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Informe INESME

Health Systems in Europe and comparative analysis of criteria for access to innovative diagnostic procedures and therapies in oncology

This report was elaborated by the Spanish Institute of Scientific Medical Studies (INESME) in collaboration with the Spanish Society of Medical Oncology (SEOM), coordinated and directed by Jose M. Martin-Moreno, MD, PhD, DrPH, Professor of Preventive Medicine and Public Health at the University of Valencia, Spain



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Foreword

The concept of health as a basic right forms part of the indivisible and universal values of human dignity, freedom, equality and solidarity, pillars upon which the European Union was founded. In this sense, the 25 Ministers of Health of the European Union met in 2006 to endorse a declaration on common values and principles of European health systems. In it, the essential values of universality, access to good quality healthcare, equity and solidarity (widely accepted in different Institutions of the EU), constituted a global set of shared values all over Europe.

However, currently there are circumstances which represent an obstacle to the goal of quality healthcare. These obstacles include public cost containment measures carried out by individual countries, which have repercussions on social expenditure (the so-called *management care*) and sociodemographic factors such as the ageing population, the new family structures, the incorporation of women in the workplace, and the arrival of immigrants. These policy decisions have had especially acute effects on Southern and Eastern Europe.

These factors, together with the concrete performance of national and regional health systems, are the main reasons why the objectives of universality, access to good quality healthcare, equity and solidarity are not always met. In oncology, even a partial lack of fulfilment of these principles translates to tangible inequities regarding patient survival and quality of life due to the seriousness of oncological diseases and the reach of the medical-scientific advances achieved in the past several years. The present study was elaborated by the Spanish Institute of Scientific Medical Studies (INESME) in collaboration with the Spanish Society of Medical Oncology (SEOM), and was coordinated and directed by Prof. Jose M. Martin-Moreno. It aims to objectify the diversity and typology of health systems in the EU Member States, describing patterns and differences by comparing criteria in decision-making on access to new technologies and treatments in oncology. It also considers the opinions held by patients regarding current access to diagnostic and therapeutic solutions in their countries. Best practices were identified so that new initiatives could be formulated in order to assure the best diagnostic and therapeutic care to patients suffering from cancer.

In this respect, the passage of time is demonstrating that "efficiency" is not always synonymous with "savings," and that spending money efficiently does not always mean spending less, although it should mean spending better. It is also worth noting that cancer patients and oncology professionals who think that there are limitations in access to innovative treatments are involved in the decision-making process with respect to initiatives and projects which aim to improve oncological care.

While the study acknowledges the general lack of information and transparency on the decision-making criteria and procedures in the Member States, France is identified as a model to follow in its management of health services and oncological care. In addition, the development of national and European initiatives is proposed in order to establish reference criteria for the processes of regulation and implementation of innovative treatments. Likewise, the initiation of coordinated, flexible health policies is necessary in or-

der to track the current and future advances in oncological treatment, guaranteeing high quality care for cancer patients and increasing its homogeneity, not only at the national level, but also throughout Europe.

The MAC group (**M**embers of the European Parliament **A**gainst **C**ancer) should be commended for their work on these issues, as they have not only kept this group of pathologies on the European agenda, they have also supported prioritizing health policies to improve prevention, early diagnosis, treatment and quality care in oncology. This initiative can serve as a model for other countries so that in Spain, for example, we could have a group of Spanish MPs against Cancer, whose objective (among others) would be to make oncological diseases a priority on the national political agenda.

All of this would have repercussions on the awareness of politicians and policy-makers, and subsequently on all sectors of the society, regarding the need to control the disease by developing and expanding better health policies which improve all aspects of care for cancer patients in Spain.

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0. Executive Summary

The constituent members of the European Union share essential values with regard to issues of health protection, including the tenets of universality and equity in access to good quality healthcare. However, the Member States use different operative and practical approaches in order to provide these services to their citizens. In the field of oncology, the approval process and the allocation of public resources for innovative diagnostic procedures and therapeutic treatments reflects this diversity, and the criteria for coverage of diagnostic and therapeutic innovation varies widely.

The organization and provisions of each health system condition the quality and speed of access to preventive, diagnostic and therapeutic techniques; in turn, these factors roughly correspond to objective indicators on cancer incidence, mortality and survival within and between Member States. Simply put, this situation is conceptually incompatible with our collective values of health equity.

Conscious of the challenge facing us, the Council of Public Health Ministers drafted a resolution for the reduction of cancer incidence (approved in April of 2008 in a plenary session of the European Union), in which they signalled the necessity to improve prevention, early detection, access to the most effective treatments, integrated care and research in order to resolve the most pending issues for European patients. The text approved by the Council of EU Ministers calls for the organization of multi-disciplinary oncological teams as well as personalized treatment for those who suffer from these pathologies. Furthermore, it reiterates the rights of patients, particularly to information, and the advisability of enlisting patients in health policy decision-making.

This investigation of the Institute of Scientific-Medical Studies (INESME), in collaboration with the Spanish Society of Medical Oncology (SEOM), begins a line of work in which we intend to examine the operation of the different European health systems, including a comparative analysis of the criteria and results on accessibility to innovative diagnostics and treatments in oncology. With the notable exceptions of France and the UK, the analysis of secondary information (publicly available and grey literature) highlighted the scarcity of explicit information available on the criteria used by health authorities in decision-making (in the context of national cancer plans or other policy avenues) with regard to the inclusion of innovative diagnostics and treatments in the public health system.

Although we have been able to identify the main actors and their roles in this process for most of the countries, there are no studies on what weight the different factors have, such as cost-efficiency, therapeutic value and the opinions of specialists, patients, investigators and industry. In short, it does not seem that oncological care can be defined, operatively speaking, as a priority for Member States or the European Union.

Based on the evidence gathered from available data, we can conclude that certain inequalities persist in access to new techniques and treatments in European countries. There are variations in the allocation of public resources dedicated to this end as well as diversity in the approval processes and coverage criteria for oncological services. Even

after a drug or procedure has been formally approved for inclusion in the system, other obstacles can come up at a micro level which impede the equitable use of innovative diagnostic or therapeutic techniques, a circumstance which inevitably has some impact on patient survival.

Another conclusion that emerges is that there is a lack of information and transparency on the criteria and decision-making procedures, which signals the need to carry out studies with primary data to permit an objective comparison on the generic solutions which each country has found *ad hoc*. Further research is important in order to identify mechanisms to guarantee better treatment for cancer patients which is sustainable to the system but also encourages innovation. Two models which deserve preliminary recognition are those in the UK (for the transparency and clearly defined criteria emerging from the National Institute of Clinical Excellence, or NICE—though this criteria can be questioned) and France (for the systematic and integrated character of its national cancer plan).

The development of clear ground rules is essential in order to assure ethical relationships between authorities, specialised medical professionals and industry, thus permitting the appropriate planning of research and development as well as the open and transparent operation of the system. The goal we must pursue, then, is to promote coordinated health policies in the field of cancer and a relatively homogeneous catalogue of services to reduce inequalities. This coordination, which must be basic at a national level, should also be expanded to the scope of the European Union. The noble objective of seeking the best care for citizens and cancer patients is at stake.

1. Conceptual framework and study objectives

The foundation of our conceptual framework is the idea that the delay in access to medical care and accurate diagnosis and the difficulties in accessing the best available treatments for specific tumours are factors which cause suffering, compromising both patients' quality of life and their survival. This point of reflection motivated us to use this review to characterize the health system diversity, the criteria of action and the results obtained.

The investigation is a first step in a systematic benchmarking exercise, understanding that the utilization of this technique allows us to make decisions based on facts rather than intuition. The key is to identify solutions in each context with the goal of learning from experiences which can serve as an inspiration for our health system.

This can be systematically summarized with the following operative objectives:

1. Characterize the diversity and typology of health systems in the EU Member States with regards to cancer control structures and operations
2. Identify patterns and differences in criteria for decision making with reference to new technologies (including innovative treatments) in oncology
3. Characterize the heterogeneity present in data on cancer incidence, mortality and survival
4. Examine patients' opinions regarding current access to diagnostic and therapeutic solutions in their countries
5. Identify the strategies used by those countries and systems which obtain the best results and patient outcomes.

