthodontic dental care, incise-canine group treatments due to agenesis of all or any of its pieces, group traumatisms of the incise-canine group when there are third payers obliged to, prosthesis of any type.

Such as Extremadura, as soon as Castilla La Mancha received the transfer of competences and thanks to their highest per capita budget it started the process of offering dental care benefits by Decree 262/2004. Castilla La Mancha Department of health offers for their resident children between six and fifteen years old an annual revision, basic dental treatments (sealed of graves and fissures of first and second permanent molars, topical fluorine treatment and health prevention and education, clogging of permanent molars, extraction of temporary and/or permanent pieces, tartrectomy (supra-gingival tartar removal) in permanent teething), emergency dental treatments (application of basic treatment, application of palliative treatment with pharmacological therapy or extraction of the affected piece, indication and derivation of special treatments in case of upheavals of the incise-canine group when caused by traumatism), special dental treatments (treatment of problems of the incise-canine group, pulpy treatment of permanent pieces, specific treatments of orthodontic and mouth pathologies for children with disabilities, precise diagnostic procedures for the application of treatments such as the orthopantomography), orthodontia (it will be offered to disabled people and those that undergo severe malocclusion after having had part of palatal fissure removed, leporine lip or another face skeletal malformation). Next services are excluded: temporal teeth repairing treatments, prosthesis treatments, orthodontia in those cases that do not accomplish the requirements established in this law.

Cantabria offers orthodontic treatments in a special centre "Infant Dental Health Care Centre" to children under 18 depending on economic and social status (Order October 3rd 2001). Castilla Leon offers dental health care to disable people, elders over 75, and children in the 6-14 years group. Galicia has a special program in infant dental health care. Navarra offers dental health care to children under 18, and psychologically disable.

Finally, the latest AC that has decided to offer extra dental care benefits Catalonia (AC Decree SLT/213/2004). It offers periodic rinsing of fluorine solutions program for primary school students and those in the first two courses of secondary school.

- Special treatments:

Balearic Islands offers Neurological-reflexology by an agreement with the Kovacs Foundation.

It also has to be remarked in this part that the Department of Health of Catalonia has started a Pilot experience of offering acupuncture for arthritis treatment in two primary care centres.

1.4. Services of curative home care

The Royal Decree 63/1995, Law 16/2003, Ministerial Decree 03-03-1999, and the Ministerial Decree 02-06-1998 regulate these entitlements at National level. These four laws define the service groups included in the Spanish Benefits package as:

- The oxygen therapy service at home will be provided through specialised centres authorised by the health services, and which are capable of carrying out gasometry and spirometry. (RD 63/1995). The Ministerial Decree 03-03-1999 has developed this services, considering next benefits: a) Oxygen therapy at home, b) Mechanical ventilation at home, c) Ventilation treatment of the sleep apnea symptoms, and) Aerosol therapy.

- Enteral nutrition at home, regulated by the Ministerial Decree 02-06-1998. This service is given to those patients who have the following symptoms: swallowing, transit, digestion or absorption of foods in its natural form problems, or when special requirements of energy and/or nutrients exist that cannot be covered with foods of daily consumption.

- Home hospitalisation (included by the Law 16/2003 not very much developed in practice so far).

In Spain, by the categorisation of health care services, services of curative home care are included in the outpatient care group.

2. Services of rehabilitative care

OECD categories include within this definition. HC.2.1: In-patient rehabilitative care (inpatient rehabilitation), HC.2.2: Day cases of rehabilitative care, HC.2.3: Out-patient rehabilitative care (ambulatory rehabilitation), HC.2.4: Services of rehabilitative home care.

These entitlements are regulated at National level by the Royal Decree 63/1995, and also in the Law 16/2003 (which does not change the benefit characteristics). These two laws define the service groups included in the Spanish Benefits package as:

- Basic rehabilitation treatments, on medical recommendation, in accordance with the programmes instituted by the health services.
- The specialised hospital assistance will comprise rehabilitation.
- Rehabilitation in patients with a recoverable functional deficit (Added by the Law 16/2003).

There is no specific regulation on services of rehabilitative home care although primary care takes the facto responsibility over it. In 1998 the former INSALUD created the Supported Team Home Care Program (*Programa de Atención Domiciliaria con Equipo de Soporte – ESAD*), which works together with primary care teams. In Catalonia there is a specific program called PADES (Home Care Support Units) created by the Department of Health and Social Security in 1986 within the *Vida als anys* Program (Life in the elderly Program).

The main responsible actor is the Central (Federal) Government, which has defined this level of benefits by a Royal Decree. After this general definition, the Parliament passed the law 16/2003, which enlarged Spanish Health Care benefits with the purpose of equalisation of benefits among regions (Autonomous Communities). Since 2002 the Autonomous Communities have been decentralised the competences in planning, financing and providing health care services to its population. Therefore, although they do not have real competences in regulating or developing new benefit packages for their population, they may enlarge the benefits package through provision and financing of new benefits. The Interregional Council is responsible for granting equality of benefits and access among regions.

The definition of this level is extremely vague, because no definition of rehabilitation has been specified. So, basic rehabilitation treatments are something that is left to self-appreciation by health professionals, obviously determined by the availability of resources, especially medical technology. Definitions are therefore different depending on each hospital, primary care centre or outpatient clinic guidelines. The services of rehabilitative home care are not excluded in any law, however in practice practitioners and nurses prefer to order regular patient transportation for them in case that it is needed or normal public transportation (taxis) if that is sufficient, and to offer the rehabilitation treatments in the out-patient settings.

3. Services of long-term nursing care

Long-term care nursing is probably the second less developed category in the Spanish model of health care provision after the mental health one.

The OECD includes within these categories; HC.3.1: In-patient long-term nursing care, In-patient long-term care services, Special area: hospice care, HC.3.2: Day cases of long-term nursing care, and HC.3.3: Long-term nursing care: home care, Ambulatory long-term care services.

These entitlements are regulated at National level by the Royal Decree 63/1995, and also in the Law 16/2003. The first law defines the service groups included in the Spanish Benefits package as:

- The specialised ambulatory health care delivered in “day-hospitals” for those patients in need of continuous specialised care, physicians or nursing services, including major surgery as long as it does not require hospitalisation.
- Specialised health care in the hospitalisation regime, which includes medical attention, surgery, obstetric, and paediatric services for acute processes, worsening of chronic processes or delivery of recommended diagnostic treatments or procedures.
- The primary care provided to people over fourteen years of age shall comprise in-home services for immobilised or terminal patients; health education, attention and assistance to chronic patients, and attention to specific health problems of the third age according to the regulations of article 50 of the Spanish Constitution.

The following categories are included in the Law 16/2003, although the law indicates that they need to be further regulated:

- Long-term care.
- Convalescence care.
- Rehabilitation in patients with recoverable functional deficit.

Most responsibilities within the field of social affairs have been now transferred to the ACs, which gradually enacted legislation in the 1980s to govern social services provision within their area of responsibility. At a national level, the Sectorial Conference on Social Affairs ensures coordination between the State and the Autonomous Communities. In general terms, this body is the social affairs equivalent of the Inter-territorial Council of the National Health System. Within this latter body, an agreement was reached in the late 1990s to elaborate a framework for legislation to be passed on the coordination of social and community care.

Nevertheless, the issue of the elderly requiring continuing medical care has not been resolved satisfactorily and there is no uniform, national approach. Primary social care is a municipality's responsibility (Local Entities Law, *Ley de Bases de Régimen Local, dated* 1985). On the other side, ACs have the responsibility on providing, and managing social benefits. The Royal Decree 63/1995 does not include social care and the Law 16/2003 does only includes three types of benefits (long term care, health care to the convalescence and rehabilitation in patients with any recoverable functional deficit), and, it determines that this type of care will be carried on in the levels that each AC determines. Home care is being expanded and within most municipalities, a basic infrastructure exists to deliver basic support to those being cared for or caring for others at home. However, accessibility to these services is very restricted, and coordination with medical care is very low. These services are free of charge subject to a prior classification of needs by the corresponding administration, which in this case is not usually the Regional Department of Health but the Social and Welfare Affairs Department. There are co-payments for some social services with users contributing part of the cost although, in general, care at social service centres and day hospitals are free of charge.

In fact, until 2003, with Law 16/2003, long-term care services didn't exist as themselves in the Spanish regulation.

The responsible institution for these benefits is the Central (Federal) Government, which has defined it by a Royal Decree. After this general definition, the Parliament has passed a law (16/2003) which enlarged Spanish Health Care benefits with the purpose of equalisation of benefits among regions (Autonomous Communities).

In January 2005 the Ministry of Labour and Social Affairs published the Dependency White Book, which owes to serve as a state of the art of the actual situation and the basis for the future law on dependency services.

For a better idea of the different situation across ACs, we have to mention six long-term care programs:

Denomination	**"Vida als anys" Program Catalonia. MD 29-5-1986**	**Long-term care plan. Castilla y León. D 16/1998**	**"PASOS" Program Galicia. D 48/1998**
Long term care definition	Specific network continuous long term care	Long-term care network. Long-term care space. Systems integration	Long-term care coordination. Continuous welfare.
Model criterion	Integral, global and interdisciplinary	Integral, interdisciplinary and rehabilitative	Integral, multidisciplinary and synergic
Population objective	All population with dependence problems. Special reference to old people, mental illness and terminals	All population with dependence problems. Special reference to old people (18.9% dependents –85000-, from which 7.8 are acute: 35000 people)	All population with dependence problems: elders, mental illness, disabled and terminals. Elder population dependent: 17% -82966- from which 7% are acute: 34000)
Identification/ Evaluation necessity	Coordination Commissions by health areas.	Coordination Commissions by health areas. Cases	Teams of multidisciplinary assessment

	Managements teams for multidisciplinary cases	management teams, primary care teams, social action teams	
Resources	a) Long term care: long term care, convalescence, palliative care, Aids. b) Alternative services: day hospital, home care programme or PADES, UFISS	Palliative hospital Units, Regional Centres of reference, Hospital Units of reference, Long term Units, Dementia Assisted Units, Social Action Centres, Disabled Centres	a) Inpatient long term care, psycho geriatric long term care b) Home care and social services. PADSS
Financing	Co-financing of SCS (Public Catalan Health Care Purchasing Agency) and ICASS (Catalan Social Services Agency) with a co-payment system depending on dependence grade and resources	Public budget of 50000 millions plus co-payment depending on resources	Financing modules with co-payment depending on resources
Denomination	**Long term Programmes of Basque Country County Council**	**"PIASS" Programme (PALET) Valencia. MD 30-3-95**	**"Proyecto Plan de Acción Sociosanitario para el mayor 1999-2005". Cantabria**
Long term care definition	Long term care space	Long term care area of intervention in the health and social network with health predominance	Social and Long term care integral System
Model criterion	Integral, coordination and interdisciplinary	Integral, interdisciplinary, rehabilitative and integrated	Integral, multidisciplinary, relating to the community, rehabilitative and flexible
Population	Elder dependent	Chronic and terminal	Elder dependent

objective	people, terminals and disabled. Special attention psycho-geriatric	patients	people
Identification/ Evaluation necessity	Territorial and sectorial Commissions of CSS	Autonomous Coordination Commissions by Health Areas	Long term care Commission of Area and Case Management Team
Resources	Social Services relating to community and institutional predominance	Autonomous Coordination Commissions by Health Areas	To promote social services and natural nets of social and long-term care attention
Financing	Compensation agreements of costs between Public Health System and Social Services	Not specific	Free health model. Social model depending on resources

Eligible people for long-term can be classified on the following way:
- People with a chronic illness or physically or cognitively handicapping.
- Physically, mentally or sense handicapped people.
- Caregivers.

There is no explicit exclusion of benefits, despite all the described implicit exclusions.

Besides the different programs described above, some ACs have regulated long-term care or as it would be in the Spanish description, Social and Community care. Andalusia has raised different laws to help elder (law 6/1999) and disable people (Law 1/1999), and their families (Decree 13/2002). Catalonia integrated in a single program social and community care, and health care (Decree 215/90).

4. Ancillary services to health care

The benefits package described in this section is the equivalence to the following OECD categories: HC.4.1: Clinical laboratory (laboratory tests), HC.4.2: Diagnostic imaging (diagnostic imaging, i.e. ultrasound, X-ray, CT, NMR), HC.4.3:

Patient transport and emergency rescue (patient transportation), and HC.4.4: All other miscellaneous services.

These entitlements are mainly defined and regulated at national level by the Royal Decree 63/1995, and the Law 16/2003.

The definition of the Service Groups by the Decree 63/1995 is as follows:

- Medical examinations and diagnostic tests, including neonatal examination, as well as the application of therapeutic treatments or procedures needed by the patient, regardless of whether or not the need was originated or caused by the procedure or by the reason for admission and hospitalisation.
- Imaging diagnosis: general radiology, ultrasound scanning, mammography, computerised axial tomography (C.A.T.), magnetic resonance, angiographies and grammagraphy, as well as osteo-densitometry according to the health services programme.
- Laboratory services: pathological anatomy, genetic biochemistry, haematology, immunology, microbiology, and parasite test.
- Ambulance services: The provision of ambulance services comprises the special transportation of patients or people involved in an accident when one of the following circumstances is present:
    a) An emergency situation which implies vital damage or irreparable damage to the health of the interested party and when so ordered or determined by the attending physician.
    b) Physical impossibility of the interested party or other medical reasons that in the opinion of the attending physician incapacitate or render impossible for said party the use or ordinary receiving the necessary medical attention.

The evaluation of need of the ambulance service or health transportation shall fall on the attending physician who is providing the medical services, and his instructions will ensue only for medical reasons which make travel impossible using ordinary means of transportation.

Emergency rescue: Generally free of charge, but another department within the regional budget assumes costs. Catalonia has lately developed and approved a law on charging a 100% co-payment (on the overall costs- health care and

others) for those mountain', traffic', and any other risk situation' rescues, which have been originated by a negligent behaviour (Catalan Law 12/2004, on financing measures).

Balearic Islands enlarged the health transportation benefits by refunding the necessary expenses and monetary compensation for movements outside the AC when needed to receive health care (Decree 37/2003);

The main responsible actor is the Central (Federal) Government, which has defined this level of benefits by a Royal Decree. After this general definition, the Parliament passed a law (16/2003) which enlarged Spanish Health Care benefits with the purpose of equalisation of benefits among regions (Autonomous Communities).

The lists of laboratory tests and diagnostic imaging are explicitly defined. When listing ambulance services or patient transportation, it is quite explicit too, although there are some concepts, such as "vital damage" or "irreparable damage to the health" that should have been further developed.

Examinations and studies or biological testing voluntarily requested or carried out by third party requests cannot be financed by Social Security or by Government resources assigned to health services and assistance, and therefore, they are excluded.

Finally, a brief view of medical certificates. Each sector that requires a medical certificate has passed its own regulation in this matter. In December of 2003, the Spanish Parliament passed a law that establishes the price of the sheets for medical certificates in 3 euros in all the country. Medical Associations cannot increase this price.

5. Medical goods dispensed to out-patients

An agency for the assessment of health technologies was founded in 1994 to replace the technology assessment unit of the Ministry of Health Planning Department.

This agency is responsible for setting technical criteria for the election, incorporation and dissemination of health care technology. Health care technology

assessment, however, is shared with the special regions, and accordingly, some of these Autonomous Communities have developed their own agencies (see the section on Health care delivery). In addition, the Spanish Agency for Pharmaceuticals was created, in April 1997 by the Law 66/1997, dated December 30th and which responsibilities were enlarged by the Law 50/1998, as a semi-independent body supervised by the Ministry of Health, and is in charge of the scientific evaluation and registry of new pharmaceutical products. Given that these changes are so recent, it is not possible to evaluate whether these measures will succeed in making the system more rational and efficient.

5.1. Pharmaceuticals and other medical non-durables

In this section we will describe the current situation of the following OECD categories of services: HC.5.1.1: Prescribed medicines; HC.5.1.2: Over-the-counter medicines, Goods: pharmaceuticals, and Alternative & complementary medicine - goods (homeopathic drugs…)

The Pharmaceuticals Act of 1990 is the legal basis of pharmaceutical regulation in Spain. More recently, the Cohesion and Quality Act of 2003 explicitly established that "the State will retain full responsibilities for the authorisation, registry, safety and control of drugs". In addition, the regulations define the responsibilities of a new Agency for Pharmaceuticals and Health Products (*Agencia Española del Medicamento y Productos Sanitarios, AEMPS*) responsible for the evaluation and authorisation of drugs, while the Directorate-General of Pharmacy deals with both price setting and public reimbursement once the products have been authorised by the AEMPS. Since 2003, the Agency's steering committee has involved representatives of the Autonomous Communities in decisions concerning the reimbursement of new drugs. Furthermore, in conjunction with the AC governments the MoH is responsible for policies relating to the rational use of drugs and for the provision of education for both the general public and health care professionals.