Using the available data, we aim to formulate options and alternatives to ensure the best diagnostic and therapeutic care for patients suffering from cancer.

2. Methodology

This initial report is based on data collected by means of a systematic revision of published scientific literature, “grey” literature (documentation which is published, distributed or indexed in an unconventional way) and other sources of information. The manuscript has been elaborated in accordance with the terminology that emerged in articles which cover a wide range of subject matter, from the very definition of health, health system models, current reforms in European health systems, demographic information on different countries, etc., to the analysis of European inequalities in the incidence and mortality of malignant tumours as well as the characterization of national cancer control plans.

In order to collect primary data, and taking into account the preliminary character of this study, initial contact has been made with organisms of the Health Ministries of Member States, scientific societies in the field of oncology and patient associations. This was done by means of questionnaires sent to the three groups of study in each EU country (the text of the formulated questions is available upon request).

- The public directories of the European Cancer Patient Coalition (ECPC) and the European Cancer League (ECL) were used to facilitate contact with the multiple associations of cancer patients based in the EU. A questionnaire was sent to all of them to request their opinion regarding the treatment available in their country, although at the time of concluding this preliminary report, a great number of responses were still pending.
- The European Society of Medical Oncology provided us with a list of their member institutions, but due to confidentiality agreements, they did not provide us with their contact information. In any case, these contacts were identified by an internet search engine and through personal contact with professionals who have had contact with our research team in the past. Thus, communication was initiated with leaders of these societies to find out their opinion on the role of research in decision-making processes dealing with health technology.
- Finally, the directors of national medicines agencies and/or health technology assessment institutions (or the official, relevant institutions which depend on the health ministries in Member States), were identified. A more detailed questionnaire was sent to them requesting a formal description of the decision-making process and criteria employed in their countries.

In some cases, we received notification that the e-mail addresses we had were incorrect or that the association or agency was appropriate. We followed up in these cases, requesting the contact information of the correct person(s).

A total of 208 questionnaires were sent to patient associations, 20 to national oncology societies and 46 to health authorities. Of these, we received 12, 4 and 2 responses, respectively. This work continues, and the findings presented here are mainly confined to our initial phase of secondary data collection.

One source of complementary information was facilitated by the personal contacts that the study coordinator, (Dr. Jose M. Martin-Moreno), maintained with other specialised investigators in this field. The two researchers who made important contributions to this endeavour were Dr. Nils Wilkings, of the Karolinska Institute (Sweden) and Dr. Rifat Atun, who was an active professor at the Imperial College of London (United Kingdom) until September of 2008, when he assumed new responsibilities on the leadership team of the Global Fund against AIDS, Malaria, and Tuberculosis. Dr. Wilkings provided valuable information on the latest results of his investigations on access to oncological treatments, while Dr. Atun shared the preliminary results of an evaluation on national cancer control plans, which he had started developing prior to beginning his new post. Following that initial contact, Dr. Martin-Moreno subsequently joined the project as a co-investigator.

3. Introductory concepts on health, health systems and oncological care

3.1. Conceptual elements of health, healthcare models, and health systems

Health is people's most prized asset, highly valued by those who do not have it. In 1978, the World Health Organization (WHO) signalled that as one of the most important human rights, health is an end in and of itself. It is common for people to want "good health," to "keep health," or to "improve health."

Health, considered both from an individual, global and population perspective, is increasingly important in contemporary society. Despite the individual and community health advances already achieved, everyone wants to have *more* health in order to make the most out of life.

Although health systems may be adequately defined and fulfil their mission objectives, citizens worry less about the actual technical mechanisms than the results of the same. This legitimate desire for health and the subsequent and insistent demand for more and better services—particularly in individual health care services—have as a consequence the constant revision and updating of health systems in order to provide the highest possible degree of health to individuals and to the community.

In our European social context, a healthcare model is understood to be the way in which the public administration organizes resources to offer health services to the population and to satisfy individual and community health needs.

Throughout history, diverse healthcare models have been developed. Currently, the following designs are in use (Mossialos et al, 2002):

a) Bismarck (or Social Security) Model.

Its origin dates back to 1883, when Chancellor Bismarck of Germany promoted social legislation which defined the human being as a motor of economic production and declared that workers are entitled to health protection from the society.

Other countries which employ this model include Austria, France, Belgium and Holland.

Healthcare services are financed through mandatory payments from companies and workers into public insurance funds which allow beneficiaries to use services in the future.

The funds obtained through these payments are managed by worker representatives; in France this is done by labour unions and in Germany there are specific legal entities in place. Healthcare coverage for citizens who do not have access to this type of funds is taken care of through an impositive system, or through voluntary insurance.

The relationship between financiers (fund managers) and providers (physician and hospital network) is based on contracts which regulate service provision and compensation.

b) Beveridge (or National Health System) Model

This model emerged in the United Kingdom when the British National Health Service (NHS) was created on 5 July, 1948 by the government of Clement Attlee and the Ministry of Health led by Aneurin Bevan. The intellectual reasoning underpinning the establishment of the NHS is contained in the report "Social Security and Connected Services," by William Beveridge.

Along with the UK, Denmark, Ireland, Spain, Portugal, Greece, Italy, Norway and Finland are among the countries which structure their services around this model.

The National Health System is based on the social, political and economic realities of each country and responds to centralized criteria which is then regionalized and organized hierarchically. The financing comes from the Central Government through public funds, and the provision of services is developed globally, guaranteeing free access to citizens without previous affiliation or participation in the economic regime of state insurance.

Each person is assigned a doctor; healthcare staff is paid by salary in specialized medicine, but in primary care, compensation is calculated according to the number of families who are attended. In some countries, this model has evolved towards a *civil service* construction for all healthcare staff, with the freedom to choose doctors and centres for patients as well as a standardization of the care models and types of services within decentralized management.

c) Semashko Model (or centralized)

The former USSR and the countries within its sphere of influence conceived this model, which is characterized by the universality of care, the concentration of medical services and the absence of a private practise alternative.

The system is completely financed, planned and organized by the State, which exercises its control through the government. Currently, there is no EU Member State which follows this model.

d) Private (or free market) Model

This model developed in the United States and is characterized by the supply of highly technified services and a demand which is controlled by medical collectives, insurance companies and the health industry. Centres run by private capital dominate the market, with access given to people by means of individual, voluntary insurance. The most vulnerable, poorest population with few resources obtains the services through national programmes and charitable organizations.

Although there is access to private services in EU countries, this type of model is not the dominant one in any Member States.

d) Mixed Models

The previous models are usually recognized as the most defined and clearly characterised, but mixed models, which adopt one or more elements from more traditional schemes, are the most common.

Thus, we find that health services are supplied in some European countries and regions through public centres, foundations, public companies, trading corporations, consortia, non-profit organizations, etc. Their infrastructures and economic activity are financed with public funds, with the use of managerial organizational techniques to increase the efficiency and profitability of public health resources.

These new formulas of health centres run by private parties seek greater flexibility in management and in commercial and occupational relationships with the financiers, buyers, providers, clients, and service users of the health systems.

Based on the explanation in the preceding paragraphs, we can speak about the conceptual elements of health systems. In this sense, and although it seems subtle, we should differentiate the terms "healthcare model" (which we have just discussed) and "health system."

Just as different definitions exist for the term "healthcare models," different definitions have been formulated for a "health system." Among the most straightforward and clear is that which refers to the sum of organizational structures, installations, equipment, mediums, rules, methods, procedures and programmes which, in accordance with the established method and articulated in an operative way, aim to prevent disease and maintain or improve the health of the population through the appropriate health policy.

Another way of understanding the concept of a health system is to define it as the activities of a society which are directed at protecting or restoring health, whether these activities are aimed at the individual, the community or the environment. These activities are articulated by transforming resources or *inputs* (knowledge, personnel and resources) into specialized *outputs* in the form of health services oriented towards the society's health problems.

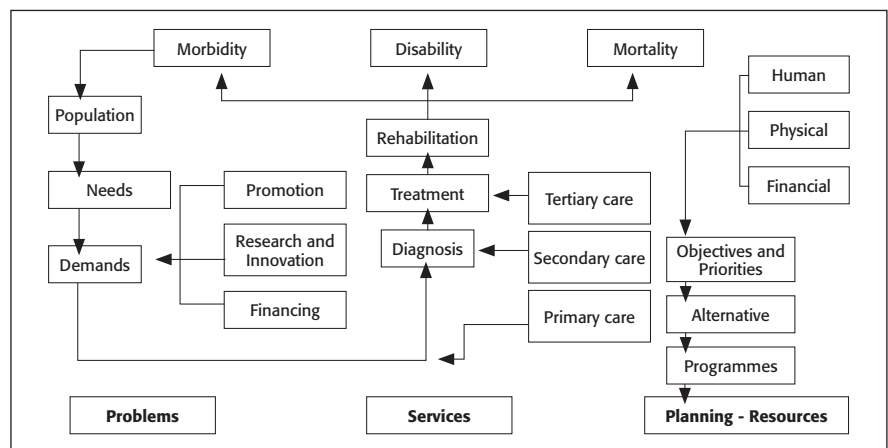


Figure 1. Health system organizational scheme.

3.2. Elements to establish the basis for a debate on health systems from the perspective of the best outcomes for citizens/patients

3.2.1 System outputs

The real use of health services is affected by the accessibility and acceptability of the same. It is necessary to identify the physical, economic and sociocultural factors that may inhibit or curb appropriate use of the services.

First of all, accessibility can be defined as the degree to which individuals that need care access it and benefit from health system services. Geographical, architectural, transportation and financial factors are among the aspects which influence this capacity. Generally, this dimension refers to whether patients obtain the services that they need at the adequate time and place.

The facility of access, which should be effectively provided in a timely manner and an accessible place, can also be added to this dimension. Concepts such as opportunity and continuity of care should be kept in mind.

Regarding the evaluation of the acceptability in the use of health services, the scientific-technical perspective, the functional (or interactive) perspective and the corporative perspective must all be considered.

Scientific-technical or physical perspective: This refers to the care which the patient actually receives according to the *Lex Artis*. It represents professionals' point of view and is established on the basis of scientific evidence.

Through protocols and clinical guidelines, essential aspects of clinical practise are monitored. This is the most familiar perspective for professionals, summarizing all the pillars which reflect the best applications and best methods to exploit knowledge and the available technology. All parallel characteristics which are indissoluble from this technical quality should be included, such as safety, pertinence and optimization of actions. Its development demands the elaboration of criteria and indicators for the correct provision of health services.

Functional or interactive perspective: This is the interpersonal component of the care process (how the patient-professional interaction develops).

This perspective is gradually gaining consideration in professional contexts. It is relatively common to see mentions of patient satisfaction in the consideration of care objectives for health services. The perception of quality began to be tracked with the initiation of patient surveys conducted in hospitals among admitted patients. Currently, evaluating the differential between patient expectations and perceptions is considered more adequate to identify opportunities for improvement in perceived quality.

In any case, the interpersonal relationship with the patient and the characteristics of the setting in which care is delivered should reflect the appropriate respect for the patient.

Corporative perspective: This corresponds to the image that patients, professionals and even the general population have of health services.

This perspective conditions the evaluation of technical and functional value, given that the image that one has of the services influences his/her perception of them. Cultivating a positive image is important because it has a globalizing effect for patients which is difficult to modify. A good image provides a "credit" which forgives or mitigates (at least for some time) unfavourable impressions which patients might otherwise have. Conversely, a bad image contaminates both the perceptions that patients have about the services received and the expectations that they may have of future encounters. Thus, the analysis of patient perception, or corporative image, should be integrated into the activities of service provision.

These different perspectives allow approaches with a common methodology: monitoring indicators, *ad hoc* assessment, process management and training groups.

3.2.2. "Outcome" elements

The *outcome* (effect or consequence of use) is the combination of clinical data and the perceptions of the service users, and it is useful for the evaluation of health systems. They can be described with diverse formulas, including the following:

- **QALY (Quality Adjusted Life-Years):** This is a measure to quantify health outcomes and consists of a combination of the change in quality of life and the change in life expectancy due to the health intervention. It is defined as the product of quality of life and longevity.
- **DALY (Disability Adjusted Life-Years):** Unit used to measure both the global burden of morbidity and the efficacy of health interventions, calculated by the reduction of the morbidity burden. It is the sum of years of life which will be lost and the years which will be lived with disability.
- **Cost-effectiveness analysis:** type of analysis which compares interventions or programmes which have common health outcomes in a situation where resources are limited and the managers responsible for decision-making want to maximise the medical services offered to the population of interest. This type of analysis can be used to evaluate the cost-efficacy or efficacy according to cost.

Health outcomes are measured in a multifaceted way, given that the quality of services provided is conditioned by factors such as technology, interaction between service users and specialists, and the tools or support which accompanies the treatments offered.

These components are established upon the basis of the potential capacity and/or competition among human resources and the managerial capacity of the system. All of this architecture should have one objective: the improvement of individual and community health.

The result obtained by the assessment of health benefit or impact observed among citizens and the consequences of the programmes applied in health service provision are the elements which determine the level of health in the population.

3.2.3. Criteria of efficacy, efficiency, equity and quality: establishing the conceptual basis for debate

In order for health services to be effective, it is necessary for the provider to at least try (Walsh, 1995):

- To define the service and be capable of overseeing its quality
- To be aware of the relevance of the service provided
- To know the number of service users
- To have sufficient resources to be able to substitute or replace necessary professionals
- To be able to resolve the potential conflicts inherent to each role or function
- To explicitly or contractually regulate rights and obligations and to formally oversee and monitor their fulfilment
- To have up-to-date information systems

To this minimal list of essential elements, it is necessary to add the following aspects to ensure optimal system effectiveness: incentives in decision-making in order to incur minimal costs as well as adequate training, service-user orientation, reliable information and freedom to overcome conflicts of interest.

The concept of a health system is characterized by the participation of multiple and interrelated agents and organizations in the pursuit of a common goal: the maintenance and improvement of population health according to criteria of maximum efficacy, efficiency, equity and quality.

3.2.3.1. Health system criteria

EFFICACY:

This is the accomplishment of the proposed objective. If the aim is achieved in its totality, it can be concluded that the intervention has been efficacious; the degree to which this is true determines the level of efficacy achieved. Applying this concept to the health system, efficacy is determined by the success of the objectives pursued in each process.

It should be noted that costs and benefits do not influence the evaluation of efficacy, but only the realization of the objective. Therefore, the difficulty in measuring efficacy resides in the identification and adequate use of indicators which accurately reflect the outcomes.

EFFICIENCY:

The concept of efficiency does take into account the costs of the productive process. The term is used when the proposed objective is achieved with a minimum cost, or conversely when limited resources are used to obtain maximum productivity. These two facets of efficiency are classified in the following way:

- **“Assignative” or “Paretian” efficiency** refers to the endeavour of trying to minimise the cost of reaching a given level or quality of production or service, modifying the proportions of the production factors used according to prices and marginal productivity. Assignative efficiency implies obtaining maximum production while maintaining cost, through the readjustment of the production factors according to the costs of use. This

scenario, observed frequently in certain health systems, limits the capacity to advance in interventions which improve the survival and quality of life for patients.

- **Technical efficiency** is more commonly used to calculate economic efficiency; it is obtained by achieving a minimal cost at a given level of production or service with a specific combination of production factors. Technical inefficiency is said to exist when the consumption of at least one factor can be reduced without necessitating the increase in consumption of another factor. Ideally, technical efficiency should be compatible with diagnostic and therapeutic advances as well as with system equity.