These entitlements are entirely regulated at national level since the pharmaceutical policy is one of the few which has not been delegated to AC. Benefits in this category are regulated by the following laws: Decree 3157/1966, Royal Decree 63/1995, Law 25/1990, Law 16/2003, and described as follows by the first one:

Medicines in Spain are classified into the following groups of medicinal products:

- Prescription-only medicines (partially or fully reimbursed)
- Non-prescription medicines, including: a) Non-prescription reimbursed medicines, which can be prescribed by a medical doctor (in which case they are reimbursed) or not prescribed (and not reimbursed). They cannot be advertised to the consumer.

b) Non-prescription, non-reimbursed, non-EFP (*Especialidades Farmacéuticas Publicitarias*- Allowed for Publicity Pharmaceutical Specialities) medicines. They cannot be advertised to the consumer. Their price is not controlled by Health Authorities.

c) EFP or OTC medicines, which are non-prescription medicines whose prices are set by the manufacturer. They can be advertised in all media and are never reimbursed.

Article 42 of the 25/1990 Spanish Medicines Act, dated December 20th established that: plants and their preparations such as extracts, tinctures, etc., making therapeutic, diagnostic or preventive claims will follow the system of magisterial formulae, officinal preparations or pharmaceutical specialties.

Responsible actors within this category are the state, the AC and the regional health services. The state regulates and authorizes clinical trials, issues marketing authorizations for pharmaceuticals, controls the advertising of drugs and health care products directed towards the general population, licenses pharmaceutical laboratories, regulates the quality and manufacture of pharmaceutical products, fixes the price of drugs, sets co-payments and decides on the inclusion or exclusion of pharmaceuticals on the list of publicly-financed medicines. AC controls the planning of pharmacies, fixes criteria for the opening or allocation of outlets. Finally, Health services are in charge of day-to-day administration of pharmaceutical benefits, set the conditions of the agreements with pharmacies, implements professional driven cost-containment policies, and pays de bill. The Spanish Pharmaceuticals Agency, in charge of ensuring that pharmaceuticals products registered in Spain meet the criteria of quality, safety and clinical efficacy.

Benefits are distributed as follows depending on the level of care:

a) In the case of inpatient care: Pharmaceutical benefits provided are according to the Decree 63/1995: Necessary medications, cures, medicinal gases, consumable materials and necessary health products. All of them are free of charge if they administered within the hospital or health care centre.

b) Meanwhile, in the case of outpatient care: Since 1966 there is a co-payment for medicines in the Spanish National Health Service (at that moment Social Security System). It started with a fixed amount of 5 ptas (3 cents of euro) and was replaced by a 20% of the price co-payment in 1978. On 1979 was increased to 30% and finally on 1980 it was set at 40%. This 40% (of the price) co-payment is fixed on pharmaceuticals consumption by users of the system on those products financed by the National Health Service (former Social Insurance System). This rule is not applied to retired population (under 65), individuals with permanent disability or chronic illness (10% co-payment on medicines), neither those receiving inpatient care. The evolution of pharmaceutical co-payments in Spain may be observed in the table below. Another exception to this rule is that applied to civil servants, which are under the MUFACE scheme. MUFACE affiliates have a 30% co-payment for all pharmaceutical products, both employed and pensioners. There is also an exception for chronic patients included in the Decree 83/1993. Their contribution will be only 10% of the price of the medicines.

Chronological evolution of co-payment regulation for NHS	
Period	System
December 23rd 1966 Decree 3157/1966	Definition of the Public Pharmaceutical Specialities Catalogue.
December 23rd 1966 - April 14th 1978	• Drug price < 30 ptas ⇢ co-payment 5 ptas • Drug price — 30 ptas ⇢ 10% price co-payment • Max. co-payment 50 ptas
April 14th 1978 - January 1979 Decree	• No co-payment for pensioners and its beneficiaries. • 20% price co-payment for employed and its beneficiaries. • New pharmaceuticals catalogue.

945/1978	
January 1979 – September 1980	• No co-payment for pensioners and its beneficiaries. • 30% price co-payment for employed and its beneficiaries.
September 1980 – January 1999	• No co-payment for pensioners and its beneficiaries. • 40% price co-payment for employed and her beneficiaries. • 10% price co-payment for chronic disease products.
1-1-1999	• No co-payment for pensioners and its beneficiaries • 10% price co-payment for chronic disease products. • 40% for the rest of residents

Note: it does not include MUFACE affiliates or other special groups

The Spanish Government used the exclusion of benefits mechanism in 1993 to control the pharmaceutical expenditure by introducing a "negative list" on medicines, the Royal Decree on Selective Financing of medicines (RD 83/1993). The Spanish Royal Decree of 1993 was based on two main objectives: (a) Prioritise public financing for those drugs whose need or severity of the illnesses for which they were used was higher, and (b) exclude from public financing those drugs with low therapeutic value.

1.692 pharmaceutical specialities were excluded from the Social Security supply according to their objectives: hygiene, lower symptoms relieve, or lower dermatological symptoms treatment. Some of the main groups of products excluded were (RD 83/1993):

- Cosmetics, dietetics and diet products, mineral water, oral elixirs, toothpaste, medicine-sweet goods, medicine soaps.
- Pharmaceuticals qualified as advertising.
- Pharmaceuticals authorised as food supplements, anabolic steroid or anti-obesity products.
- Pharmaceuticals with hygienic or dermatologist therapeutic purpose.
- Other pharmaceuticals assigned to minor symptoms.

Among them, products such as: shampoos, antiseptics, creams, laxatives, constipation treatments, and so on, could be found. Those pharmaceutical specialities amounted in 1993 for the 19,8% of all PS publicly financed.

Further, in 1998 the Royal Decree 1663/1998, which regulated the exclusion of medicines of public financing, came to enlarge the list of excluded medicines of

public financing. It also established control measures of the use of these pharmaceuticals.

Finally, Royal Decree 1348/2003 adapted previous classifications of medicines into the ATC System (Anatomical, Therapeutic and Chemical Classification System). With this adaptation some pharmaceuticals, both excluded of public financing and reduced contribution ones, were modified.

ACs have also added different benefits in this category. As a reaction to the Royal Decree 1663/1998, Navarre passed the Foral Decree 258/1998, dated September 1st, by which Navarre would cover with its own funds some of those excluded medicines. Andalusia did the same with the Decree 159/1998, dated July 28th. Andalusia and Navarre, Balearic Islands, Catalonia, and Extremadura also added the post-coitus pill (or abortive pill), which may have a 100% co-payment if it is bought in a pharmacy (with the necessary prescription), or 0% co-payment in administered in the hospital, primary care centre or family planning centre. Navarra also pays nicotine substitution therapy: nicotine patches and bupropion.

Valencia finances tuberculosis pharmaceuticals, offer in-kind pharmaceuticals for low-income people (such as it was in the in-patient setting), urine bags for spinal cord damaged and other groups, test strips for people receiving oral anti-coagulate treatments.

5.2. Therapeutic appliances and other medical durables

In this section we will describe the current situation of the following OECD categories of services: HC.5.2.1: Spectacles and vision products; HC.5.2.2: Orthopaedic appliances and other prosthetics; HC.5.2.3: Hearing aids; HC.5.2.4: Medico-technical devices, incl. Wheelchairs; HC.5.2.5: All other miscellaneous medical durables, Goods: medical devices for patient use (from dressing via spectacles to wheel chairs).

These entitlements are regulated at National level by the Royal Decree 63/1995, Law 25/1990, Law 16/2003, and Ministerial Decree 18-01-1996.

Service Groups as classified by the Royal Decree 63/1995 are the following:

- Application and reposition of gallbladder and nose-gastric catheters.
- Prosthetic implants and their timely renewal.

- Necessary medications, cures, medicinal gases, consumable materials and necessary health products. (the latest are only provided to inpatients, outpatients would have to pay for them)
- Orthoprosthetic services:
    a) Fixed surgical prosthesis and its timely renewal.
    b) Permanent or temporary (external prosthesis) orthopaedic prosthesis and its timely renewal.
    c) Vehicles for impaired people as justified by their disadvantage.

The specialised medical personnel will prescribe these services but following the rules set in the duly authorised catalogue. Orthesis, dental prosthesis and special cases will be provided or will justify some financial help according to the case in question and to the book of lists of tariffs regulated in the appropriate catalogue. The Ministerial Decree 18-01-1996 has developed this catalogue. Goods and accessories, and sportive orthoprosthetic items are excluded. From the point of view of their public financing, are completely covered by the National Health System fixed surgical prosthesis, external prosthesis and wheelchairs. However, there is a co-payment (the user contribution is between 12 and 36 euros) in orthesis, special prosthesis and hearing aids (for children since sixteen years old; for this case is fixed a maximum price covered by public funding).

Orthopaedic prosthesis are developed at the Ministerial Decree 18-01-1996. There is a co-payment of 40% for orthopaedic prosthesis with a maximum of 6.000 ptas (36 Euros). According to this legislation, each Regional Health Service may decide the prices for the orthopaedic products for outpatients, which publishes as public information. This catalogue establishes the products, the price and the public participation on this price (60%), including orthopaedic prosthesis, wheel chairs for handicapped, and special prosthesis. For inpatient cases where surgery is needed there is no co-payment for this process.

The social services system also covers part of the cost of spectacles, dentures, technical aids, etc., which are not covered by the National Health System for those users in particular need. A detailed description of MUFACE structure for prosthesis is included in part III of this report.

There are some AC that have decide to offer extra orthopaedic benefits, Andalusia offers the orthopaedic insoles. Andalusia also covers the user co-payment on any orthesis and special prosthesis of the catalogue, pays orthopaedic insoles and soft

material wheel chairs (Decree 195/1998). Galicia offers the anti-eschar mattress and soft material wheel chairs (not included in the State Order 18.1.1996). The Ministerial Decree dated on January 18th, 1996 had excluded all this mentioned therapeutic appliances. The Finance Department of Catalonia approved in the Law 30/2002, dated on December 30th, financial aid to handicapped people to pay among other purposes those prosthesis not covered by the Health Care Benefits System. Basque Country offers credits for soft material wheel chairs (Decree 9/1997 and Order 3.2.1997). Valencia offers hearing aids until the end of study life.

6. Prevention and public health services

In this section we will describe the current situation of the following OECD categories of services: HC.6.1: Maternal and child health; family planning and counselling; Reproductive health (maternal care, birth, abortion, IVF, contraception, sex change…) ; HC.6.2: School health services; HC.6.3: Prevention of communicable diseases; HC.6.4: Prevention of non-communicable diseases; Health promotion, primary prevention, immunizations, screening; HC.6.5: Occupational health care; and HC.6.6: All other miscellaneous public health services.

These services are regulated at National Level by the Royal Decree 63/1995, Law 16/2003. Executive competences and provision are under the AC responsibilities, which in certain cases delegate part of these activities into large-medium size municipalities.

Service Groups as described by the Law 16/2003 (which introduces slight changes to the Royal Decree 63/1995) are:

a) Epidemiological information and surveillance.
b) Health protection.
c) Health promotion.
d) Diseases and deficiencies prevention.
e) Vigilance and control of the possible risks for health coming from goods importation, exportation or traffic and international travellers traffic.
f) Environment health promotion and protection.
g) Labour health promotion and protection.
h) Food security promotion.

The aforementioned services shall also include preventive measures and health assistance which the authorities consider necessary in case of communicable diseases or risks or a danger to the health of the population, as stated in the articles 1 and 2 of the Organic Law 3/1986, dated April 14, which refer to special measures related to public health. Personal services of a preventive nature are considered as included in the aforementioned categories, according to the specifications formulated in each particular case.

Primary health care will comprise the activities programmed by the health services in matters concerning health education, vaccinations, health examinations and other activities or measures programmed for the prevention of diseases, health promotion or rehabilitation.

The bulk of preventive medicine and health promotion is integrated with primary health care and carried out by practice nurses as part of their normal workload. From 1999, a unified vaccination calendar came into use, as agreed by the Interterritorial Council.

Other public health services regulated and included in the Spanish Health Benefits Basket by the Royal Decree 63/1995 all free of any charge are:

- *Health Care for Women:*
    a) Early pregnancy car and follow-up health services.
    b) Preparation for delivery.
    c) Medical visit during the first month post-birth.
    d) Detection of groups at risk and the early diagnosis of gynaecological and breast cancer according to the programmes established by the health services.
    e) Treatment of pathological complications of menopause, according to health service programmes.
- *Infant Health Care:* (until they reach the age of fourteen)
    a) Health information and education for the interested parties, their parents, tutors, teachers, professors, or caregivers.
    b) Vaccines delivered according to the official agenda of the health services.
    c) Medical examinations of the healthy child according to programmes established by the health services.

- *Adult and Third Age Health Care:*
    a) Vaccines recommended by the health care programmes.
    b) The detection of risk factors when there are indicated measures of recognised effectiveness to eliminate or reduce said risks.
    c) Health education, attention, and assistance to chronic patients.
    d) Attention to specific health problems of the third age according to the regulations of article 50 of the Constitution.
    e) In-home services for immobilised or terminal patients.[12]
- *Dental Health Care Services:*
    a) Information and education o dental health and hygiene.
    b) Preventive and assistance measures: application of topical fluoride, obtrusions, sealing of fissures or other services for the infant population according to the annual financial budget and special programmes for dental health.
    c) Treatment of acute orthodontic problems including dental extractions.
    d) Preventive exploration of the oral cavity in pregnant women.
- *Other Primary Care Services and Assistance:*
    - Indication and follow-up services for the various contraceptive methods.
- *Specialised Hospital Health Care and Attention:*
    a) Treatments or surgical interventions geared towards the conservation or amelioration of life expectancy, self-sufficiency and elimination or reduction of pain and suffering.
    b) Nutrition according to the prescribed diet.
    c) Parenteral and enteral nutrition therapy.
    d) Infertility diagnosis and treatment. Artificial insemination is regulated in Law 35/1988, which has been modified by Law 10/1995 and 45/2003. In Spain, there are 13 gamete-banks and 14 medical centres, both private and public financed, that carry out these treatments. All these centres must be authorised as health centres in accordance with the General Health Act. Sterility treatments include ovulation inducement and artificial insemination, such as in vitro fecundation, sperm microinjection, egg donation, etc. Surrogacy services are forbidden. Artificial insemination Act only authorizes the transference of a maximum of three pre-embryos in a woman in

[12] c), d) and e) sections are also included in the Services of long-term nursing care category.

each cycle. Recently, the other limitation based in the number of eggs to fertilize in each reproductive cycle has been eliminated.

e) Prenatal diagnosis for risk groups.
f) Family planning: genetic advice for risk groups, vasectomies and tubal ligation. Voluntary pregnancy interruption within the norms included in the Organic Law 9/1985, dated July 5, which considers three special cases in which is allowed (not legally penalised) and: a) eugenetic abortion (physical or psychic conditions of the fetus, b) pregnancy after rape, c) high risk for the mothers life, so far it is not included as a benefit, although some AC such as Catalonia may partially finance the cost to low income people.

Autonomous Communities undertake education programmes within their own geographical regions. The Ministry of Health has launched national information campaigns for specific problems, such as alcohol, drugs, AIDS or work-related illnesses at state level. In addition, there is an agreement with the Ministry of Education through which health education has been introduced into the school curriculum.

AC enlargements to this benefits basket in public health are few, only Andalusia decided to do it, offering flu vaccine (to all population instead of "those in higher risk") and anti-hepatitis's vaccine.

7. Users rights on information and clinical records

Although this is not a proper category in the OECD classification, the Spanish Health Benefits package includes also an special category on the users rights on their own clinical records and the informed consent on clinical interventions.

These rights on Information Services and Health Documentation are described as follows by the Royal Decree 63/1995:

1. Information to the patient and his or her family and close friends about his rights and obligations, especially for obtaining informed consent and about the use of the health system, as well as, in each case, the other services

available which would benefit the health, assistance, care, and well-being of the patient.

2. Information about and, whenever applicable, the processing of the necessary administrative procedures to guarantee the continuity of the health care process.
3. The issuing of release orders, confirmation, discharge, and other reports or clinical documents to evaluate the incapacitation or other results.
4. The discharge report upon ending the period of hospitalisation in an institution, or the external report of a specialised physician.
5. Medical documentation or certification of birth, death and other information for the Civil Registry.
6. Communication or delivery, requested by the interested party, of his or her clinical record, or some of the information included in the record, without prejudice to the obligation to keep this information in the health centre.
7. Issuance of all other reports and certificates referring to the health status derived from the other health services or those required by legal or statutory regulations.

All Spanish residents who receive health care have the right to be informed to have access to their clinical records according to the Law 41/2002, dated November 14th, on basic regulation on patient autonomy and rights and duties in terms of information and clinical records.

	General Health Act	**Royal Decree 63/95**	**Law 16/03**	**MD 30/04/ 1997**	**MD 03/06/ 1998**	**MD 03/03/ 1999**
Functional Categories						
HC.1.1	X	X	X			
HC.1.2		X	X			
HC.1.3	X	X	X			
HC.1.3.1	X	X	X			
HC.1.3.2*		X	X			
HC.1.3.3	X	X	X			
HC.1.3.4		X	X	X		

HC.1.4*	X	X	X		X	X
HC.2.1	X	X	X			
HC.2.2	X	X	X			
HC.2.3	X	X	X			
HC.2.4						
HC.3**		X	X			
HC.4.1		X	X			
HC.4.2		X	X			
HC.4.3		X	X			
Legal status	Law	Presidential Decree	Law	Ministry Decree	Ministry Decree	Ministry Decree
Decision-maker	Parliament	Government	Parliament	Government	Government	Government
Degree of explicitness: 1 (all necessary), 2 (areas of care), 3 (items)	1	3	2	3	3	3
Positive/ negative definition of benefits	P	P	P	P	P	P
Original Purpose	General definition of entitlements	Basket	Equity and equality among citizens and AD	Basket	Basket	Basket
Criteria used for defining benefits:						
Need	X	X	X	X	X	X
Costs		X	X	X	X	X
Effectiveness		X	X	X	X	X
Cost-Effectiveness						
Budget						

Updating	No	No	No	regularly	regularly	regularly

* See Autonomous regulation. (part 3).