EQUITY:

Equity with respect to public health services depends on four principles:

- The protected population has equal rights to the same health services in the face of identical health contingencies.
- There should be no significant differences or difficulties in accessing health resources.
- There is no rationing of health resources, which is manifested by the lack of waiting lists. Waiting lists tend to expel those patients who can afford to pay for private care, leading to an adverse selection of patients according to income levels: those who cannot pay for private care will be the most likely to have to wait.
- There is no “ticket moderator” which obligates patients to finance, totally or partially, the costs of care received.

QUALITY OF HEALTH SERVICES:

Quality is the positive result of: health policy; doing the right thing correctly; the image of the organization perceived by providers and service users; the definition of the service given to inpatients and outpatients and the adequate coordination between the two.

QUALITY OF CARE:

This is defined by the scientific community, professionals, patients and society. The priorities to achieve it are:

- Practising evidence-based medicine
- Providing care which satisfies the patient
- Assuring continuity of care and respecting the chain between provider and user
- Caring for patients according to their individual needs

3.3. Oncological care: principles of equity and efficiency (balancing system sustainability and incentives for innovation while seeking the good of the patient)

Health systems assume an ethical obligation when they commit to providing healthcare to all citizens, and many lives depend on this commitment. Given that resources are always limited, they must be distributed efficiently and equitably, trying to exploit them to the fullest without sacrificing the quality of the services. In oncology, these principles must be maintained despite the complexities and challenges that the mission entails.

The resources must be allocated with a holistic viewpoint in mind, including primary and secondary prevention, curative and palliative care and research. Furthermore, health resources and social services need to be considered in addition to the morass of complementary interests which do not always facilitate consensus among stakeholders.

The Council of the European Union has drawn the rough lines of a strategy to reduce the cancer burden in European population, publishing its conclusions in June of 2008 (*Council of the European Union, 2008*). With a special emphasis on prevention and early detection and in accordance with the European Code Against Cancer (ECAC), the Council encourages Member States to develop an integral, interdisciplinary plan which tackles the challenge of this disease and addresses the persistent inequity between and among EU countries.

European collaboration, especially in research, is vital to reduce these divides and to involve the main stakeholders in this fight. The recommendations of the European Council have been echoed by many others, including patient associations who advocate for prevention and early detection as well as pharmacological innovation. From a European perspective, efficiency and equity are achieved through coordination.

3.3.1. The role of government (or public administration) in efficiency and equity

In the context of each country, governments have a responsibility to maximise efficiency. Health authorities must employ a wide gamut of measures to ensure that costs are controlled.

The first step in this endeavour is to guarantee maximum transparency and accountability from the highest political level down to the health and administrative professionals closest to the patient. Ultimately, efficiency is best fostered by an environment in which public actors feel accountable to taxpayers and patients.

According to the WHO, corruption is responsible worldwide for up to a 25% public loss of efficacious treatments (Anello, 2008), and poor use is associated with nearly 10% of health resources in some European countries. Good governance should promote the correct use of diagnostic techniques and medicines through guidelines for clinical practice which optimize the use of resources. These guidelines must be based on scientifically proven evidence.

Cost-efficiency needs to be taken into account, but the weight of “cost” when making decisions depends on the resources available, the strength of the evidence, innovative therapeutic value and preferential factors or personal and social priorities.

Within the context of secondary prevention (screening) and clinical care for patients who have already developed a cancer, innovation emerges as the brightest hope for early detection and cure. As necessary as this is in order to face the complexity of oncological services, ensuring that we find new solutions through innovation remains one of the main challenges for the sustainability of European health systems. On the one hand, the effort to find new solutions is an enormous challenge; it is estimated that the cost of producing a new medicine for cancer exceeds US\$400 million. (DiMasi et al, 2003). The private sector tries to recover this expense by charging health providers prices which compensate its investment. On the other hand, health systems try to limit costs as much as possible in order to ensure the sustainability of care provided to citizens.

In the measure which is possible without increasing the budget, there is an inherent conflict between these two opposing perspectives, introducing an element of confusion

which clouds the fact that both parties have complementary—not confrontational—goals. These objectives can be mutually strengthened by the maximum efficiency, transparency and ethical practise.

Efficiency, necessary and desired in all systems, should always be accompanied by the principles of equal access and quality. One controversial measure adopted by many countries is the “co-pay,” a supplemental charge which the patient assumes directly for each health intervention. The formula, conceived to help lower pharmaceutical costs, can be counterproductive in the search for health equity. Although theory argues that patients will stop buying less essential medicines in order to avoid the personal economic burden, in practise many patients cannot distinguish between essential and non-essential medication, leading to a situation which can result in higher costs in other sectors of the health system (readmissions or avoidable hospitalization) when patients do not follow their physician’s recommendation.

Another dimension to keep in mind is the patient population which suffers from chronic diseases, as is the case with cancer. Although a small sum may not constitute a financial burden for someone who buys an antibiotic for an occasional infection, the expenses accumulate quickly for those with chronic conditions. In both cases, the most vulnerable populations suffer the most with these measures.

It is important to note that many EU countries have considered these issues, and there are special exceptions in pharmaceutical co-pay requirements for chronically ill patients. In order to improve oncological care, it is essential that other countries adopt these precepts (Gemmill et al, 2008).

3.3.2. Functions and interaction between Health Technology Assessment agencies and the pharmaceutical industry. Space for the necessary synergy and collaboration.

Given the role that pharmaceutical and health technology companies play as the principal providers of innovation in diagnostic techniques and medicines for cancer care, the necessity to recognize their legitimate interest in the efficiency and sustainability of the system as a whole seems obvious.

Promoting the correct utilization of their products, tracking patient outcomes and collaborating in research ventures with independent scientists from qualified university centres and institutions are all important steps. Although these companies have a clear and inherent interest in negotiating a price for their products which justifies their investment, they also have an interest in assuring the sustainability of the health system because their future depends on it as well.

For this reason, society will always benefit from the existence of clear and explicit ground rules which ensure that ethical standards are met in the relationship between health systems and health technology industries. This will allow appropriate planning of research and development as well as open and transparent operations while the shared objective of improved patient health is pursued.

4. Generic description of health systems in Europe

4.1. Indicators

In the following sections, we will summarize the most important indicators for each of the European countries we have evaluated in this report. In addition, in the Annex to the present report, the general indicators of each country are detailed.

4.2. Structure, organization, planning and regulation

In this section, we will describe the fundamental structural and functional characteristics of the health systems in the European countries selected for this comparative analysis. It should be noted that the present report only includes certain countries in the EU-27, which have been selected upon the basis of two criteria: the degree to which they represent the larger EU and the availability of information on them from indexed references and grey literature (not accessible through traditional bibliographic search engines, but available through other sources).

4.2.1. Austria

Since the introduction of mandatory health and accident insurance in 1887, the proportion of the Austrian population with health insurance has been stable at approximately 97.6%.

The Austrian health system is characterized by the federal structure of the country (like in Germany, in *länders*) (Horfmarcher y Rach, 2006).

The transfer of competencies to the relevant stakeholders in the social security system is done through the *länders* with the supervision of the Ministry of Health in the matters of planning, coordination and financing.

The Austrian Parliament and the government's Ministry of Health are the entities responsible for health legislation. Through collaboration with different subordinate authorities, these bodies execute the activities assigned to them, including food safety, health protection, regulation of health professionals, etc. In accordance with the Austrian legal framework, the 9 *länders* are responsible for the provision of hospitals and the creation of social-health institutions as well as the maintenance of their infrastructures. Some of these tasks are delegated to local authorities.

In addition, the *länders* (as regional structures) are responsible for public health services, training for vocational health professionals, management of aid for long-term care and ambulance services.

This social security system is comprised of 21 institutions which are grouped in the Austrian Federation of Social Security along with 5 other bodies which are responsible for pensions and accident insurance.

The Federation's competencies include the coordination of the administrative activity of the institutions under its umbrella, mainly through the creation of statutes. It also identifies the obligatory guidelines and has the authority to approve budgets.