** See socio-sanitary programmes of the Autonomous Communities (part 2).

	General Health Act	**RD 63/95**	**Law 16/ 2003**	**Decree 3157/ 1966**	**Law 25/ 1990**	**RD 83/ 1993**	**RD 1663/ 1998**	**RD 1348/ 2003**	**MD 18/01/ 1996**
Functional Categories									
HC.5.1	X			X	X	X	X	X	
HC.5.1.1					X				
HC.5.1.2					X				
HC.5.2									
HC.5.2.1									
HC.5.2.2*		X							X
HC.5.2.3*									X
HC.5.2.4*									X
HC.6.1		X	X						
HC.6.2		X							
HC.6.3	X	X	X						
HC.6.4	X	X	X						
HC.6.5									
Legal status	Law	Presid. Decree	Law	Law	Law	Presid. Decree	Presid. Decree	Presid. Decree	Minis Decree
Decision-maker	Parliament	Government	Parliament	Parliament	Parliament	Government	Government	Government	Government
Degree of explicitness: 1, 2, 3	1	3	2	1	2	3	3	3	3
Positive/ negative definition of benefits	P	P	P	P	P	N	N	N	P
Original Purpose	General definition	Basket	Equity and	General definitio	Target rule	Exclusion	Exclusion	Exclusion	Basket

	of Entitlements		equality among citizens and AC	n of Entitlements					
Criteria used for defining benefits:									
Need	X	X	X	X	X				X
Costs		X	X		X	X	X	X	X
Effectiveness		X	X		X	X	X	X	X
Cost-effectiveness.									
Budget									
Updating	No	No	No	No	No	Regul.	Regul.	Regul.	Regul.

* See Autonomous regulation. (part 3).

PART III. Description of benefit catalogues, involved actors and decision criteria

The definition of a benefit catalogue of services covered by the National Health System of Spain raises technical and political problems. A relevant issue related with the implementation of this strategy is the instrument to define the services covered by the public system. The way a benefit catalogue is defined is closely related to the Health Care Model implemented. Then, a system that guarantees universal cover should specify a minimum basket of health care services.

As this is the case in many countries, the possibility of using regional plans as the basis for resources allocation and capacity planning has not yet been considered, and therefore they have mainly played the role of instruments for information development and needs assessment. An additional problem in Spain is that the majority of health care plans offer unrealistic large lists of objectives, which are often not sufficient based on the available epidemiological and cost-effectiveness evidence, and the accomplishment of which has seldom being evaluated. Neither, they can be considered as benefit catalogues since they are not sufficiently strong legal instrument and therefore, users cannot claim the objectives contained in the health plans as benefit rights.

Despite all this, we can consider a large number of benefit catalogues. For a complete picture of the Spanish description of the benefit catalogues we need to distinguish two levels: one according to the government level that has passed the benefit catalogue (central state or AC), and the other referring to additional or specific benefits. In this part of the report we will consider eight benefit catalogues, as the other lists of services can only be considered as benefit baskets due to their broadness and lack of explicit description. Two of these catalogues provide a general definition of benefits (and therefore strictly speaking can not be considered as catalogues), the rest refer to specific or additional benefits. Five of them have been passed by the Central Government or Parliament, the rest by Autonomous Communities. Finally, civil servants (MUFACE) benefit catalogue is defined.

1. RD 63/1995

The fundamental step on health benefits regulation was done through the Royal Decree 63/1995, dated January 20th, on the organization of health services provided by the National Health System. It provides inclusion and exclusion criteria, and defines the current level of provision as the guaranteed basic health care package. It adopts a comprehensive, generic form. In fact, this is not a specific benefit catalogue. The Ministry of Health and Consumption chose an strategy based in the establishment of an explicit process of decision taking on the health benefits planning instead of defining a detailed benefit catalogue. According to Elola Somoza (1995) this strategy is the one that best adapts to NHS needs. The advantages of this formulation are a) it is better addressed to health necessities coverage; b) it is not linked to payment systems by act; c) it means less administrative costs than the development and management of a benefit catalogue; and d) it is more flexible.

This document was passed by the Central Government as a decree. We can distinguish in the Spanish legal system different categories of rules: the fundamental rule is the Constitution of 1978, the following hierarchical level are laws (passed by the Parliament), and finally we can find government and administrative regulations, such as Royal Decrees, Ministerial Decrees, Orders, etc. Each hierarchical level must observe its superior. This Royal Decree was passed as a development of General Health Act of 1986 and Social Security Act of 1974. Final legal provision 14 of General Health Act authorises and indicates that the Government can adapt health care benefits publicly financed to the new ideas introduced in that law (which transformed the system in to a National Health System), something that it does not get done until the Royal Decree 63/1995. However, if we consider that subjective rights are defined, the rule chosen had insufficient rank. Then, they should better have opted for developing a law.

Moreover, the development of the National Health System is too important to regulate it without consensus, as it affects the whole population and involves many public and private actors. The lack of consensus may hinder the reform and development process. The way of implementing this regulation, which has been directly approved by the Government, has avoided the difficulty but also the possibility of reaching consensus.

Constitutional right to health protection was conceived as a mere expectation of right. This made it necessary its transformation, through ordinary legislative procedures (this means parliament law), in true subjective rights susceptible of

being claimed by legal proceedings. Moreover, certainty and juridical safety suggested to stop using the way of facts as the means to entitlement to health care, that is, leaving entirely to the autonomy of health care professionals the decision concerning the utilisation of techniques and procedures, based on clinical freedom.

Royal Decree 63/1995 does not stipulate an updating period. Nevertheless, some initiatives have been taken in order to update health benefits contents. Among these initiatives we find Evaluation Reports, Experts Group criteria and the Tutelary Use focused to evaluation. In additional legal provision 2 the decree establishes the procedure to pass new health benefits (though it does not determine their financing): by Royal Decree, prior consultative report of the Inter-territorial Council and opinion of the Council of the State. Safety, efficacy and efficiency will be the tests for new services and procedures to be financed.

The decision about the general structure of the catalogue was made by the Ministry of Health and Consumption, taking into consideration the previous reports of the Professional Health Organizations, of the Board of Consumers and Users and of the Inter-territorial Board of the National Health System.

This rule pursued two fundamental objectives: a) to define with more precision welfare rights of users and b) to demand a prior evaluation for the introduction of new benefits. It is basically a definition of entitlements.

In the text it is not clear the difference between benefits and techniques or procedures to make benefits effective. It adopts a comprehensive, generic form. As it includes different groups of services, several benefits classifications are taken. By way of example, benefits are itemised by service delivered in specialised health care in the inpatient regime, case-based for mental health as long as hospitalisation is included “when required”, etc.

The Royal Decree is structured in six articles, six additional legal provisions, one repealing legal provision and three annexes. The structure of the guaranteed entitlement to public health care contains, first, a checklist of services that constitute the entitlement. Then, some exclusion criteria are established. Thirdly, there are some references to the provision conditions of services, which are limited to the resources available to the NHS. Fourthly, the introduction of new

technologies and procedures as well as new entitlements is considered. Lastly, a call for coordination between health and social care is made.

Five types of services are considered: primary care, specialised care, pharmaceuticals, complementary services and health care information and documentation. Primary care includes general and emergency care, home care and outpatient clinics and health centres, diagnostic as well as promotion and prevention activities (vaccinations, health checks, and the like). It contains some specific lists of services provided to specific population groups, women, children, adult and elderly, and dental care.

Specialised care can be outpatient and inpatient, general and emergency, including day hospital. There is a specific reference to mental health care. Access to this level of care requires referral from GP, or specialist in case of inpatient care. Hospital care is described in detail as consisting of diagnostic procedures, treatments needed including those directed to preservation or improvement of life expectancy, or merely palliative of pain and suffering, rehabilitation, and so on, as well as basic hotel services including shared room (simple room if needed). There is a specific mention to diagnostic procedures and laboratory tests, organ transplantation and family planning.

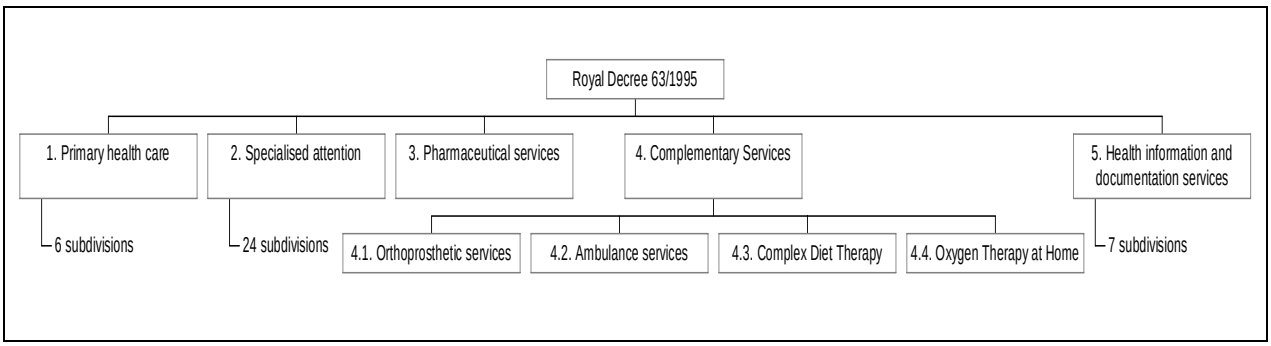
Concerning pharmaceuticals, the decree refers to its specific legislation. There is a negative list of drugs since 1993. Complementary services comprise prosthesis, crutches and vehicles for handicapped, health care transport, diet treatments and oxygen therapy. Information and documentation services include information to patient and relatives on their rights and duties, in particular to exert informed consent, administrative documents, such as sick leave procedures, information on patient's medical record, health certificates and the like.

The approximately generic description of services included is complemented by exclusion criteria. Services, activities or procedures for which any of the following circumstances occurs: a) There is no sufficient scientific evidence on their clinical safety and efficacy or are clearly outdated related to other available. b) It has not sufficiently proved their effective contribution to prevention, treatment or cure illnesses, preservation or improvement of life expectancy, self-help and elimination or reduction of pain and suffering. c) There are merely activities of leisure, rest, comfort, sport, aesthetic or cosmetic improvement, spa, residential or similar. All these criteria are included in the decree.

There is a loosely regulation on the condition of services provision. The text says these will be made according the organisation, functioning and regime rules of the health care services and provided by legally recognised health care professionals. The scope for utilisation of services is confined to the health personnel and network own or contracted out, of the NHS.

Once defined the extent of the basic health care package and the conditions for access, the introduction of new technologies, procedures and new entitlement is considered (mentioned above). The last point refers to the social problems in situations of health loss that require social care. The decree guarantees continuity of care through coordination between health and social authorities. This contrasts with the traditional asymmetry of care and social rights in Spain, where the latter are much more limited than the former.

Table 2. Taxonomy of the RD. 63/1995



Source: Own elaboration.

2. LAW 16/2003

Law 16/2003 of 28th May, concerning the Cohesion and Quality of the National Health System, is a reform that developed the previous policy with the purpose of coordinating a strongly decentralised activity. Its aim is to establish the legal framework for the coordination and cooperation of the Public Health Administrations guaranteeing equity, quality and participation in the system. It is particularly a question of guaranteeing the common basic conditions for providing primary health care, specialised health care, social and health care, emergency assistance, pharmaceutical services, orthoprosthetic treatments, dietetic products and health transport. These guarantees refer to accessibility, mobility, time, information, safety, and quality in the services. Likewise, it establishes criteria for

workers training, professional development and labour mobility in the health area.

Since 2002, all Autonomous Communities have health competences. This means that they manage their Health System and they can legislate on this matter. In this sense, with the health system decentralised to the Autonomous Communities, the law is intended to sustain coordination and basic guarantees between all the territories. Therefore, the original purpose of the text is a mixture between definition of entitlements and target document (even though it does not include any sanction procedure).

The initiators were the Spanish Parliament and the Spanish Government, and later on the bill was passed by the Parliament. The target groups and the target regions are the whole Spanish population, thus.

The text is structured in a preliminary chapter and other eleven chapters. Chapter I refers to health care benefits of the NHS and it defines a benefit catalogue, which includes public health care, primary and specialised health care, so-called socio-sanitary services, emergency assistance, pharmaceuticals, orthoprosthesis, dietetic products and health transport. From article 11 to 19 each group of services (public health, primary health care, specialised health care, socio-sanitary health care, emergency care, pharmaceuticals, orthoprosthetic services, dietetic products and transport care, respectively) include a definition and a sub-classification itemised by service delivered in most cases.

This catalogue incorporates, in addition to the benefits defined by the Royal Decree 63/1995, public health benefits. These benefits are defined as the set of initiatives organized by the society to preserve, protect and promote the health of the population, through activities directed, among other purposes, to the information and monitoring epidemiologist, the prevention of the diseases, the promotion of the food security and the prevention and control of the effects of the environmental factors on the human health.

It is important to emphasize that law 16/2003, on cohesion and quality on the NHS defines social care only in the strict health area. This definition comprises long-term care, convalescence care and rehabilitation in patients with recoverable functional deficit. The development of the “socio-sanitary” (in the Spanish way, which would be social and community care in English) services supposes the

coordination with social services policies. Primary health care must guarantee a total and continuous service during all the patient's life, working as a manager and coordinator of cases and as a flow regulator.

Chapter I takes care of the benefits of the National System of Health, whose guarantee constitutes one of the main objectives of the Law, reason why a preferred attention is dedicated to them. In first place, the classification of benefits is regulated. The catalogue of benefits is defined as a set of preventive services, diagnoses, therapeutic, rehabilitative and direct health promotion to citizens, which includes public health, primary and specialized care, social and community care, dietetic urgencies, pharmacy, orthoprosthesis, products and sanitary transport benefits.

In primary care, community care gets included, the palliative care to end of life patients, the oral and dental health and mental health. In specialized care, power the surgical activity in consultations and hospitals by day, doctors and, including, in addition, the hospitalisation at home, the palliative care to terminal patients and mental health. The benefits of long-term care in the strictly health area, that will include the health care needs which need continued and permanent care, health care to the convalescence and the rehabilitation in patients with recoverable functional deficit that will be carried out in the care levels that each AC determines. The pharmaceutical benefit includes medicines and health products and the set of formula that patients are prescribed adapted to their clinical needs, in the precise doses according to their individual requirements, during the period of suitable time and to the smaller possible cost for them and the community.

The benefits included in the catalogue become effective through a set of techniques, technologies and procedures that integrate the portfolio of services. A Royal Decree will approve the portfolio of services of the National System of Health, with the necessary report of the Inter-territorial Council of the National System of Health. New techniques, technologies or procedures will be put under previous evaluation to their incorporation to the portfolio of services for their public financing. The portfolio of services update will be approved by Order of Minister of Health and Consumption, also, previous report of the Inter-territorial Council.

In this chapter one of the law the right of all citizens to get a second medical opinion is also guaranteed, the right to receive medical assistance in their

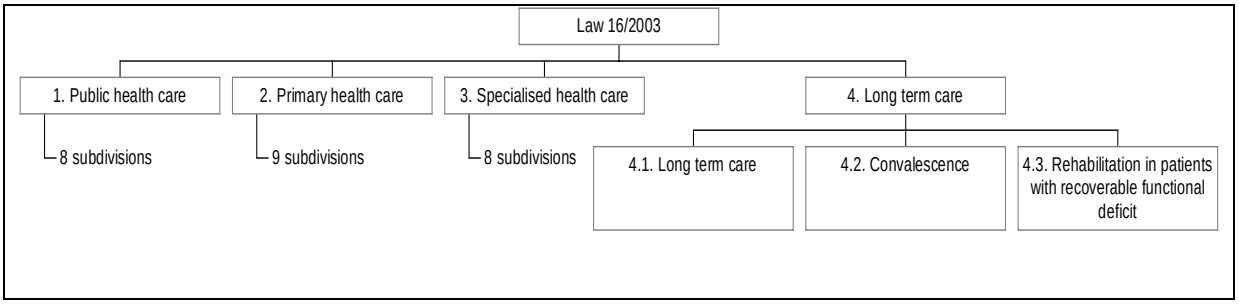
Autonomous Community of residence in a maximum time and the right to receive by the Health Service of the Autonomous Community of residence the medical assistance of the defined benefits of the NHS, with the same conditions and guarantees than the citizens resident in that Autonomous Community. Finally, the law establishes that Autonomous Communities can approve their respective Health Care Baskets ("Carteras de servicios") on their competences level. These Health Care Baskets must include at least benefits defined by the NHS. We can define them as all the techniques, technologies or methods based on scientific knowledge and experimentation

Regarding new benefits, the only new aspect is that as it says article 10 "the inclusion of a new benefits in the benefits catalogue of the Spanish National Health System will include an economic report which evaluates the positive or negative impact in costs. The Fiscal and Financing Policies Council will then study that report for its analysis prior its authorisation.

There is a lack of homogeneous, periodic and updated information on health indicators and management of services; especially in relation to AC. Therefore it is difficult to monitor and to assess the whole development of the NHS. Chapter V includes the creation of information and monitoring system, based on homogenous criteria for data collection. Information systems are essential to guarantee the quality of services in mixed system of publicly and privately-managed services.

In order to improve the cooperation and coordination between Central State and AC, the law 16/2003 gives more competences to the Inter-territorial Council of the National Health System (chapter X). Likewise, it regulates the High Inspection, which is developed by the Central State. The essential function of this official body is to guarantee and verify the compliance of health competences by the State and AC (chapter XI).

Table 3. Taxonomy of the LAW 16/2003



Source: Own elaboration.

3. Pharmaceutical catalogues

Spanish Constitution establishes in its article 149.1.16 that medicine legislation is an exclusive competence of the central state. In 1990 was passed the first law related to this matter. However, since 1966 medicines were regulated by Decree 3157 although this was prior to the Social Security Act and therefore was not created as a benefits catalogue. The Medicines Act of 1990 is the basis of pharmaceutical policy in Spain, and most legislation regulating the pharmaceutical market has been updated since then but always with this act as a basis.

The original purpose of law 25/1990 of medicines is to contribute to safe, effective and quality pharmaceuticals, well identified and with suitable information. The law provides a first closed list of legal medicines:

a) Pharmaceutical specialties.
b) Magisterial formulae.
c) Officinal preparations.
d) Prefabricated medicines.

Secret preparations are forbidden. The Health and Consumption Ministry decides the attribution of substances and products to the medicine nature. General Health Law already establishes that the provision of medicines by the NHS is possible by means of public financing, which must be selective and non-indiscriminate, and patients' contribution.

Law 25/1990, of the medicine, in agreement with Directive 89/105/CEE, relative to the transparency of the measures that regulate the rules for medicine prices for human use and its inclusion in the scope of the Insurance of National Health System, establishes, in its article 94, the general, objective and published criteria

to determine which medicines are to be included or excluded from the pharmaceutical benefits of the NHS (at its expense). General criteria that must be considered are the following:

a) Seriousness, duration and later-effects of the different pathologies.
b) Needs of certain groups.
c) Therapeutic and social value of the medicine.
d) Restrictions of the public expenses assigned to pharmaceutical benefits.
e) Existence of already available medicines and other identical or better alternatives for the same diseases with lower price or cost treatment.

Those medicines whose indications are symptomatic or for minor syndromes are not to be financed by public funds. Neither those groups of medicines determined by the Government whose public financing is not justified nor it is not considered necessary. However, these exclusion criteria are not published in each case. In any case, products for cosmetic use, diet products, mineral water, elixirs, toothpastes, advertising pharmaceutical specialties and other similar products are excluded.

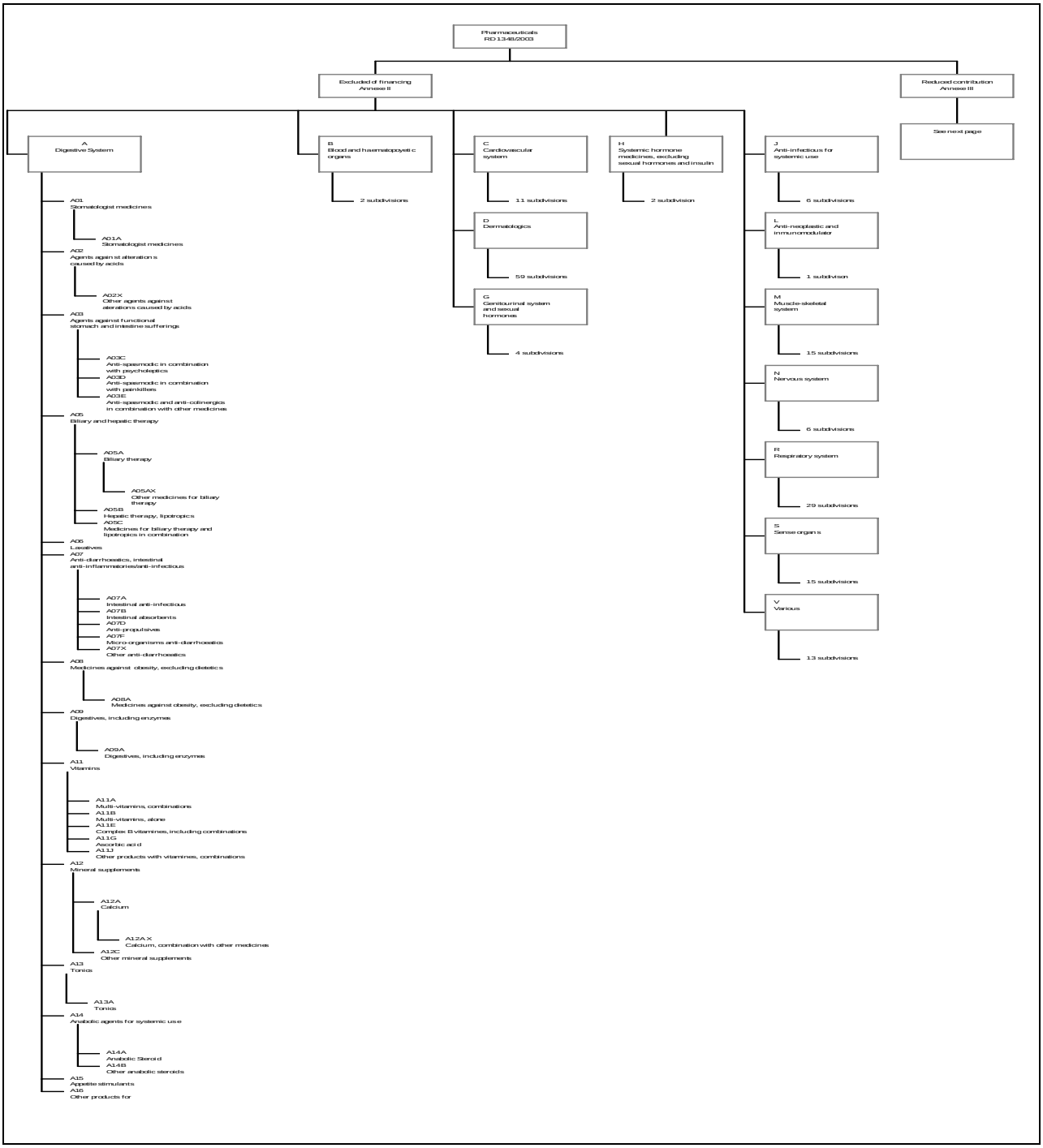
The decision to exclude total or partially or to classified under special conditions of financing medicines or health products already included in the Social Security benefits list will take into account established criteria. The decision will also consider the market price of these products and the advices of the Inter-territorial Council prior report of the National Commission of Rational Use of Medicines. The Government will review periodically and update the relation of medicines and health products included in the Social Security pharmaceutical benefits, in accordance with the available budged, the evolution of the criteria of rational use, the scientific knowledge and the criteria mentioned above.

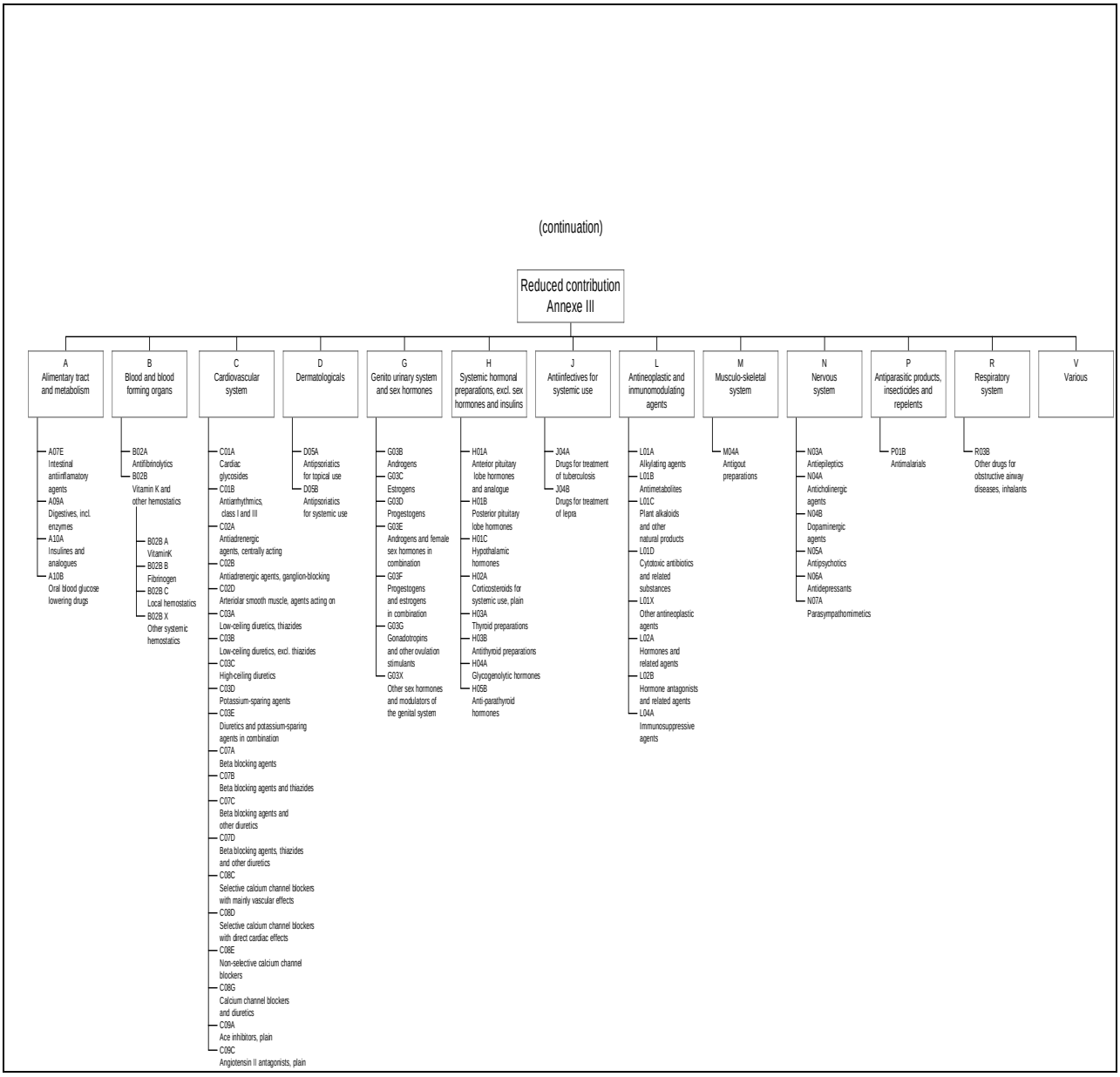
Royal Decree 83/1993 develops law 25/1990 and tries to adapt Spanish medicine regulation to European guidelines (89/105/CEE). It establishes a list of excluded medicines in annexe I, and a list of reduced contribution medicines in annexe II. The specific list can be found in Ministerial Decree 06/04/1993, which develops this Royal Decree.

Next rule came in 1998 with Royal Decree 1663/1998, which enlarges the number of medicines excluded of public financing. This rule applies for all the Spanish territory but Andalusia and Navarre that have included those medicines excluded by this Royal Decree. In additional legal provision 3 establishes a period

of three years since its coming into force to adapt the medicine classification into the ATC classification (Anatomical, Therapeutic, Chemical Classification System). For this reason, Royal Decree 1348/2003 was passed. The required adaptation supposes the modification of the corresponding annexes of the Royal Decree 1663/1998 as well as those of Real Decree 83/1993 and the Ministerial Decree that develops it. The decision about the general structure of the catalogue was made by the Ministry of Health and Consumption, in accordance with the State Council and previous deliberation of the Ministers Council.

Table 4. Taxonomy of the Royal Decree 83/1993


Pharmaceuticals
RD 1348/2003
Excluded of financing
Annexe II
Reduced contribution
Annexe III
See next page
A
Digestive System
A01
Stomatologist medicines
A01A
Stomatologist medicines
A02
Agents again st alteration s
caused by acids
A02X
Other agents against
alterations caused by acids
A03
Agents against functional
stomach and intestine sufferings
A03C
Anti-spasmodic in combination
with psycholeptics
A03D
Anti-spasmodic in combination
with painkillers
A03E
Anti-spasmodic and anti-colinergics
in combination with other medicines
A05
Biliary and hepatic therapy
A05A
Biliary therapy
A05AX
Other medicines for biliary
therapy
A05B
Hepatic therapy, lipotropics
A05C
Medicines for biliary therapy and
lipotropics in combination
A06
Laxatives
A07
Anti-diarrhoeatics, intestinal
anti-inflammatories/anti-infectious
A07A
Intestinal anti-infectious
A07B
Intestinal absorbents
A07D
Anti-propulsives
A07F
Micro-organisms anti-diarrhoeatics
A07X
Other anti-diarrhoeatics
A08
Medicines against obesity, excluding dietetics
A08A
Medicines against obesity, excluding dietetics
A09
Digestives, including enzymes
A09A
Digestives, including enzymes
A11
Vitamins
A11A
Multi-vitamins, combinations
A11B
Multi-vitamins, alone
A11E
Complex B-vitamines, including combinations
A11G
Ascorbic acid
A11J
Other products with vitamines, combinations
A12
Mineral supplements
A12A
Calcium
A12AX
Calcium, combination with other medicines
A12C
Other mineral supplements
A13
Tonics
A13A
Tonics
A14
Anabolic agents for systemic use
A14A
Anabolic Steroid
A14B
Other anabolic steroids
A15
Appetite stimulants
A16
Other products for
B
Blood and haematopoyetic
organs
2 subdivisions
C
Cardiovascular
system
11 subdivisions
D
Dermatologics
59 subdivisions
G
Genitourinal system
and sexual
hormones
4 subdivisions
H
Systemic hormone
medicines, excluding
sexual hormones and insulin
2 subdivision
J
Anti-infectious for
systemic use
6 subdivisions
L
Anti-neoplastic and
immunomodulator
1 subdivison
M
Muscle-skeletal
system
15 subdivisions
N
Nervous system
6 subdivisions
R
Respiratory system
29 subdivisions
S
Sense organs
15 subdivisions
V
Various
13 subdivisions



Source: Own elaboration.

4. Orthoprosthetic services catalogues

The orthoprosthetic benefits are regulated by the Ministerial Decree 18/01/1996, that gathers the principles for the development of this benefit and defines and establishes a group classification of fixed surgical prosthesis, external prosthesis, wheelchairs, orthesis and special prosthesis. In addition, for orthesis and special prosthesis, it determines financial aids by means testing as a way to fix user contribution, in accordance with Royal Decree 63/195 and article 108 of the Social Security General Act.

This Ministerial Decree was submitted to the report of the health professional organizations, consumers and users organizations and Inter-territorial Council. Then it was passed by the Health and Consumption Ministry prior the approval of the Public Administrations Ministry.

On the other hand, the Ministerial Decree creates the Advisory Committee of Orthoprosthetic Services, which holds meetings every six months. One of the duties of this board is to propose the update of the benefits content and the unification of criteria for the development of catalogues.

Once established the principles of the orthoprosthetic benefits by the mentioned decree, the regional health services and INGESA, which are responsible in the management of these benefits, have defined this catalogues of benefits, the procedure for the access and prescription and management of these services. All these definitions have been developed through the publication of different regulations.

The Advisory Committee of Orthoprosthetic Services decided to do different activities directed to the best knowledge of the benefit and to achieve a greater homogeneity in the different catalogues defined by the Health Services and INGESA. These activities lead to *Standardised Codes* ("Códigos Homologados"), Descriptive Guide of Orthoprosthesis ("Guía Descriptiva de Ortoprótesis"), Clinical Practice Guide for the indication of Wheelchairs, Systems of Information, etc.

The rule provides a definition of orthoprosthetic services: prosthesis, wheelchairs, orthesis and dental prosthesis. It divides orthoprosthetic services into two groups. Prosthesis and wheelchairs are provided without any charge. Orthesis an special prosthesis require a user contribution. Annexes IV and V contain a fee schedule for each service. The Autonomous Communities, reducing the users co-payment, can modify these contributions.

Accessories and orthoprosthetic products for sport use are excluded. To include new orthoprosthetic services next conditions must be observed:

- They have to have a therapeutic improvement contribution, in terms of safety and effectiveness, as a consequence of a scientific or technological advance.

- They must offer advantageous economic conditions with regard to the benefits already included in the catalogue.

On the other hand, next products will be excluded:

- Those products that, as a consequence of a scientific or technological advance, have lost their health interest or are considered inefficient.
- Those products advertised to general public.
- Those products that can mean a potential or a proved risk for health.