Planning and implementation of the Austrian health plan in each *länder* is carried out by one of nine health platforms through which the principle stakeholders in the health system—including patients—are represented. Local authorities, *länder*s and the funds from the federal health authorities converge in these platforms.

4.2.2. Bulgaria

Before the Berlin Wall came down, Bulgaria had a health system financed by tax revenue based on the Soviet model (*Semashko*). Since the structural changes in the 1990s, the organization, decision-making and health financing have corresponded to a decentralized model.

The Bulgarian Ministry of Health and its 28 regional health centres develop and implement national health policy as well as the corresponding programmes, defining the goals and priorities of the system and planning and supervising the structural reforms (Georgieva et al, 2007). In addition, the Ministry of Health is responsible for emergency services and public health.

The National Health Insurance Fund (NHIF) is the semiautonomous organism in charge of raising funds and financing service providers. The fund's activities are decentralized in 28 regional offices.

Privatization is another important characteristic of the health reforms carried out in Bulgaria. In 1992, local entities became the managers of health facilities. Since private practice was legalised in 1991, it has expanded notably, from 32 establishments in 2003 to 40 in 2004. Sixteen percent of hospitals are private along with 2% of the beds.

4.2.3. Czech Republic

The enormous political changes which followed the destruction of the Berlin Wall in 1989 had repercussions in virtually all aspects of domestic policy in the Czech Republic, and the health system was no exception. The biggest change in this area (at the beginning of the 1990s) was the transformation of State system financing to a mandatory General Insurance Fund (GIF), which pays providers (usually private) through contracts (Rokosová & Háva, 2005).

The three main characteristics of the Czech health system are: the existence of mandatory health insurance financed by contributions from employees and the State; diversity in the provision of services (fundamentally through private providers of outpatient services and public hospitals under contract from the insurance companies); and lastly, negotiations among stakeholders to determine coverage and reimbursement.

All residents of the Czech Republic must contract health insurance, which he or she can freely choose every year.

The State guarantees healthcare and the social security system and participates in the supervision of insurance funds.

The Ministry of Health is responsible for healthcare legislation, public health, scientific investigation and regulation of health technology.

Some of the biggest hospitals are under the direct control of the Ministry, and small hospitals are usually managed by local and regional governments. Many other sectors, including outpatient, dentistry and pharmaceutical services, are effectively private.

Insurance entities are relatively independent of the Ministry of Health, and they have the sole responsibility of service provider contracts, which normally last 2 years.

The portfolio of services, the value of reimbursable services and the conditions of service provision are all included in the negotiations, which, after government approval, are considered as the skeleton of the health system.

4.2.4. Estonia

The Estonian health system has undergone extensive reforms since the beginning of the 1990s, as well as more recent changes which reflect the lessons learned from the first phase of healthcare reforms (Koppel et al, 2008). For example, the degree of health system decentralization was not comparable to the degree of territorial decentralization which took place in the late 90s.

The most recent reforms have been directed towards increasing efficiency in the provision of services, including reinforcing primary care, introducing a “gate keeping” role into these services, and changing the financing mechanisms. At the same time, efforts have been made to maintain the access and the quality level of the system.

Through the Ministry of Social Affairs, the Estonian government carries out its responsibilities in the development and implementation of health policies, including public health, quality supervision and access to the health system. Its main function is regulatory.

Since 2001, the Estonian Health Insurance Fund (EHIF) has acted as the responsible financing agency for contracting service providers, paying for health services, reimbursing pharmaceutical expenses and financing sick and maternal leave for workers.

The provision of services has been completely decentralized since 2002, and providers are totally autonomous.

It is worth mentioning Estonia’s role in promoting the “European Ministerial Conference of the WHO” on “Health Systems, Health and Wealth,” which took place in the capital of this country (Tallin, June 2008). The purpose of this conference was to formulate the principles which allow an adequate articulation of health systems.

4.2.5. France

The French health system is based on national social and medical insurance, with elements of financing from general taxes (mainly the General Social Tax – CSG), complemented with Voluntary Health Insurance (ASV).

This system is regulated by the State (Ministries, Government Cabinet and Parliament), which sets the maximum level of statutory funds for health insurance based on an annual report on health and trends in social security. Levels of services and their regulation are adjusted in accordance with the stipulations in this document. An organizational structure exists to channel these funds.

There are three coverage schemes within the statutory system of French health insurance:

- The general scheme, which covers close to 84% of the population (usually employees in the commercial and industrial sector and their families)
- The agricultural scheme, which covers 7.2% of the population, represented by farmers and their families
- The scheme for the self-employed, which covers 5% of the population.

In 1999, “universal medical coverage” (UMC) was instated for all residents (coverage of 99.9% of the population). Voluntary Healthcare Insurance (ASV in French), which had already spread significantly in the decades leading up to that decision, was made available for free for people with low incomes.

In addition, in 2004 the Specific Insurance Fund was created for “dependent elderly women.” In one way or another, Voluntary Health Insurance, which in 2000 covered less than 85% of the population, now covers more than 95%.

From an organizational perspective, the traditionally centralist French Health System is gradually undergoing a process of decentralization from the national to the regional and local level. At the same time, decision-making on services and regulations has changed positions, from the originally centralized micromanagement of the administrators of the healthcare insurance funds towards more politicized and managing structures of the State. This perhaps reflects the importance and social demand that the health sector is acquiring in the national, regional or municipal sphere—as evidenced by the high social and media profile of problems such as the HIV-contaminated blood transfusions, the 2003 heat wave and the intense debates about the excessive consumption of antibiotics and how to best tackle these problems.

With respect to oncological care, it is worth highlighting the systematic organization on the National Cancer Control Plan, which not only set up the services stipulated in the plan, but also articulated the aspects of financing, resource generation and governance (Atun et al, 2009).

4.2.6. Germany

The beginnings of the German health system date back to 1883, when medical insurance became mandatory. The system is articulated as a Social Security model (Busse & Riesberg, 2004), otherwise known as the “Bismarck model,” due to the name of its promoter, Chancellor Otto von Bismarck. Currently, the following healthcare coverage schemes co-exist in Germany:

- Using the most recent data (2003), we can affirm that the majority of the population (around 87%) is covered by the statutory medical insurance, which is based

on income. Affiliation with social security is obligatory for approximately 77% of the population and voluntary for another 10%.

- With regards to the remaining population:
- 10% has private medical insurance
- 2% is protected by complementary governmental structures
- 0.2% is not currently covered by any formalized system

The healthcare system is decentralized. It is characterized by federalism and delegation to non-governmental cooperatives (essential actors in the system of medical-social insurance) such as medical and dental associations or sickness funds and their legal associations.

Hospitals are not represented by any legal corporative institution, but rather by organizations based on private law.

The actors are organized within the decentralized federal scheme (*Länder*).

The Ministry of Health and Social Security proposes health actions which, if and when approved by the Parliament, define the legislative framework of the social medical insurance system. Likewise, it supervises the cooperative organisms and, with the help of subordinate authorities, carries out licensing and supervision functions. The Ministry also has a key role in scientific consulting and provides information services.

The so-called health insurance (or sickness) funds have evolved over time, decreasing in number (Table 1). The nearly 300 health insurance funds collect the contributions from the statutory insurance for health and long-term care as well as care for those with chronic conditions. They also negotiate contracts with healthcare providers.

	1993	1995	1997	1998	1999	2000	2001	2002	2003	2004
General regional funds	269	92	18	18	17	17	17	17	17	17
Company-based funds	744	690	457	386	361	337	318	282	255	229
Substitute funds	15	15	14	13	13	12	12	12	12	10
Guild funds	169	140	43	43	42	32	28	25	24	20
Farmers' fund	22	21	20	20	20	20	19	17	15	14
Sallors' fund	1	1	1	1	1	1	1	1	1	1
Miners' fund	1	1	1	1	1	1	1	1	1	1
Total	1,221	960	554	482	455	420	396	365	325	292

Table 1: Evolution of the number of insurance funds in Germany, 1993-2004 (Busse & Riesberg, 2004)

Since 1996, practically all insured persons have had the right to freely choose a health insurance fund. Since 2004, decision-making regarding the statutory health insurance has been integrated in a federal trans-sectoral committee which is supported by an independent institute of quality and efficiency. However, today data is scarce on what impact this institute has in practise and its operational repercussion in the decisions regarding the incorporation of oncological diagnostics and treatments.