Another Ministerial Decree on Advisory Committee of Orthoprosthetic Services suggestion and informing the Inter-territorial Council on the National Health System can update the annexes of the Ministerial Decree.

STATE AND AUTONOMOUS ORTHOPROSTHETIC REGULATION :

State regulation

- Ministerial Decree 18/01/1996, on development of Royal Decree 63/1995, for the regulation of the orthoprosthetic benefits.
- Ministerial Decree 23/07/1999, which modifies the Ministerial Decree 18/01/1996, for the regulation of the orthoprosthetic benefits.
- Ministerial Decree 30/03/2000, which modifies partially Ministerial Decree 18/01/1996.
- Ministerial Decree 19/07/2001, which brings up to date the composition of the Advisory Committee of the Orthoprosthetic Services.

Autonomous regulation

Andalusia

- Decree 195/1998, of the 13th of October, on regulation of the orthoprosthetic services.
- Decision 9/11/1998 of the Andalusian Health Service, on regulation of the orthoprosthetic services and the procedure to access to the products of the General Catalogue of orthoprosthetic services.

- Circular 1/12/1998 of the Health Care Head Office, which determines complementary instructions for the organization of the orthoprosthetic services.
- Circular 12/01/1999 of the Health Care Head Office, on procedure to obtain the doctor's order approval for ambulatory patients.
- Circular 29/01/1999 of the Health Care Head Office, which brings up to date the relation of multiple prescription products.
- Decision 15/04/1999 of the Andalusian Health Service, which authorizes the procedure for the expenditure reimbursement in the orthoprosthetic services in some cases.
- Decision 7/06/2000, on the establishment of periods for the signing for collaboration agreements between orthopaedic establishments and the Andalusian Health Service.
- Ministerial Decree 1/06/2000, which modifies the General Orthoprosthetic Catalogue (wheelchairs).
- Ministerial Decree 7/02/2001, which brings up to date the content of the General Orthoprosthetic Catalogue.

Canary Islands

- Decision 13/12/1996 of the General Secretary, on regulation of orthopaedic material.
- Decision 29/11/2000, which adapts the General Orthoprosthetic Catalogue to the Ministerial Decrees 23/07/1999 and 30/03/2000.

Catalonia

- Decree 79/1998, of 17th March, which passed rules related to orthoprosthetic services.
- Ministerial Decree 4/06/1999, which creates the Orthoprosthetic Services Consultant Commission and the monitoring committee of the health areas.
- Decree 128/2001, of 15th May, which modifies the Decree 79/1998.
- Decision 29/05/2001, which establishes the conditions and procedures that must observe the dispenser centres of orthoprosthetic products to facilitate the access to orthoprosthetic services without previous economic benefit from the Catalonian Health Service.
- Decision 14/12/2001, which modifies the orthoprosthetic catalogue.

Galicia

- Ministerial Decree 17/07/2000, which modifies the orthoprosthetic regulation.
- Ministerial Decree on correction of mistakes of the Ministerial Decree 17/07/2000.
- Ministerial Decree 21/03/2001 (modifies transitional legal provision 4 and annexe V) and Ministerial Decree 29/12/2000 (abolishes article 2.3).

INSALUD

- Circular 4/96 (29-3) on regulation of orthoprosthetic material. Catalogue 2001.

Navarre

- Statutory Decree 17/1998, of 26th January, which regulates the orthoprosthetic benefits of the Health System of Navarre.
- Statutory Ministerial Decree 170/1998, of 16th November, which establishes the early detection of deafness in the newborn period.
- Statutory Decree 224/2000, of 19th June, which modifies the Statutory Decree 17/1998.
- Statutory Decree 233/2001, on 27th August, which modifies the Statutory Decree 17/1998.

Basque Country

- Decree 9/1997, of 22nd January, on regulation of orthoprosthetic services related to external prosthesis, wheelchairs, orthesis and special prosthesis.
- Decree 62/2000, of 4th April, on modification of the Decree 9/1997.
- Ministerial Decree 5/09/2000, which passes the General Orthoprosthetic Catalogue and the range of socio-economic conditions that entitles for the direct income of the orthoprosthetic services.
- Ministerial Decree 10/10/2000, which determines the general conditions of the collaboration agreements for the provision of orthoprosthetic benefits.

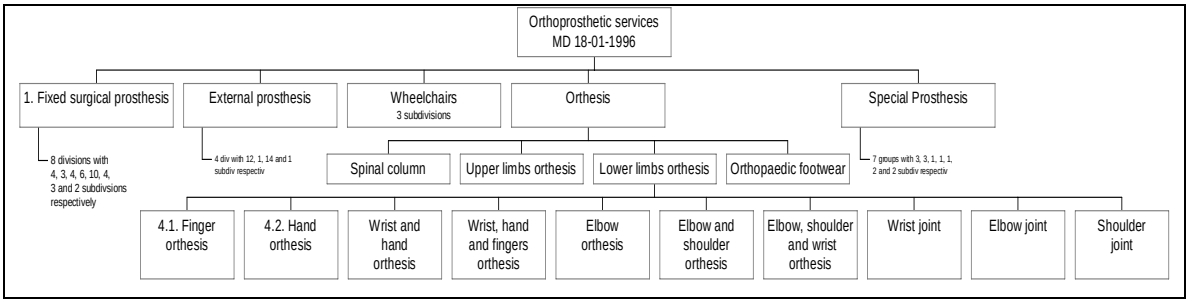
Valencia

- Ministerial Decree 17/02/1997 of the Health and Consumption Regional Ministry, which regulates the purchase of surgical implants through the Head Office of the Valencian Health Service.
- Ministerial Decree 4/08/2000, of the Health and Consumption Regional Ministry, which establishes the conditions for the implementation of the orthoprosthetic services included in the article 108 of the Social Security

General Law through the adapter establishments in the Valencian Autonomous Community level.

- Decision 7/07/2000, of the Health and Consumption Regional Ministry, which modifies the General Orthoprosthetic Catalogue in the Valencian Autonomous Community level, related to products included in the article 108 of the Social Security General Law.

Table 5. Taxonomy of Orthoprosthetic Catalogues.



Source: Own elaboration

5. Oxygen therapy at home catalogues

More and more people are using oxygen therapy outside the hospital, permitting them to lead active, productive lives. People with asthma, emphysema, chronic bronchitis, occupational lung disease, lung cancer, cystic fibrosis, or congestive heart failure may use oxygen therapy at home.

With the purpose of dealing with the regulation of the techniques of oxygen therapy at home was created a Group of Experts in which was represented the Spanish Society of Pneumonia and Thorax surgery and the Spanish Society of Paediatrics. From the proposal of this Group, the Ministerial Decree 03/03/1999 was passed. This rule develops the Royal Decree 63/1995 in relation to the techniques of oxygen therapy at home financed by the National Health System. It was passed by the Health and Consumption Ministry prior Inter-territorial report. The same procedure must be observed to update or approve new oxygen therapy services.

The Health Services and INGESA were providing these benefits but it did not exist a rule with state rank regulating them. The Ministerial Decree 03/03/1999 clarify and standardize the criteria, clinical situations and other matters for the direction, prescription and treatment of this benefits as:

- It defines the concepts of the different techniques of oxygen therapy at home in terms of their financing by the National Health System.
- It establishes the basic requirements that justify their prescription.

The Ministerial Decree 03/03/1999 provides a common regulation from which Health Services and INGESA must develop their own procedure to provide and control these benefits so that the fulfilment of the established in this decree is guaranteed.

In 1999 there was an updating of these benefits done by the Inter-territorial Council (25/10/1999 agreement). This agreement established the tutelary use of some techniques or procedures (on which we do not have the sufficient information on its security, effectiveness or efficiency) prior their general application in the National Health System.

A physician must write a prescription for oxygen therapy. In article one are determined which techniques are considered as techniques of oxygen therapy at home:

- Chronic oxygen therapy at home.
- Mechanical ventilation at home.
- Ventilation treatment of the sleep apnea.
- Aerosol therapy.

Annexe I provides a list of advices to take into account when prescribing techniques of oxygen therapy at home. Annexe II defines which are the clinical situations and the criteria for prescribing these techniques. So, in fact, the rule does not provide a benefit catalogue, as the physician will determine the specific treatment in each case.

STATE AND AUTONOMOUS OXYGEN THERAPY REGULATION :

State regulation

- Ministerial Decree 03/03/1999, on regulation of the techniques of oxygen therapy at home in the National Health System.

Autonomous regulation

Andalusia

- Circular 6/1997, of 17th July, which establishes the protocol for the prescription of continuous oxygen therapy at home and follow-up standards for patients treated by the Andalusian Health Service.
- Circular 2/1998, of 22nd June, protocol for the prescription of liquid oxygen therapy and follow-up standards for patients cared by the Andalusian Health Service.
- Decision 20/09/2000, of the Andalusian Health Service, which regulates the techniques of oxygen therapy at home.

Canary Islands

- Instruction 2/98 of the Director of the Andalusian Health Service for the updating of the techniques of continuous oxygen therapy at home, aerosol therapy and mechanical ventilation at home.

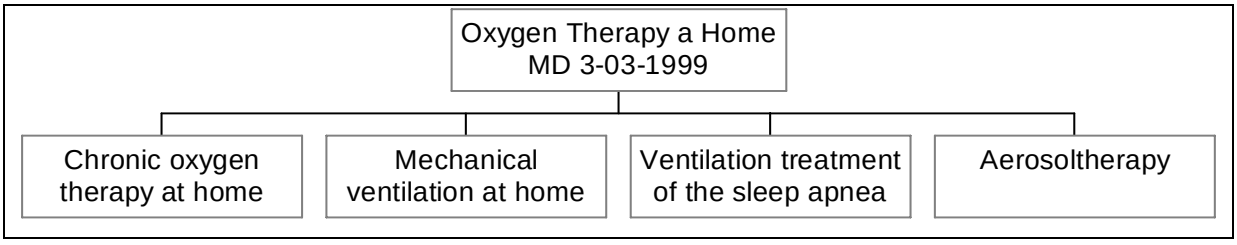
Navarre

- Decision 1517/2001, of 7th November, of the Director of the Health Service of Navarre-Osasunbidea.

Valencia

- Decree of the regional Ministry 02/04/1993, which regulates the continuous oxygen therapy at home service with officially approved means in the Autonomous Community of Valencia.
- Decree of the regional Ministry 16/03/1994, which modifies Decree of the regional Ministry 02/04/1993.

Table 6. Taxonomy for Oxygen Therapy at Home.



Source: Own elaboration

6. Description of sickness who entitle to receive diet products benefits

Royal Decree 63/1995 has been developed, with regard to benefits with diet products, in two ways: complex diet therapy regulation and enteral nutrition at home regulation.

Complex diet therapy has been regulated trough the Ministerial Decree 30/04/1997, which makes specific the relation of congenital metabolic upheavals of carbon hydrates and amino acids included in this benefit, as well as the type of diet in each case. Likewise, it points out that the prescription of these treatments will be done by the special physician of hospital units, specifically authorized by the Health Administration in charge for the management of this benefit. To update the metabolic upheavals list capable to receive complex diet treatments is necessary to pass a order, previous report of the Inter-territorial Council of the NHS. The metabolic upheavals list is determined in the annexe of the Ministerial Decree.

Enteral nutrition at home was regulated by the Ministerial Decree 02/06/1998. This rule defines the requirements and the clinical situation of the patient that justify the necessity of prescription. It establishes the list of pathologies financed in the annexe.

On the other hand, Autonomous Communities and the INGESA must regulate in their level the procedure to provide these products. For this reason a wide range of rules has been passed.

Ministerial Decree 2/06/1998 created the Advisory Committee for benefits with diet products for the follow-up and updating of both benefits (complex diet therapy and enteral nutrition). The Committee was constituted in 17th November of 1998 and meet once a year. They have reached several agreements with the following results:

- Clinical Practice Guide of Enteral Nutrition at Home.
- Inter-territorial Council Agreement 12/04/1999, which establishes the coordination procedures for diet treatments to displaced patients.
- Ministerial Decree 15/12/2000, which determines identification conditions for diet products capable of financing by the National Health System.
- Information System of benefits with diet products.

- Criteria for the products authorization to children older than two years old with allergy and intolerance to cow milk proteins.

STATE AND AUTONOMOUS DIETETIC REGULATION:

State regulation

- Ministerial Decree 30/04/1997, which regulates complex diet treatments.
- Ministerial Decree 02/06/1998, which regulates the enteral nutrition at home in the National Health System.
- Ministerial Decree 15/12/2000, which establishes identification conditions for foodstuffs directed to medical use capable of financing by the NHS.
- Ministerial Decree 11/06/2001, which modifies the Ministerial Decree 15/12/2000.
- Order SCO/585/2002, which brings up to date the annexe of the Ministerial Decree 30/04/1997.

Inter-territorial Council Agreements

- Inter-territorial Council Agreement 06/07/1998, which passed the report that justifies the prescription of the enteral nutrition at home treatments.
- Inter-territorial Council Agreement 12/04/1999, which established the coordination procedures in diet treatments to displaced patients.

Autonomous regulation

Andalusia

- Decision 18/97 of the Andalusian Health Service, on treatments with complex diet products in the Health Service of Andalusia scope.
- Decision 16/98, on enteral nutrition at home treatment in the Health Service of Andalusia scope.
- Decision 31/99, on modification of the Decision 16/98.

Canary Island

- Instruction 7/97, of the Head Office of the Canary Health Service, on the treatments with complex diet products for patients with congenital metabolic upheavals of carbon hydrates or amino acids in the Canary Health Service.
- Instruction 6/99, of the Director of the Canary Health Service, which regulates the enteral nutrition at home provided by the Canary Health Service.

Galicia

- Circular 11/03/1996, on provision of diet products in the Health Service of Galicia.

INSALUD

- Decision of the INSALUD Executive Board 19/12/1997, on complex diet products.
- Instructions 02/02/1998, of complex diet products invoicing.
- Decision of the INSALUD Executive Board 30/09/1998, on enteral nutrition at home and complex diet treatments.
- Instructions 23/10/1998, of enteral nutrition at home invoicing.

Navarre

- Decision 1333/1998, on directions for prescription, authorization and dispensation of diet products for enteral nutrition at home at the Health Service of Navarre expenses.

Basque Country

- Decision 01/02/1999, which regulates, transitionally, enteral nutrition at home benefits and complex diet treatments in the Basque AC.

Valencia

- Decision 01/03/2000 of the Health Regional Minister, which regulates the benefits with diet products in the AC of Valencia.

7. Dental care benefits catalogues

Royal Decree 63/1995 establishes a brief list of primary dental care benefits:

- Information and education on dental health and hygiene.
- Preventive and assistance measures: application of topical fluoride, fillings, sealing of fissures or other services for the infant population according to the annual financial budget and special programmes for dental health.
- Treatment of acute dental problems including dental extractions.
- Preventive exploration of the oral cavity in pregnant women.

There are nine Autonomous Communities that have regulated free dental care for some collectives (children, handicapped, etc.). In these regulations is where we can find different benefit catalogues:

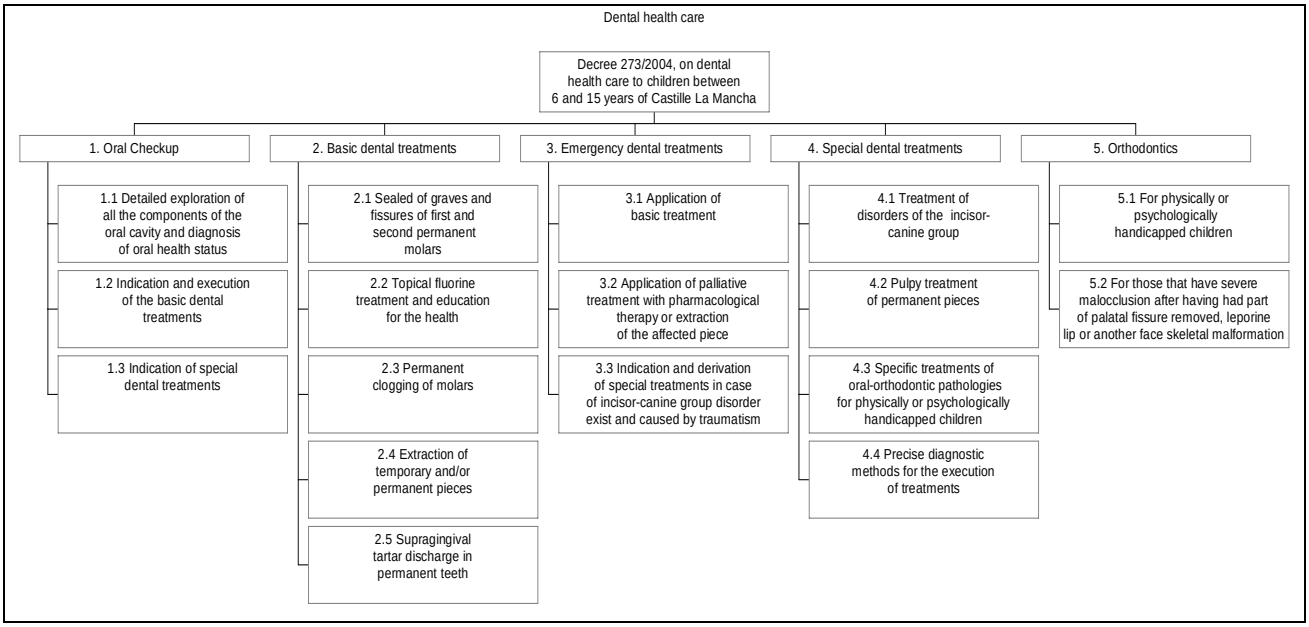
1. Navarre. Decree 58/1991, passed by the Government of Navarre. It authorizes the Health Regional Minister to enact the additional rules for developing and executing this Decree.
2. Basque Country. Decree 118/1990, passed by the Basque Government Council on Health and Consumption regional Minister suggestion. It authorizes the Health and Consumption regional Minister to adapt the endowment of this programme and to enact the additional rules for developing and executing this Decree.
3. Andalusia. Decree 281/2001, passed by the Government of Andalusia on Health regional Minister suggestion, prior a report made by the Oral Health Advisory Council of Andalusia. It authorizes the Health Regional Minister to enact the additional rules for developing, implementing and executing this Decree.
4. Extremadura. Decree 195/2004, passed by the Government of Extremadura on Health and Consumption regional Minister suggestion, prior a report made by the Advisory Council. It authorizes the Health Regional Minister to enact the additional rules for implementing and executing this Decree.
5. Castilla La Mancha. Decree 262/2004, passed by the Government of Castilla La Mancha on Health and Consumption regional Minister suggestion, prior the reports made by the Advisory Council and by the Health Council. It authorizes the Health Service Management to enact the necessary measures for implementing this Decree.
6. Cantabria. Order 03/10/2001, passed by the Health, Consumption and Social Services regional Ministry, entitled by additional legal provision of the Decree 8/1990.
7. Castilla y León. Decree 142/2003, passed by the Government of Castilla y Leon on Health regional Minister suggestion.
8. Murcia. Order 27/12/2002, passed by the Health and Consumption regional Ministry, entitled by article 6.2 of the Autonomous Law 4/1994 and by article 49 of the Autonomous Law 1/1988. It authorizes the Managing Director of the Health Service of Murcia to enact all the necessary measures to implement and execute this order.

9. Galicia.

As all these catalogues are quite similar we will analyse the dental care benefit catalogue of Castilla La Mancha. The original purpose of the Decree is to promote oral health through the approval of an Infant-Young Dental Care Plan. This plan defines the group of measures and activities, both preventive and welfare, and procedures to provide dental care. Benefits are classified into:

- Oral check-up.
- Basic dental treatments.
- Emergency dental treatments.
- Special dental treatments.
- Orthodontics.

Table 7. Taxonomy of dental care catalogues.



Source: Own elaboration.

8. MUFACE catalogue

All civil servants and beneficiaries are entitled to receive the benefits determined by MUFACE catalogue. In addition, civil servants' wives and those people who had been living in common with them, although are not beneficiaries, will have right to the maternity care and assistance.

The benefit package of MUFACE is equivalent to the one of the National System of Health. Next services are included:

- Primary health care. Vaccinations and attention to HIV-AIDS patients are specifically included.
- Specialized health care that includes all the medical and surgical specialties, both in outpatient and inpatient regime; The specialties are structured in four levels according to their complexity and geographic scope.
- Sanitary transport, oxygen therapy, aerosol therapy at home.

All these services are free of charge.

Medical assistance abroad. Regulation establishes that MUFACE beneficiaries will have coverage abroad equivalent to the medical assistance in national territory, distinguishing between two situations:

1. Civil servants destined abroad and their beneficiaries receive medical assistance through ALICO (American Life Insurance) Insurance firm, by means of an insurance policy that MUFACE has subscribed with this insurance firm.
2. Resident civil servants and their beneficiaries in national territory who move temporarily abroad and receive medical assistance can demand the reimbursement of their expenses to MUFACE, except for the following: a) When the assistance they received or the demanded expenses are included in some type of health coverage abroad. b) When a deliberate intention to elude the correspondent health services is noticed, using the displacement to use other means.

Orthoprosthetic benefits. MUFACE includes within its coverage a wide range of orthoprosthetic benefits. The content of these benefits is determined by the Order 18/09/2001, of the Public Administrations Ministry, on regulation of MUFACE complementary services. According to this order, orthoprosthetic benefits include:

a) External prosthesis, defined as those health products that require individualized adaptation, directed to replace an organ or part of it and that do not need surgical implantation in the patient.

b) Vehicles for disabled: wheelchairs.

c) Orthesis, defined as those non-implant health products for external use that, individually adapted the patient, are destined to modify the structural or functional conditions of the neuromuscular system or of the skeleton.

e) Special prosthesis, considering those not included in the General Orthoprosthetic Catalogue that appears in the annexe I of the Ministerial order mentioned before.

In this Catalogue appears the maximum amount of financing that guarantees the access to the benefit, as well as the terms for its renovation, the exclusions and limitations in regard to the age of the patients and, in general, the requirements for its concession.

Dental care benefits.

- Complete Set of teeth (superior and inferior): 270.46 euros.
- Superior or inferior Set of teeth: 135.23 euros.
- Piece, each one: 30.05.
- Filling, each one: 15.03 euros.
- Tooth implant: 60.10 euros.
- Orthodontic treatment: 270.46 euros.
- Endodontic procedures: 30.05 euros.

Provisional pieces, covers and provisional fillings do not receive economic aid. Orthodontic treatment will be granted only in those cases initiated in people younger than eighteen years, for a single time and for an only treatment.

Ocular benefits.

- Spectacles (far or close): 33.06 euros.
- Progressive/bifocal spectacles: 60.10 euros.
- Tele magnifying spectacles 150.25 euros.
- Glass substitution (far or close): 12.02 euros.
- Progressive/bifocal glass substitution 24.04 euros.
- Tele-magnifying glass substitution: 36.06 euros.
- Contact lens: 30.05 euros.
- Disposable contact lenses: 60.10 euros.
- Therapeutic contact lens, each one: 60.10 euros.
- Prism: 30.05 euros.

There are certain limitations of these benefits depending on the characteristics of the products.

Pharmaceutical benefits. The medicines included are the same than the General Regime. For inpatients medicines are free of charge. For the rest there is a co-payment of the 30% of the price of the medicine. In those considered

medicines of reduced contribution, there is a 10% co-payment. In MUFACE pharmaceutical benefit the affiliates are the deposit takers of their prescription check-books, and they must keep bring them to the physician so that he or she can make the prescription.

Socio-sanitary benefits. A Decision of MUFACE Head Office announces these benefits annually. There are the following programmes:

1. OLD PEOPLE ASSISTANCE PROGRAMME. Within this programme four modalities of benefits for older than 65 years old are considered. The amount of the aid depends on the economic circumstances of the coexistence unit of the applicant. b) Aids for day centres assistance. The quantity is conditioned to monthly income per person. In no case it will be higher than 601.01 euros per month. c) Aids for domiciliary support. Same amount of aid than in the previous case. d) Aids for service of domiciliary phone assistance. Benefit of 24.04 euros per month. To access to the three first modalities it is necessary that the beneficiary has a minimum degree of disability of 65%.
2. ASSISTANCE PROGRAMME TO CHRONIC PSYCHIATRIC PATIENTS. The maximum aid is 57.43 euros per day of hospice.
3. ASSISTANCE PROGRAMME FOR DISABLED. Are entitled to this programme people with a degree of disability of 33% at least. We can distinguish two kinds of aids. Aids for maintenance and involution of the residual capacity, with a maximum amount of 300.51 euros per month. Aids for personal autonomy, which are at the same time divided in aids for elimination of architectonic barriers (maximum 1,803.04 euros and minimum 120.20 euros), and aids for technical means (maximum 601.01 euros and minimum 42.07 euros). The annual quantities are based on the degree of disability and the level of monthly income per person.
4. ASSISTANCE PROGRAMME TO DRUG ADDICTS for beneficiaries who need an integral treatment of their drug addiction directed to their rehabilitation and labour reintegration, prescribed by psychologist or physician responsible of their assistance. Treatments for smoking habit are excluded. The initial amount of the aid will be 200.00 euros per month, for a maximum of ten months a year. This amount can be reduced depending on the level of income per person.

PART VI. Analysis of the Spanish Health Care Benefits package

After a structured review of the Spanish health care benefits we have to state that most of the literature on health care benefits has been more devoted to discuss about the legal rights aspects and policy implications in terms of equity and equality of conditions for all the Spaniards than to the efficiency and/or cost containment implications.

This is probably due to the own purpose and structure of the Spanish Health Benefits package. The purpose of this package is twofold; the purpose when it was initially created by the Social Security act, was to serve as a budgetary more than a cost-containment measure; and the fact that even after the General Health Law 1986, there is a need that either the Ministry of Labour and/or the Ministry of finance approve new benefits, clearly confirms that fact. However, on the other side as the Royal Decree 63/1995 and the Cohesion Law 2003 recognised, they are only an ordering of benefits, indeed they only try to describe what is being offered in practise.

Two ideas on this topic are clear among key agents in the health care system in Spain: a) there is a need for the definition of a more explicit benefits package, as so far the vague definitions let the final decisions onto practitioners, what makes expenditure to be very volatile if it wasn't because of waiting times, and b) there is a need for better transparency in the process of approval/rejection of new benefits (technologies, therapies, pharmaceutical products…), transparency towards agents in the health sector, but also towards citizenship; and the need to include economic considerations (cost-efficacy, cost-effectivity or so) into the decision process.

So after all what we have included and reviewed in this report we have to conclude that in Spain it still remains de lemma "all for everyone and almost everything for free"; which obviously means high waiting times, a dual system (public-private) for those who want to skip those cues, and high public pressure over resources devoted to the National Health System.

There are some remaining problems in the Spanish Benefits Basket. On equity terms, the fact that MUFACE type schemes have not been fully integrated to the

NHS keeps extra benefits for these groups although in terms of funding they contribute as the rest of the population. There is a lack of real control of managers over the health care services. Autonomy of practice decisions for practitioners might mean an obstacle for the prior evaluation of new technologies, since in fact under the "uso tutelado" (monitored use) doctors start using them. In the present financing system there is no relation between this and the benefits provided, nor a control mechanism over what is provided in reality.

1. From legal definition to daily practice: from the fears of defining an explicit catalogue to the "it will be developed" included in the Cohesion Law 16/2003

The present basic health benefits package mainly defined by the Royal Decree 63/1995 and the Law 16/2003 it is an open and dynamic one. Development in future years, both by the Central government and ACs, won't be centered in enlarging benefits, which we have seen are quite broad, but in increasing quality (new technologies or clinical procedures) of the existing ones. Improvements are to be around managing actual benefits (waiting times), better user information, higher choice options and probably the most important and those that have higher social impact, the development of a long-term care or dependency system with the coordination of the welfare and health care units, and a real network of mental health. The two latest are clearly priorities for ACs, as one could observe in their health plans.

With the decentralisation process it is clear that information systems (all databases centralised by the federal government on: health expenditure, clinical records, health status of the population…) are the main loss. The Ministry of Health, to avoid this problem, created a new observatory of the health system. Even if new benefit differences across AC appear this would not affect equity such as it can affect clinical practices and access to equipment. Therefore main purposes of Spanish health policy should aim to promote (at the Inter-territorial level) common clinical guidelines and evaluation processes, a single registry on new infrastructure, and the creation and regulation of a common procedure for new benefits approval.

In a certain sense the package described during this report does serve for providers to know which services will be publicly financed and which not. In any case, each regional health service will add to all the mentioned regulation some

internal rules on how to proceed to receive certain levels of expensive technology or diagnostic procedures. However, the autonomy of professionals is full and only in certain cases they may need the approval of a " health inspector", which in most cases just delays decision for a while (prior authorisation mechanisms).

It is foreseeable that next reforms in Spain will go by top adds of the benefits package by the different ACs, as we have seen dental care and progressively natural and alternative medicines (acupuncture, homeopathy...) are going to be the first ones; and, the definition of a basic long-term and social and community care benefits basket (more than a catalogue) such as its equivalent for health care. There has not been any solution so far for long-term and social and community care benefits, neither there is a clear definition of what do include each one.

2. Assessing the impact of the benefits package

The only information regarding the possible impact of the health benefits package is the one indirectly provided by studies of factors or components of the growth of public health expenditure in Spain. Different studies (Puig-Junoy (1994), Blanco and Bustos (1996), López G and Casado D (1996), Pellisé L 2001, and Puig-Junoy J, Castellanos A, and Planas I, 2004) have carried on this type of study.

This non parametric type of studies are based on a decomposition of the health growth rate into different price and growth indexes according to the main variables which are commonly accepted to affect health growth.

In the last one (Puig-Junoy et al, 2004) we can see that the evolution of this growth can be attributed to both the increase on input prices and the per capita average benefits received. Considering that the real wages have not changed much during these years, one could consider that most of the public health care expenditure growth in Spain is attributable to the provided benefits (both in terms of cost and quantity).

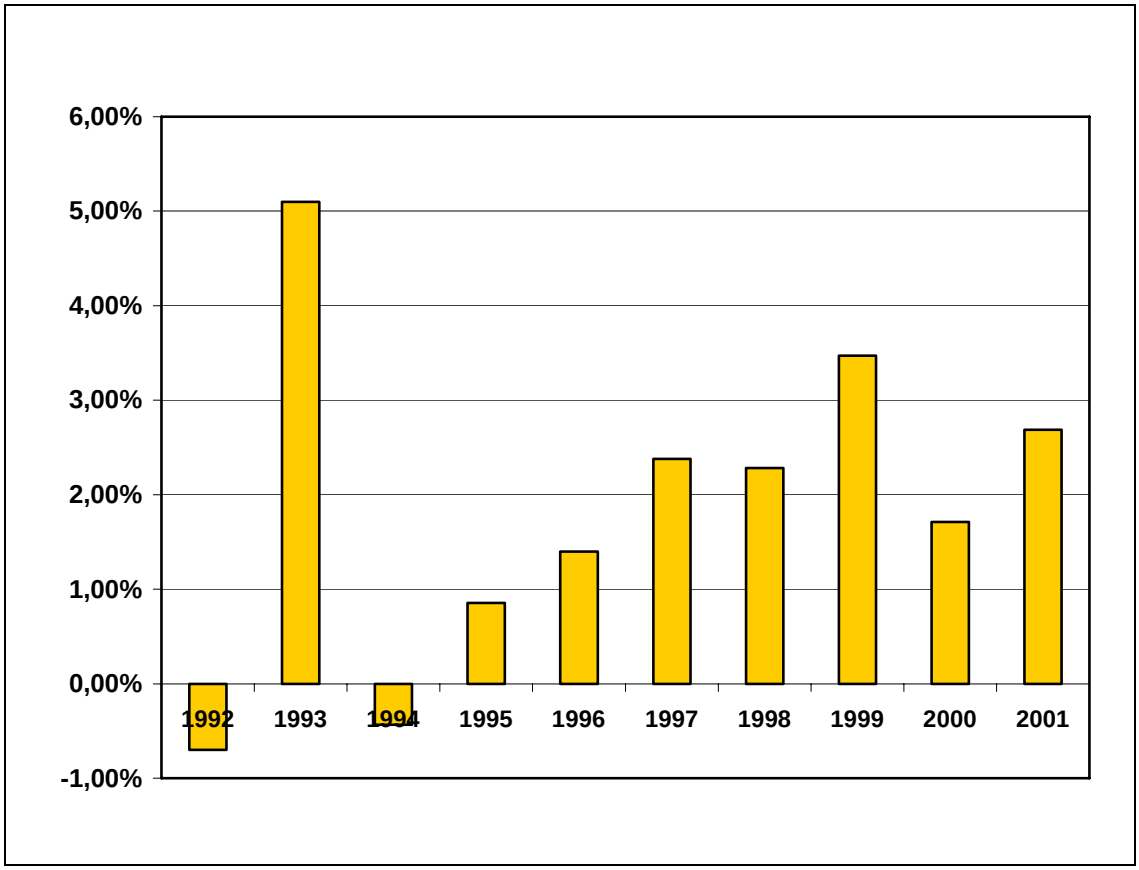
Table 8. Inter-annual variations (%) of the public health expenditure growth determinants, 1991-2003

Years	Public Health	Demography	Per capita average	Health Input prices	Input prices index

	Expenditure		benefits		
1991-1992	12,98%	0,78%	-0,70%	7,16%	5,35%
1992-1993	6,83%	0,81%	5,10%	-3,91%	4,93%
1993-1994	3,26%	0,79%	-0,43%	-1,38%	4,34%
1994-1995	5,67%	0,76%	0,85%	-0,32%	4,32%
1995-1996	6,47%	0,76%	1,40%	0,97%	3,21%
1996-1997	4,63%	0,80%	2,38%	-0,61%	2,01%
1997-1998	6,14%	0,89%	2,28%	1,42%	1,41%
1998-1999	7,31%	1,04%	3,47%	-0,26%	2,92%
1999-2000[p]	6,34%	1,27%	1,71%	-0,69%	3,96%
2000-2001[p]	7,48%	1,34%	2,69%	0,56%	2,71%
2001-2002[e]	7,23%				3,70%
2002-2003[e]	6,24%				2,80%[1]
ACT 1991-2001	6,68%	0,92%	1,86%	0,26%	3,51%

Notes: (p): provisional calculation (e): estimated data. (1) November 2003. ACT: Annual cumulative tax.
Source: Puig-Junoy et al (2004).