4.2.7. Italy

The current National Health Service (*Servizio Sanitario Nazionale*, SSN) of Italy was created following reforms initiated in 1978 which had the objective of transforming the health system from a social security (*Bismarck*) model to a *Beveridge* model, financed by general taxes and universally accessible and equitable throughout the country.

Nowadays, the goal of universal coverage has been obtained; however, there are wide differences in care and health expenditure among the different regions, with a clear north-south division (Donatini et al, 2001).

Following the constitutional reform in Italy in the year 2001, the central government and the regions (currently there are 20 officially defined regions) share healthcare responsibilities. The State is solely responsible for defining the basic portfolio of services to be offered equitably across the country (*Livelli Essenziali Di Assistenza*) while the regions handle the organization and administration of healthcare services and the local health authorities are in charge of the provision of services to their populations (the average local population is 300,000 inhabitants).

In short, Italy has a decentralized model in which insurance is obligatory and services are funded through general taxes and provided through the SSN.

4.2.8. Netherlands

The Dutch health system is divided into three types of coexisting insurance schemes:

- The first, denominated health insurance for exceptional medical costs, is mandatory for all of the population
- The second is sickness insurance, one type which is mandatory for those with low income and another which is private and voluntary.
- The third is complementary private insurance.

The three divisions and the systems which constitute them are supervised by different ministries.

The Ministry of Health, Welfare and Sport defines the policies aimed at maintaining the population's welfare and an optimal level of health (Den Exter et al, 2004). One of its main objectives is to guarantee access to a high quality health system.

Since the mid-20th century, this health system has evolved from a decentralized system to one which is progressively more centralized.

4.2.9. Poland

During the period of Polish independence between 1918 and 1939, a limited number of health services were gradually implemented, covering approximately 7% of the population through a Bismarckian, social security system.

The Ministry of Health, created in 1945 under Soviet occupation, adopted the responsibilities of administrating a strongly centralized health system which evolved over time.

The administration, management, and financing of the Polish health system are divided among the Ministry of Health, the National Health Fund (NHF) and the regional administrations (Kuszewski & Gericke, 2005).

The central government, represented by the Ministry of Health, is responsible for national health policy, most investments in medical science and training, and administrative responsibilities over directly financed entities.

The NHF, governed by 9 members, finances Polish health services through its social contributions. It also contracts the services with the providers and handles their planning and management.

Regional governments are mainly in charge of strategic planning in line with regional needs, health promotion and management of public health institutions.

Thus, in Poland, the NHF plans the health services on the basis of the National Health Plan, which details the different levels of health services offered to the population. These plans, in turn, are approved by the Ministry of Health and then the NHF contracts the providers through public bidding or negotiations with the providers.

4.2.10. Slovenia

The Slovenian health system has gone through significant reforms since the country's independence was obtained in 1991, but it has also faced problems of liquidity which led to the modification of legislation in 1992 (Albrecht et al, 2002).

The number of actors implicated in the Slovenian system is high; a short summary of the main institutions follows:

- The National Health Board is a consulting body for the government, and it is responsible for maintaining health policy in the agenda. Its role is currently under review.
- The Ministry of Health develops national health policy and provides regulatory support and supervision of the health system.
- The Health Council is another consulting organism of the government in health matters.
- The Parliamentary Committee on Social, Occupational, Family and Health Affairs is in charge of the preparation of legislative proposals and other materials for consideration in the Parliament.
- The Health Insurance Institute (HIHS), created in 1992 as a public non-profit entity and supervised directly by the state, is facilitated by the statutes to provide obligatory health insurance to the population. It has 56 offices.
- The Institute of Public Health of the Republic of Slovenia (IPH), with 9 regional institutes, was founded in 1992 and covers the following fields: social medicine, hygiene, environmental health, epidemiology, health statistics and health research.
- Local or autonomous governments have been delegated certain autonomy in primary care planning, but they have not yet taken an active role in decision-making.

The Ministry of Health is responsible for the great majority of healthcare; as far as the introduction of innovative medical technology, there is no kind of explicit planning.

In short, the Slovenian health system still remains relatively centralized. Most administrative and regulatory functions are exercised by the State, and the supportive organisms handle the executive tasks.

In the section dealing with oncological care, we note that during Slovenia's turn in the presidency of the European Union in the first semester of 2008, cancer issues were established as a health priority. The activities carried out during this period have substantially contributed to formalizing agreements and resolutions which are cited throughout this report.

4.2.11. Spain

The 1978 Constitution consecrated the right to health protection for all citizens, allowing a transition from a social security health system with restricted coverage, financed by contributions from workers and businesses, to the National Health System (*Sistema Nacional de Salud*, SNS) which is in place today. This system is characterized by universal coverage and financed through the General State Budgets.

The General Health Act of 1986 (LGS/1986) defines the Spanish healthcare model as having the following fundamental features: universal coverage, public financing, mostly public management and decentralization of competencies to the regions, or autonomous communities (ACs), as they are known in Spain. The devolution of these services to regional governments culminated in 2002. Thus, the SNS was conceived as a combination of the health services provided by the state administration and those dispensed by the regions.

A year after the process of devolution of competencies to the ACs was completed in 2002, the Act of Quality and Cohesion of the National Health System was enacted, establishing a framework for the coordination and cooperation between the different regional services. Each AC has a regional body, known as the Health Services Body, to manage health services. This entity is responsible to the Regional Government Council. With respect to the devolved competencies, there is no hierarchy between the Central Government and the Autonomic Government; the former is only responsible for ensuring coordination and cooperation as well as for guaranteeing the quality of services and equity of access in all national territory. Tangentially, the Central Administration is also responsible for Border Health Services, foreign affairs, medicines policy, fostering research and quality inspection.

The Interterritorial Council of the National Health System (CISNS in its Spanish acronym), according to article 69 of the Act of Quality and Cohesion of the National Health System, is:

"the permanent organ of coordination, cooperation, communication and information for health services, among each other and between them and the State Administration. Its aim is to promote the cohesion of the National Health System by effectively guaranteeing citizens' rights in all national territory."

In the CISNS, decisions must be adopted by consensus in the form of recommendations, given that they affect regional competencies. In some cases, ACs and the Central Administration can sign binding accords.

The SNS offers virtually universal coverage (99.1%) and guarantees a set of services to all citizens, independently of their ability to pay. Within the Spanish population covered by the mandatory system, two main groups can be identified: approximately 95% are covered by obligatory affiliation in the social security and health services system, while 5% comprise civil servants and their families, who are covered through several mutual insurance companies established for that purpose (the main one called MU-FACE). These companies allow beneficiaries to choose between health services within the national public system or private services managed by private insurance companies (although they are publicly financed).

Close to 8% of the Spanish population is covered by private voluntary insurance, mostly in larger cities; in Barcelona and Madrid, it is estimated that up to 25% of the population is covered by this additional insurance. If we count the civil servants who choose private services over public ones, and the fact that about 3.8% of workers receive private health insurance as a company benefit, this figure would increase even further. In 2004, it was estimated that 15% of the population was covered by private insurance.

Legislation regarding health services in all of the regions, without exception, affirms the principle of universality in individual and collective healthcare coverage. As the competent governing bodies responsible for guaranteeing these established rights, the overwhelming majority of ACs reproduce the stipulations in the basic state laws, recognizing Spanish citizens residing in the region as well as transients and non-residents (as defined by state law). Foreigners who do or do not belong to the European Community are considered beneficiaries according to the international treaties and accords subscribed to by the Spanish State.

The Ministry of Health and Consumption is responsible for the management of health policy and for those competencies exclusively belonging to the State. On the other hand, the regions are responsible for the organization and management of healthcare. These duties are further divided between the Regional Health Council (health authority) and the Health Services Body (the body which manages and provides the services). Most health councils have given up the duties related to social and consumer matters to other councils.