Table 9. Evolution of the average per person benefit received in the Spanish National Health System.



Source: Puig-Junoy et al (2004).

Variations in the health care benefits, although showing a non-constant behaviour, keeping the rest equal, are responsible of a 1,86% annual increase in the expenditure, which is almost two thirds of real public health expenditure growth (tables 8 and 9).

However, this method doesn't allow to distinguish whether this per capita benefits factor is due to the number and characteristics of benefits in the catalogue, the administrative restrictions to receive them, doctors diagnostic and prescription habits or waiting lists, all this having the same implications over the benefits that patient receive.

3. Assessing the impact of pharmaceutical exclusions and co-payments

Since the impact of most exclusions have not been assessed in Spain mainly because there has not been many changes in the benefits package, we are to be focused in analysing the impact of the two pharmaceutical negative lists and the restrictions to access that co-payments may mean for a certain part of the population and/or the behaviour changes, in terms of over-utilisation that these

measures have achieved. Indeed, at present no health economist has believed in the Spanish Health benefits package as a cost containment measure.

Public expenditure on drugs represents nearly a quarter of public health expenditure, which is much higher than the European average. The Regional Health Services assume 87% of the pharmaceutical expenditure, which added to the patient co-payment amounts for the 90% of the total pharmaceutical expenditure. Pharmaceuticals account for 59% of private health expenditure, which includes both co-payments and direct payment for prescription drugs and OTCs. In 1999, private pharmaceutical expenditure totalled €3,107 million, equivalent to €79.35 per capita.

Due to the type of pharmaceutical co-payments in Spain, fix percentage over the product price, and independent of the therapeutic value of it, a substitution effect may occur towards cheaper and maybe less effective products. Another type of substitution effect that may occur is that between groups of population when a different type of co-payment for each group is set up. Especially, when the characteristics that are used to differentiate among several groups are other than the ones that strictly related to the sick episode, such as income, professional status, or situation (unemployed, retired). This substitution effect has had special relevance in Spain since a high proportion of co-payments have been avoided by using elderly members of the family's prescriptions to get a 0% co-payment instead of a 40%.

The study by Arbas et al (1998) showed that population older than 65 they identified problems of bad prescription in 32% of the cases (55% interactions with other medicines, 37% were non adequate, and 8% had both problems). Another bad prescription habit in Spain is the low percentage of classic antibiotics (such as penicillin and Rifampicina), in front of the European percentages.

Puig-Junoy (1988) used 1983, 1984 and 1985 data to estimate the evasion of co-payment (using pensioners prescriptions -0% co-payment-, by non-pensioners – 40% co-payment-) on 30 to 40% of the total pharmaceutical expenditure, with a 15-20% of total prescriptions. On the period 1978-84 pensioners increased from 15.1% to 17.7% of the covered population and the number of prescriptions reached a 50% of the total and 65% of the public pharmaceutical expenditure. This substitution effect seems to be very reduced between chronic individuals and the other groups because of the specificity of the consumed drugs and the

administrative and legal requirements. The level of adequacy of medicines is another problem of the Spanish case. The following issues reflect this problem: Evidence of inadequacy of medicines in 30% of the cases.

Spain has experienced a gradual reduction in the effective co-payment rate from 15% in 1985 to 7% in 2002, responsible for an annual rise of 0.4% of the proportion of pharmaceuticals in public health care expenditure (Puig-Junoy, 2002). After Austria, the United Kingdom and the Netherlands, Spain is the EU country with the lowest level of cost sharing. Simultaneously, the share of pharmaceutical spending of the retired population (who amount to around 15% of the total population and are exempt from co-payments) practically doubled (from 39% to 72%). The effective co-payment rate for MUFACE insured population was 21.7 of the consumer price in 1991, and exactly the same rate in 1997. And fourth, current co-payments present a high level of concentration among individuals: 2% of the population concentrates one-third of co-payment revenue. These observations clearly reveal that severe efficiency and even equity problems affect the present system.

Negative lists - Pharmaceuticals exclusion from the Spanish health benefits basket (1993 and 1998)

We will describe the effects of the two negative list experiences. The first was conducted in 1993 by the Socialist government, and the second was implemented in 1998 by the conservative PP government. However, the effects of both plans were mainly short-term, and were unable to contain spending in the long run. This may have been due to the low therapeutic use of these drugs or to a strategic adaptation of prescription patterns to substitutes for which reimbursement was maintained. Other features to bear in mind are the reduction in the value added tax (VAT) applicable to medicines from 6% to 3%, followed by an increase to 4% in 1995, and the low level of drug competition in Spain in spite of the widespread presence of drug copies. Certain problems persist in the area of the negotiation process with the industry, the pharmacist payment system and the traditionally marginal role of generic drugs.

The Spanish Royal Decree of 1993 was based on two main objectives: (a) Prioritise public financing for those drugs whose need or severity of the illnesses

for which they were used was higher, and (b) exclude from public financing those drugs with low therapeutic value. As mentioned prior in the text 1.692 pharmaceutical specialities were excluded from the Social Security supply. Those pharmaceutical specialities amounted in 1993 for the 19,8% of all PS publicly financed. Average price of excluded products was 291 ptas (1,75 Euros), which compared with the total average price, 1.247 ptas (7,51 Euros), might predict the low economic impact that this reform could achieve.

Several studies have evaluated the impact of this measure although none of them has used national data. Catalán and Parellada (1995) using Catalan Regional data found a decrease of consumption on the number of units (-11,70%) lower than the theoretical predictions before the Decree (-12,20%). However, reduction of costs was much higher (-7,28%) than what theoretical studies had predicted (-4,70%). But when other variables are controlled in the study one realises that only the 35% of the reduction of consumption in 1993 can be attributed to the Decree.

According to Costa and Puig-Junoy (2004), the change in real terms of public pharmaceutical spending was 74.7%, between 1991-2001, with an annual accumulated rate of 5.4%. In the annual accumulated growth rates, 58.1% refers to changes in general/specific inflation and quality, 11.4% to ageing, 5% to the reduction in cost sharing and 4.6% to population growth. Overall, of each €100 in pharmaceutical expenditure increase between 1991 and 2001, €8.40 can be attributed to demographic patterns, €3.10 to a rise in prescription intensity, €28 to the change in general inflation, €29.70 to changes in specific inflation and quality and €2.60 to a reduction in cost sharing.

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

1663/1998), which excluded 834 additional drugs used mostly to cure minor symptoms, although certain exceptions were explicitly established according to the patient's severity.

Nevertheless, negative lists were never compiled with sufficient care. Indeed, some drugs were not excluded in spite of their limited social utility because of their popularity among pensioners. Examining the quality and costs of publicly financed pharmaceutical supply, Martin et al (2003) highlighted a pattern towards an increase in the intrinsic value of single component pharmaceuticals resulting from the implementation of a 1993 programme which undertook a selective revision of all drugs even if it meant rising costs. The other problem is the persistence of "me-toos". There is a disproportion between the number of pharmaceutical products and the number of active ingredients registered, and the inclusion of innovative active ingredients is minimal. Products included in the 1993 programme had been on the market for 10.9 years whereas those included in the 1998 plan had been on the market for 20.1 years. Furthermore, by 2002, 40% of the medicines delisted in 1990 had subsequently disappeared from the market, together with 25% of those excluded in 1998 (Martin et al, 2002).

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

Although selective financing experiences also had therapeutic aims, they were mainly envisaged as cost-containment tools. The 1993 plan excluded approximately a fifth of all drugs supplied, on the whole inexpensive products whose prices amounted to 23% of the average. In fact exclusion had little or no influence on expenditure: at best it was merely transitory. This was even more the case of the second plan, which was expected to reduce spending by €210.4

million. The result was that after the first programme, between 1994 and 1998, public pharmaceutical expenditure grew at a rate of 10%, and at a rate of 9% from 1998 to 2000. However, it is difficult to evaluate the effects of these policies as they were combined with other features such as price reduction and political pressure to reduce prescriptions.

The measure to reduce public expenditure on drugs had a strong opposition in 1998. The proposal was qualified as unfair and discriminatory by the opposition parties and by many social organisations (trade unions, local organisations, consumer organisations, pensioners' organisations and some associations of doctors and pharmacists. Some regional governments and city councils protested and stated that they would seek for specific sources to finance this expenditure. The alternative policy proposed by all these groups is the promotion of generic prescription and generics sales.

4. Users opinion over the level of benefits and health care system size

First of all we need to say that Health Care ranks in first place for Spaniards in their priorities of public intervention. During the last decade this ranking has been stable with around 30% of the population considering it as the main responsibility for the government policies. Housing is a growing worry for Spaniards although it still stays far from health care.

27% of interviewed people on the Spanish Health Barometer had received assistance in a health care unit of a different AC than the one is resident, using their regional health service card as a mean of identification in most cases, although one third used the social security card instead. On the level of satisfaction 38% did not have very clear if that was better than the one in his own AC, 14,6 % consider them better, 36,3 % equal and a 10,2% worse.

Most people would opt of the public system in case of choice. By categories of care would opt for a provider of the type: for Primary care (GP and paediatrics) 65,10% public 27,78 private 6,43 both; for Specialised care (except of dental care) 53,49% public, 35,94% private 9,96% both; for inpatient care 69,10% public, 24% private 6,10% both; Emergency care 71,80% public 21,00% private 6,30% both.

75,33% of the population considered that once the devolution process has been completed, ACs should coordinate and reach agreements when adding new benefits to their baskets. 4,77% do not agree with that idea. If we do the same question to different residents by AC, those most in favour of coordination in new benefits are those from Aragon, Castilla-La Mancha, Castilla Leon, Extremadura, Murcia, Madrid, and Navarre, all around 80%, while those less in favour are the ones from Canary Islands, Galicia the Basque Country and La Rioja (except the last one all had received transferences before 2002).

Less valued aspects in the Spanish National Health Service are the level of information that the provider gives to patients, and waiting times. Main problems related with benefits according with Spanish population are: a) waiting lists and b) long-term nursing care as social care. In year 2003, population that thing that there are waiting lists for diagnosis and treatment in specialised and in-patient care is between the 80-90%. In the 2000 barometer we can observe that one third of the claims are due to waiting times.

Another important issue is the level of knowledge that Spaniards have of their health care issue. Since long-term care nursing and social and community health have been the most neglected issues, the Spanish Health Barometer introduced specific questions about these matters. The less known type of providers within this category are the palliative care units (23,2%), followed by the day-hospitals (55,1%). On the other side, the most known are the geriatric hospitals. By type of benefits offered, the temporal stays and the distance care (phone or similar) are the less known while home care is the most (78%). The population as the experts in this field also considers that there is a lack of resources in this category of care (in 2002 59% of the population agreed with it). Indeed, 80% of the population considered that informal care carried on by families should be substituted by public provision of care. At least, during this transition time, it would be very important to establish mechanisms for short stays in residences to allow some resting time to families who provide informal care.

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Annexes

Table 1. HEALTH CARE REGULATION in Spain at the federal government

	Post Constitution (1978)	Contains Health Benefits
Decree 3157/1966, on pharmaceutical specialities in General Regimen of Social Security.		
Decree 2766/1967, Basic Social Security Act.		X
Decree 1075/1970, on health care to migratory workers who reside over the country.		
Ministerial Decree 10-6-70, which develops D. 1075/70.		
Adjudication 14-6-71, which develops D. 2766/1967.		
Adjudication 14-1-72, for resin temporary workers.		
Decree 3091/1972, which modifies D. 2766/1967.		
Adjudication 6-3-73, which interprets D. 2766/1967.		
Adjudication 21-3-74, on migratory workers health care right conservation.		
Decree 2065/1974, Social Security General Law joined text.		X
Adjudication 27-1-78, on health care expenses compensation for workers moved abroad.		
Royal Decree 945/1978, on beneficiary contribution in pharmaceuticals.		X
Ministerial Decree 19-5-78, which develops RD 945/1978.		X
Adjudication 15-3-79, on medicine payment exemptions for pensioners.	X	
Law 5/1979, on social and health care to Spaniard deceased in Civil War relatives'.	X	
Royal Decree 1605/1980, that checks the participation percentage of medicine prices.	X	
Adjudication 22-7-80, on health care when breaking up	X	

marriage engagement.		
Ministerial Decree 27-1-81, which develops Law 5/1979.	X	
Law 30/1981, of divorce.	X	
Royal Decree 391/1982, for republican disabled war veterans.	X	
Ministerial Decree 14-9-84, for dismissed workers.	X	
Adjudication 11-11-85, on health care during adoption process.	X	
Constitutional Act 3/1986, of special measures in Public health services.	X	X
Law 14/1986, General Law on Health.	X	X
Ministerial Decree 20-5-87, about health services to displaced beneficiaries.	X	
Adjudication 21-5-87, which complements MD 20-5-87.	X	
Adjudication 16-9-87, on health care for children in family sheltered regime.	X	
Law 33/1987, General Budget of the State. (Additional legal provision 16)	X	
Royal Decree 1682/1987, which enlarges Security Social protective action on health care.	X	
Royal Decree 1088/1989, which extends health care to people without means.	X	
Ministerial Decree 13-11-89, which develops RD 1088/1989.	X	
Ministerial Decree 29-12-89, which regulates health care to conscientious objectors.	X	
Adjudication 29-12-89, which establishes requirement procedure for recognising health care right to people without means.	X	
Law 25/1990, of the medicine.	X	X
Royal Decree 851/1992, which regulates some extraordinary benefits due to terrorism acts.	X	
Royal Decree-Law 5/1992, of urgent budget measures.	X	
Royal Decree 83/1993, which regulates medicine selection in order to plan its financing.	X	X
Ministerial Decree 6-4-93, which develops RD 83/1993.	X	X
Royal Decree 1575/1993, which regulates free choice of	X	

physician in primary health care.		
Ministerial Decree 23-5-94, about official models of prescription.	X	
Royal Decree Legislative 1/1994, which approves Social Security General Law joined text.	X	X
Royal Decree 63/1995, on the organization of health services provided by the National Health System.	X	X
Royal Decree 450/1995, on cash income in INSALUD centres.	X	
Ministerial Decree 18-10-95, which brings up to date the maximum amount of the pharmaceutical contributions.	X	
Royal Decree 1867/1995, on pharmaceutical care to Aids patients.	X	X
Ministerial Decree 24-11-95, which develops RD 1867/1995.	X	X
Royal Decree 1993/1995, which approves the regulation of Mutual Insurance Companies and Social Security Professional Illnesses	X	
Royal Decree 8/1996, on free choice of physician in specialised health care.	X	
Ministerial Decree 18-1-96, on regulation of orthoprosthetic services.	X	X
Royal Decree-Law 11/1996, which enlarges pharmaceutical services to population.	X	
Adjudication 27-6-96, which publishes RD-legislative 11/1996.	X	
Law 13/1996, on tax, administrative and social order measures.	X	
Adjudication 21-4-97, on specialised agreements.	X	
Law 15/1997, on entitlement of new ways of management.	X	
Ministerial Decree 30-4-97, on complex diet therapies.	X	X
Law 63/1997, of urgent measures for improving labour market and indefinite hiring.	X	
Law 66/1997, on tax, administrative and social order measures.	X	
Ministerial Decree 20-4-98, which modifies MD 25-11-66.	X	