The legal status of the Health Services Body varies among regions. Of the 17 regions, 11 adopted the form of autonomic organism with an administrative character, belonging to the Regional Health Council. Another 5 adopted the form of public entities, and the last opted for a regional public company model. The lack of a definitive organizational model for regional health services in Spain has led, according to many professionals, analysts and even citizens, to a trend of divergence among different regions. When identifying problems, this divergence translates to problems in equity of access to services for all citizens.

The necessity of a State Pact among political parties, which sets aside confrontation in areas relevant to health, has been considered as one way to better achieve the objective of equity and clarity for healthcare services. This initiative is denominated by the term "State Healthcare Pact."

On 2 June, 2008, and as a result of the above circumstances, the Minister of Health and Consumption, Dr. Bernat Soria, proposed a global pact in all health matters to all of the political parties during his testimony to MPs at the Parliamentary Health Commission. This pact would include six basic principles: Equity in health services for all citizens; cohesion among regions; quality; innovation; patient safety; and sustainability.

On 30 September, 2008, the Minister took further steps to advance this initiative, presenting a proposal to create institutional committees which would be responsible for shaping the contents of the “State Health Pact.” The committees would look for points of consensus among all health administrations in order to guarantee and reinforce the quality and sustainability of the National Health System.

It is expected that these committees be composed of about one hundred representatives of the Ministry of Health and Consumption and the regions. The working method would follow a model similar to that established by previous processes used to elaborate national “Health Strategies” (for example, the National Strategy on Cancer Control, the National Strategy on Palliative Care, etc.). In addition, the Minister has pledged that the process will be transparent and inclusive, making room for other stakeholders who are implicated in the National Health System in one way or another, including professional, business and patient organizations.

By means of this “Health Pact” and through the work of the recently established committees, the Ministry hopes to foster consensus on the common goals—and the strategies to achieve them—of the entire National Health System. It will be necessary to work in the decentralized framework which characterizes the SNS, respecting the competencies of each body but also joining efforts to improve the system. Time will tell if this initiative will be successful, but the potential is there to create a useful tool to improve service provision, including favouring equitable access to innovative diagnostic techniques and treatments.

4.2.12. Sweden

The Swedish Health System is organized on three levels of competency: the national (central government), regional (counties) and local (municipalities).

The responsibilities of the health sector fall, on the national level, to the Ministry of Health and Social Affairs. The National Board of Health and Welfare, a semi-independent organism, executes the supervision in the counties, acting as a council body for the central government (Glenngard et al, 2006).

Regionally, there are 18 existing counties, which are in charge of providing primary and specialized care. The counties are grouped into 6 health regions which were established to facilitate the cooperation between counties.

Counties plan and develop the organization of the health system according to population needs. Planning responsibilities also include medical services dispensed by other providers, such as physicians who exercise in public practise and occupational medicine.

Locally, there are 290 municipalities with their corresponding areas of responsibility, including matters such as maintenance of basic services for citizens (schools, social services, roads, water and energy). In Sweden, the provision of health services goes beyond the simple financing of care and includes health services in schools, environmental hygiene, elderly care and care for dependent persons.

4.2.13. United Kingdom

The UK serves as a point of reference of the *Beveridge* type health system, which is financed by general taxes and aims to guarantee homogeneous service coverage to all citizens. As we mentioned earlier, the name of this model comes from a report authored by William Beveridge and which was used as a base by Minister Aneurin Bevan for the creation of the NHS on 5 July 1948. This model is also sometimes referred to as the *Beveridge/Bevan* type.

Currently, the United Kingdom delegates healthcare responsibilities to its constituent countries: England, Scotland, Wales and Northern Ireland. Each of these countries mainly finances the healthcare of its population through tax revenues, administering it through public healthcare providers. Purchasing responsibilities are delegated to specific institutions: in **England**, to Primary Care Trusts; in **Scotland**, to health boards; in **Wales**, to local health councils; and in **Northern Ireland**, to Primary Care Associations.

Coverage is available for all legal residents of the United Kingdom, citizens of EU Member Status and other countries with which Britain has bilateral agreements. Perhaps because of this wide coverage, the possession of private medical insurance is relatively low (in 2001, only 11.5% of the population had supplementary insurance).

The NHS provides a wide range of services, but explicit definitions of these services were not found.

Since 1999, the State Secretary of Health in England and the Welsh Government Assembly in Wales have received recommendations from the National Institute for Clinical Excellence (NICE). This body judges if a specific service is effective and efficient and if it should be provided to all or part of the population.

Although the implementation of NICE recommendations is theoretically obligatory, a recent evaluation indicates that in practice, its application varies throughout the territory.

4.3. Healthcare financing and expenditure

Next, we will describe the budgetary and financing elements of the European countries selected for this comparative analysis.

4.3.1. Austria

The financing of the Austrian health system is plural, in accordance with the federal constitution and the laws on social security.

In 2004, 45.3% of the total funds devoted to healthcare came from the social security system (Horfmarcher & Rack, 2006).

This mandatory social insurance covered close to 98% of the population in 2004, and the rest of the Austrian population received healthcare services through regional entities of social care.

The mandatory social insurance is based on the professional category of the worker or place of residence. This is applied to the majority of employees and self-employed workers as well as pensioners, working students and the unemployed.

Employees with low income can opt for voluntary insurance, as can the self-employed.

Children and other household members who are not active workers are subsidiaries of the principal earner of the family nucleus.

Contributions to social insurance do not depend on the health status of the insured, or on the risk of expenses to be incurred. Rather, they are proportional to income. These contributions are fixed annually by *Nationalrat*; 50% of costs are shared between the employee and employer, 25% is financed by the federal government, *länder* and local authorities through general taxes, and the remaining 25% is covered by private entities (data from 2004).

4.3.2. Bulgaria

Total health expenditure has been increasing progressively since 1998, as has the GDP. Paradoxically, there has been a decrease in public health expenditure and an increase in financing from private companies (Georgieva et al, 2007).

The mandatory health insurance is handled through the National Health Insurance Fund (NHIF). The market for mandatory insurance also offers complementary insurance which covers basic services but guarantees faster access to care.

In addition to the mandatory insurance which has been covered by workers and their employees since 1999, general income taxes (with the subsequent contributions from citizens according to their income) are the other source of financing.

4.3.3. Czech Republic

Most Czech financing (80.5%) comes from the funds obtained through the mandatory insurance. For the last few years, the insured entities have experienced a series of difficulties, mainly caused by factors such as the inadequate inspection and control of professional workload, insufficient funding levels and the long term unsustainability of the fee-for-service system. The Minister of Health, Tomas Julinek, has proposed fundamental changes to tackle these challenges, raising issues such as patient rights and the conditions of service providers.

All Czech political parties have echoed their support for comprehensive reform of the health system, but there seems to be little agreement on how to carry these out, and it is difficult to predict how the process will evolve in the coming months.

Currently, contributions to the system are legally defined as follows: employees contribute 4.5% of their gross income and employers pay 9% to the mandatory health

insurance scheme. The second source of financing is tax revenue, which accounted for 10.2% of the total in 2002. These funds are primarily used to cover national hospital expenditure.

4.3.4. Estonia

Since 1992, income-scaled taxes have been the main source of financing in Slovenia, accounting for nearly two thirds of health expenditure. The coverage offered by the Estonian Health Insurance Fund (EHIF) is based on residence in Estonia and pertinence to a legally defined group (Koppel et al., 2008).

Contracted employees and the self-employed contribute to the EHIF through taxes, which are collected through the tax revenue agency. These taxes cover healthcare and the pension system, and range from 13 and 20% of gross income for contracted employees and the self-employed, respectively.

In practise, employers make the contributions on behalf of their employees, meaning that the latter do not make direct payments. The protected population is divided into geographical regions, and the EHIF covers about 94% of the total population.