Ministerial Decree 2-6-98, on enteral nutrition.	X	X
Adjudication 23-7-98, which creates the primary health care paediatrician figure.	X	
Adjudication 23-7-98, on health attention card use.	X	
Royal Decree 619/1998, on characteristics of the road vehicles on sanitary transport.	X	
Royal Decree 1658/1998, special agreement for civil servants or international intergovernmental organizations employees.	X	
Royal Decree 1663/1998, which enlarges medicines list financed by Social Security funds.	X	X
Law 49/1998, General Budget of the State for 1999. (arts. 12 and 16)	X	
Law 50/1998, on tax, administrative and social order measures. (arts. 110 and 111)	X	
Ministerial Decree 3-3-99, which regulates oxygen therapy at home.	X	X
Ministerial Decree 23-7-99, which modifies MD 18-1-96 on orthoprosthetic services regulation.	X	X
Adjudication 26-7-99, which creates the jobs of the home care support teams.	X	
Royal Decree-Law 12-1999, of urgent measures of pharmaceutical expenses.	X	
Law 55-1999, on tax, administrative and social order measures. (Additional disposition 21)	X	
Ministerial Decree 15/12/2000, on identification conditions of the foodstuff directed to special medical use capable of financing by the NHS.	X	
Constitutional Act 4/2000, on foreigners' rights and freedoms. (art. 12)	X	
Royal Decree 864/2001, which passes the executive regulation of Constitutional Law 4/2000.	X	
Royal Decree 1035/1999, which regulates reference pricing.	X	X
Royal Decree 29/2000, on new ways of management of the National Health Institute.	X	
Ministerial Decree 30-3-00, which modifies MD 18-1-96	X	X

on orthoprosthetic services regulation.		
Royal Decree-Act 5/2000, of urgent measures to contain pharmaceutical expenses and rationalize medicines use.	X	
Statutory Act 2/2000, which modifies Statutory Law 10/1990, to extend health care to immigrants in Navarre Autonomous Community.	X	
Adjudication 26-12-01, on prices revision of the fees charged for the health services or assistance that must be paid by the corresponding entities or third parties.	X	
Royal Decree 1471/2001, on transferring to the Principality of Asturias INSALUD functions and services.	X	
Royal Decree 1472/2001, on transferring to the Autonomous Community of Cantabria INSALUD functions and services.	X	
Royal Decree 1473/2001, on transferring to the Autonomous Community of La Rioja INSALUD functions and services.	X	
Royal Decree 1474/2001, on transferring to the Autonomous Community of Murcia INSALUD functions and services.	X	
Royal Decree 1475/2001, on transferring to the Autonomous Community of Aragon INSALUD functions and services.	X	
Royal Decree 1476/2001, on transferring to the Autonomous Community of Castilla la Mancha INSALUD functions and services.	X	
Royal Decree 1477/2001, on transferring to the Autonomous Community of Extremadura INSALUD functions and services.	X	
Royal Decree 1478/2001, on transferring to the Autonomous Community of Balearic Islands INSALUD functions and services.	X	
Royal Decree 1479/2001, on transferring to the Autonomous Community of Madrid INSALUD functions and services.	X	
Royal Decree 1480/2001, on transferring to the Autonomous Community of Castilla y León INSALUD	X	

functions and services.		
Law 41/2002, on patient autonomy.	X	X
Order SCO/585/2002, which brings up to date MD 30-4-97 on complex diet therapy.	X	X
Royal Decree 840/2002, which modifies and develops basic structures of the Health and Consumption Ministry.	X	
Royal Decree 286/2003, which establishes the periods for resolving administrative proceedings on Social Security matter.	X	
Order TASS/2865/2003, which regulates special agreement on Social Security System.	X	
Law 16/2003, on cohesion and quality of the National Health System.	X	X
Royal Decree 605/2003, which establishes measures for the homogeneous treatment of the waiting list information in the NHS.	X	
Royal Decree 1348/2003, on medicines adaptation.	X	X
Law 52/2003, on special arrangements on Social Security matter.	X	
Royal Decree 183/2004, which regulates individual health cards.	X	
Royal Decree 428/2004, which modifies RD 1993/1995.	X	
Royal Decree 2402/2004, on reference pricing.	X	X

Source: Own elaboration

Table 2. HEALTH CARE REGULATION in Spain passed by the AC: AUTONOMOUS REGULATION

Population coverage:
• **Andalusia** Decree 66/1990, on health care to people without means, not included in the Social Security regime. Order 26-03-1990, on the proceedings to obtain the right to health care for people without means. Law 2/1998, of Health of Andalusia.
• **Catalonia** Decree 55/1990, on enlarging health care coverage to people without means.

Decree 178/1991, which makes universal the public health care.

- **Valencia**

Decree 88/1989, which extends the right to health care to people without means.

Decree 26/2000, which regulates health care to foreigners and creates the shared health card.

- **Galicia**

Law 7/2003, on health care organization.

- **Navarre**

Statutory Decree 71/1991, on making universal public health care.

Statutory Decree 640/1996, which establishes the proceedings and access conditions for health services included in the universal public health care regime.

Statutory Law 2/2000, which extends the health care coverage of the public system of Navarre to all immigrants residents in the AC.

- **Basque Country**

Order 28-06-1982, which establishes free hospitalization to unemployed people.

Decree 26/1988, which recognizes to people without means the right to receive benefits by the Basque Health Services.

Benefits coverage:

- **Andalusia**

Law 2/1998, of Health of Andalusia.

Decree 101/1995, which determines the parents and children health rights during and after the birth.

Decree 159/1998, which regulates the provision of several medicines at the AC expenses.

Decree 195/1998, on orthoprosthetic benefits regulation.

Decision 18/1997, on treatments with complex diet products in the Health Service of Andalusia.

Decision 16/1998, on enteral nutrition at home in the Health Service of Andalusia.

Decision 09-11-1998, which establishes a provisional procedure to gain access to the General Orthoprosthetic Catalogue.

Decision 15-04-1999, on reimbursement of orthoprosthetic expenses in some cases.

Decision 20-09-2000, on oxygen therapy at home.

Order 26-12-2002, on definition of the part of the population who are entitled to dental health care.

Order 01-06-2001, which regulates the minimum existence of medicines and sanitary products in pharmacies (morning-after pill).

Decree 281/2001, on dental health care to population between 6 and 15 years

old.

Order 19-03-2002, which develops Decree 281/2001.

Order 17-12-2003, which establishes for 2004 the population entitled to dental health care.

- **Cantabria**

Order 03-10-2001, which regulates the access to dental health care.

Decision 01-08-2002, on the approval of the services document.

- **Canary Islands**

Decree 185/1995, on reimbursement of expenses caused by sanitary transport and by displacement.

Decree 154/2002, which regulates sanitary road transport.

- **Castilla y León**

Decree 142/2003, on dental health care benefits.

- **Catalonia**

Decree 215/1990, of promotion and financing of the socio-sanitary care.

Decision 04-12-2003, on revision of the orthoprosthetic catalogue in Catalonia.

- **Valencia**

Order 06-03-2002, which establishes the financial conditions for patients with tuberculosis of some specific medicines.

Decision 11-03-2003, on instructions for prescription and provision of reactive bands for the determination of glucose in blood and urine.

Order 10-11-2003, on instructions for prescription and provision of reactive bands for the determination of coagulation.

- **Navarra**

Statutory Decree 436/1992, on reimbursement of expenses by dental care to mental disabled patients.

Statutory Decree 259/1997, on organization of health benefits of obstetrics and familiar planning.

Statutory Order 161/1997, on development of Statutory Decree 259/1997.

Statutory Decree 258/1998, which establishes the complementary benefit on some medicines at Navarre AC expenses.

Statutory Decree 63/2003, on modification of the dental care program to children.

Statutory Decree 10/2003, on modification of the dental care program to disabled.

Statutory Decree 139/2003, which establishes the access conditions to the pharmacological benefit on giving up the smoking habit.

- **Basque Country**

Decree 118/1990, on dental care for children. Order 02-05-1990, which develops Decree 118/1990.
Guarantees on access time
• **Andalusia** Law 2/1998, on Health of Andalusia. Decree 209/2001, which establishes the guarantee on the period of surgical answer in the Health System of Andalusia. Order 25-09-2002, on reimbursement of the expenses by operations because of exceeding the maximum date for surgical answer. Order 25-09-2002, which establishes regulations for the implementation of the guarantee of surgical answer and the running of the surgical demand register.
• **Aragon** Decree 83/2003, which establishes the date guarantee on surgical care in the Health System of Aragon.
• **Canary Islands** Order 15-05-2003, which establishes the maximum periods of answer in some surgical procedures at Canary Health Service expenses.
• **Castilla La Mancha** Law 24/2002, on guarantees in specialized health care. Decree 28-01-2003, which establishes the maximum periods of answer, guaranteed benefits, fees and reimbursement by displacement.
• **Castilla y León** Agreement 261/2003, which passes the plan of reduction of the waiting lists.
• **Catalonia** Decree 354/2002, which establishes the maximum periods of access to some surgical procedures at the Health Service of Catalonia expenses.
• **Valencia** Order 04-06-1996, which develops Decree 97/1996, of exceptional measures to eliminate surgical waiting lists.
Decree 97/1996, of exceptional measures to eliminate surgical waiting lists.
• **Galicia** Order 15-07-1995, which completes the structure of the health information system in the hospitals of Sergas. Order 19-05-2003, which normalizes the information and monitoring system of the hospitalization service, surgery and rooms in the hospitals of the Health Service of Galicia. Law 7/2003, on health organization of Galicia.

• **Navarra** Statutory Order 29-09-1998, which establishes the guarantees of the surgical service in an appropriate period on the basis of equity and social efficiency. Statutory Law 12/1999, which regulates the evaluation program and the performance on surgical waiting lists of the Health Service of Navarre.
Right of free choice of physician and center
• **Andalusia** Decree 128/1997, which regulates the free choice of special physician and hospital in the Public Health Service of Andalusia. Law 2/1998, of Health of Andalusia. Decree 60/1999, which regulates the free choice of family practitioner and paediatrician in the AC of Andalusia. Decree 260/2001, which adapts the remunerations of some primary attention personnel to the health care and free choice. Order 09-06-1999, which regulates the procedure of free choice and establishes the assigning norms of family practitioner and paediatrician in the AC of Andalusia. Order 27-02-2002, which establishes the effectiveness of the individual nature of the free choice of family practitioner and its management by the database of users in the Public Health System.
• **Aragon** Law 2/1989, modified by Law 8/1999, of the Health Service of Aragon. Law 6/2002, of Health of Aragon.
• **Asturias** Law 1/1992, on constitution of the Health Service of Asturias.
• **Balearic Islands** Law 5/2003, of Health of Balearic Islands.
• **Canary Islands** Law 11/1994, on health organization of Canary Islands.
• **Cantabria** Law 7/2002, on health organization of Cantabria.
• **Castilla La Mancha** Law 8/2000, on health organization of Castilla La Mancha.
• **Castilla y León** Law 1/1993, on organization of the Health System of Castilla y Leon. Law 8/2003, on rights and duties related to information guides to users. Order 1325/2003, which publishes the rights and duties charter related to information guides.

• **Catalonia** Decree 84/1985, on measures for the reform of the primary health care in Catalonia. Law 15/1990, of Health organization of Catalonia. Instruction 03/2003, of the Health Service of Catalonia, which regulates provisionally free choice of primary health team and family practitioner or paediatrician.
• **Valencia** Decree 126/1999, which creates the Information System of population. Law 3/2003, on health organization of Valencia.
• **Extremadura** Law 10/2001, of Health of Extremadura.
• **Galicia** Law 1/1989, on constitution of the Health Service of Galicia. Decree 200/1993, on organization of the primary health care in the AC of Galicia. Law 7/2003, on health organization of Galicia.
• **Madrid** Law 12/2001, on health organization of Madrid.
• **Murcia** Law 4/1994, of Health of Murcia region.
• **Navarra** Statutory Law 10/1990. on Health. Statutory Decree 244/1994, which regulates the right of free choice of family practitioner and paeditrician in primary attention. Statutory Decree 259/1997, which establishes the organization of health benefits in obstetrics and family planning, developed by Order 161/97 and Decree 119/99. Order 135/1998, on development of the Statutory Decree 241/98. Statutory Decree 122/2002, which enlarges the right of free choice of family practitioner and paediatrician in primary attention in some Basic Health Areas and develops the right of free choice of specialist in obstetrics and gynecology in the women attention centers.
• **Basque Country** Decree 175/1989, which passes on the rights and duties charter of patients and users of the Basque Health Service. Order 25-01-1990 on the choice of hospital and specialized services. Decree 118/1990, on dental care to children. Law 8/1997, on health organization of Euskadi. Decree 252/1998, on the use of the individual health card, assignment of

physicians and age referring to paediatric services.
• **La Rioja** Law 4/1991, on constitution of the Health Service of La Rioja.

Source: Adapted from 'Informe anual del Sistema Nacional de Salud 2003'. Observatorio del Sistema Nacional de Salud. Unpublished. http://www.msc.es

Table 3. AUTONOMOUS REGULATION ON PHARMACEUTICALS

Catalonia	Law 31/1991, on pharmaceutical organization.
Basque Country	Law 11/1994, on pharmaceutical organization.
Extremadura	Law 3/1996, on pharmaceutical care (modified by Law 1/1997 and by Law 10/2001, of Health).
Castilla La Mancha	Law 4/1996, on organization of the pharmaceutical service (modified by Law 4/1998).
Murcia	Law 3/1997, on pharmaceutical organization.
La Rioja	Law 8/1998, on pharmaceutical organization.
Asturias	Decree 27/1998 (modified by Decree 72/2001, which regulates the Chemists' and Medicine Chest in the Principality of Asturias).
Valencia	Law 6/1998, on pharmaceutical organization.
Balearic Islands	Law 7/1998, on pharmaceutical organization.
Madrid	Law 19/1998, on organization and pharmaceutical care.
Aragon	Law 4/1999, on pharmaceutical organization.
Galicia	Law 5/1999, on pharmaceutical organization.
Navarra	Statutory Law 12/2000, on pharmaceutical care.
Cantabria	Law 7/2001, on pharmaceutical organization.
Castilla y León	Law 13/2001, on pharmaceutical organization.
Andalusia	Decree 353/2003, which establishes the pharmaceutical planning and the proceeding of authorization related to the Chemists'.
Canary Islands	It has not developed any regulation related to this matter.

Source: Adapted from 'Informe anual del Sistema Nacional de Salud 2003'. Observatorio del Sistema Nacional de Salud. Unpublished. http://www.msc.es

Table 4. Waiting times regulation by Autonomous Communities

AC	Regulation	Coverage	Maximum waiting times	Allowances, once surpasses the maximum time	Available information on internet
Andalusia	Decree 209/2001, Orders 25-09-2002.	Surgical procedures.	180 days	To choose a private hospital and payment at Administration expenses of the cost.	http://www.juntadeandalucia.es/
Aragon	Decree 83/2003.	Surgical procedures.	Between 30 and 180 days depending on procedure and priority.	To choose a hospital in any part of the State and payment at Administration expenses of the cost.	
Canary Islands	Order 15-05-2003.	Surgical procedures.	150 days	To inform about the decision of going to other hospital. If after a month there is no answer, patient can demand the cost to the Administration.	
Castilla La Mancha	Decree 9/2003.	Surgical interventions. Outpatient visits. Diagnostic tests.	180 days 60 days 30 days	To choose a private hospital and payment at Administration expenses of the cost. Maximum period of one year to exercise this right.	http://www.jccm.es/ (updated monthly)
Catalonia	Decree 354/2002.	14 procedures.	180 days	to choose any of the hospitals with which there is signed an agreement (the authority has a 30 days to derive the patient to another hospital).	http://www.gencat.es
Navarre	Statutory Law 12/1999.	Surgical procedures.	180 days	To choose an alternative hospital in Navarre and neighbouring AC at expenses of the hospital that generated the delay.	

Source: Adapted from 'Informe anual del Sistema Nacional de Salud 2003'. Observatorio del Sistema Nacional de Salud. Unpublished. http://www.msc.es

Table 5. BENEFIT DIFFERENCES WHICH ARE REGULATED BY AC

AC	Public health	Primary health care	Specialized health care	Socio-sanitary care	Pharmaceutical services	Orthoprosthetic services	Diet products	Sanitary transport	Others
Andalusia	Flu vaccination. Hepatitis B vaccination.	Basic dental care to children, 6 to 15 years. (Decree 281/2001) In family planning the "morning-after pill" is given since 2001 with universal nature (Order 01-06-2001).	Sex-change surgery in transsexuals, included by non-law proposition 11-.2-1999. Anesthesia in birth. Oxygen therapy at home (Decision 20-09-2000).	Specific regulation on elder care (Law 6/99) and disabled (Law 1/99). Decree on help to families from Andalusia (Decree 13/2002).	Financing of medicines excluded by state regulations. Decree 195/1998.				Tele-medicine.
Balearic Islands		Neurological-reflexology by an Agreement with the kovacs Fundation.						Refunding expenses and monetary compensation for movements outside the	Homeopathic medicines (Health Law).

								AC when needed for receiving health care.	
Canary Island									Specific regulation on cost refunding, money compensation and road transport.
Cantabria		Orthodontic treatments in Dental Centres for children.							
Castilla La Mancha		Orthodontic Treatments							Tele-medicine; Self-help.
Castilla y León		Dental care to disabled, older than 75 and children between 6 and 14 years old.							
Catalonia				Socio-					

				sanitary services regulation. It has included health and social benefits in the same group. (Decree 215/90)					
Galicia		Dental care for children according to special program.				Anti-eschar mattress and soft material wheelchairs (Ministerial Decree 18-01-1996).			
Navarra		Complementary benefits in obstetrics and family planning, such as menopause attention. (Statutory Decree 259/1997 and			Financing of excluded medicines (Statutory Decree 258/98). Substitutive nicotine therapy, nicotine patches and				

		Statutory Order 161/1997). Post-coitus pill (Law Proposition 10-10-2001). Dental care to children and mental disabled. Gradual increase since 18 in 2006.			bupoprion.				
Valencia			In diabetics, provision of reactive strips for the determination of glucose in blood and urine.	See Agreement 27-06-1995, which defines care and benefits.		Tuberculosis pharmaceuticals. In-kind pharmaceuticals for low-income people (also, in the out-patient setting). Urine bags for spinal cord damaged and	Hearing aids until the end of study life. Soft material wheelchairs, excluded by Ministerial Decree 18-01-1996.		

						other groups, test strips for people receiving oral anti-coagulate treatments.			
Basque Country		Basic dental care for children between 7 and 15 years old. Family dentist. It excludes orthodontics.					Decree 9/1997, Order 03-03-1997. It does not include improvements although it facilitates the advance payment by soft material wheelchairs.		