4.3.5. Italy

Despite the fact that one of the main objectives of the 1978 reforms was a rapid movement towards the progressive financing of the National Health Service through general taxes, contributions from health and social insurance still accounted for up to half of public health system financing throughout the 1990s.

In 1998, a regional business tax replaced the contributions from health and social insurance. This tax is supplemented by a centralized subsidy which is financed by means of the Value Added Tax (VAT) in order to "be able to guarantee adequate resources for each region" (Donatini et al, 2001).

Direct service user payments or co-payments are applied to shared costs anticipated in public services, such as diagnostic procedures, medication and specialist consultation. Since 1993, patients have had to pay up to 36€ (the maximum established) for external consultations with medical specialists. However, the co-pays for pharmaceuticals and specialist outpatient services have had a limited impact. Having reached a maximum in 1996, when these payments accounted for 4.8% of total revenue for the National Health Service, co-pays only comprised 2.9% of the total in 2002, after the suspension of the co-payment system for medications.

As a complement to the above, patients directly pay for private healthcare and over-the-counter (OTC) pharmaceuticals. Approximately 15% of the population has complementary healthcare insurance, which can be contracted by individuals or by companies offering it to their employees.

In 2002, health expenditure in Italy was approximately 8.5% of GDP. In absolute terms, this is US\$2,166 PPP *per capita* (adjusted for purchasing power parity). Of this quantity, 75% was covered by public funds, a lower percentage than had existed prior to the in-

roduction of co-payment requirements. Thus, private cost in 2002 accounted for 25% of total health expenditure.

In 1997, a capitative regional rate was introduced in the system to calculate the allocation of resources. This financing rate took into account population age composition and health status in order to increase real equity. That goal was further reflected in the processes by which the regions transferred funds to Local Health Units, which also use the capitative formula.

Tertiary hospitals have the status of trusts, and they benefit from broad financial flexibility. Secondary public hospitals also have certain financial autonomy, but they remain under the control of Local Health Units. A prospective payment system is articulated based on Diagnosis-Related Groups (DRG), with the exclusion of rehabilitation and chronic and long-term care.

The DRG system was designed in the early 1980s by Robert B. Fetter and his collaborators at the University of Yale as a management tool which classified patients in iso-resource groups (that is, clinically coherent groups that use a similar amount of resources) in order to achieve maximum homogeneity of resource use within each group (Fetter et al, 1980). This concept classifies care processes by homogeneously grouping patients who need a similar package of care resources, according to primary and secondary diagnosis and the consideration of other influential circumstances such as the necessary quality and time of resource consumption. DRGs constitute the basis for case-mix measuring systems which guide payment per process procedures.

DRG classifications are considered to be innovative and effective procedures for cost containment in that they provide incentives to reduce hospital use and enlist the participation of doctors in the final results in the hospital. In this sense, the DRG algorithm is constructed based on 16 general diagnoses (called Major Diagnostic Categories, MDC) which are subdivided according to other criteria such as intensity of resource use, patient age and the presence or absence of complications. The new versions of refined DRGs aim to further improve the prediction of costs, including settings which are adjusted for the seriousness of the patient's condition.

Returning to the specific situation in Italy and examining the mechanisms for health professionals' compensation within the public system, remuneration depends on where physicians work. Doctors working in hospitals are paid on a fixed salary, while GPs and paediatricians are independently contracted by the National Health Service, and their earnings are set on a capitative regime.

The reforms carried out in 1978 were aimed at providing incentives for efficiency and the possibility of additional income by charging for specific services, as well as offering financial incentives for effective cost-containment.

4.3.6. France

In 2002, the health expenditure in France was estimated to be about 9.7% of the GDP. In absolute terms, this is about US\$2,736 PPP *per capita*. Public expenditure accounted for 76% of total health expenditure in that same year.

Thus, after Germany, France invests a higher proportion of its GDP to health than any other EU Member State (data updated in 2004).

In 2002, health and social insurance constituted 73.3% of total health expenditure; the rest went towards the ASV (Voluntary Health Insurance) (13.2%), direct user payments (9.8%), and national contributions from general taxes (3.7%).

Since 1996, the Parliament has annually approved a maximum expenditure for health insurance, which is set out in the document *Objectifs nationaux des dépenses Assurance maladie* (ONDAM). Once the maximum has been set, the budget is divided into different subsections: regions, public hospitals, private “non-profit” care, social care centres, and private “for-profit” hospitals.

The main health insurance scheme pays public hospitals through global budgets, established prospectively, and the hospitals adjust their activities to these constraints. Private for-profit hospitals receive a fixed amount which covers all expenses except physician salaries. These professionals are then compensated through a fee paid per service performed. Private non-profit hospitals can choose between the two payment systems.

It is important to note that the French health system is undergoing reforms which are intended to introduce a reimbursement system linked to activities/services provided in order to harmonise the financing between the public and private sector.

Self-employed physicians perform the majority of services on outpatients and in private hospitals. Patients pay direct fees for the service, and these are subsequently reimbursed, at least partially, according to the statutes which regulate the system of health and social insurance.

A national accord between doctors and the body which manages the health insurance funds defines the exact fee per service. Between 1980 and 1990, any doctor could slightly increase the fee for specifically complex cases (the so-called “Sector 2” cases); however, since 1990, only physicians with specific skills have been able to process this increase (currently, about 24% of physicians are qualified to do so).

Physicians in public hospitals receive a salary, and since 1986, they have been allowed to combine part-time private practice with activity in their public hospital. This policy was implemented as an incentive for doctors to stay, following the flight of doctors in the public sector to the private.

4.3.7. Germany

Estimated health expenditure in Germany was 10.9% of Gross Domestic Product (GDP) in 2002. Seventy-nine percent of that came from public funds, situating Germany at the top of the list in the percentage of public expenditure on health in Europe and the third among members of the Organization for Economic Cooperation and Development (OECD) (Busse & Riesberg, 2004).

In absolute terms, total cost reached US\$2,817 PPP *per capita*.

Of the global expenditure, 57% of the funds came from the statutory health insurance in its basic scheme; 7% derived from long term care insurance (for chronic illnesses and disability); 4% originated in other statutory insurance schemes; and 8% came from complementary government sources. Private healthcare insurers financed 8%; employers contributed 4%; and non-profits added another 12%. Most direct user payments were used to buy OTC pharmaceuticals or for co-pays on prescribed drugs.

On 1 January, 2004, co-pay mechanisms were introduced for external visits to hospital specialties, and the amount of co-pays increased for virtually all other services which had this mechanism in place.

There is a "risk compensation scheme" which, along with the Healthcare Insurance Funds (Sickness Funds) aims to reduce differences deriving from age, sex and health status in the healthcare among those covered by different schemes. This system has been complemented with a deposit or special high risk fund since 2001, in addition to disease control programmes for the chronically ill since 2003.

With respect to outpatient medical care, there is a regional physicians association that negotiates a collective agreement with each sickness fund in the form a "quasi-budget" for medical services which will be provided. The association subsequently distributes the funds among GPs and specialists who claim the reimbursements corresponding to them, fundamentally according to a system of fee per service. It is important to note that limitations on service volume are applied.

Hospitals are financed through two channels: while investments are planned by governments of the 16 *Länders* and financed by the *Länders* and federal government, the recurring healthcare expenditure and maintenance costs are covered by the Healthcare Insurance Funds.

Since January, 2004, the German adaptation of the Australian model of Diagnosis Related Groups (DRG) is the system which is used to pay for the recurring healthcare expenditure in hospitals, with the exception of psychiatric care, where *per diem* charges are applied.

4.3.8. Netherlands

Dutch healthcare is mainly financed through a public and private insurance scheme (88%). Public insurance is responsible for about 40% of the health budget and covers medical treatment associated with chronic illnesses and high-cost treatment; funds come in differing percentages from income taxes and public funds (Den Exter et al, 2004). On the other hand, expenditure on private insurance accounts for about 48% of total health expenditure. The remaining percentage is covered by out-of-pocket payments and other schemes.

Normal health costs are covered by a wide variety of mandatory health insurance options which cover about 63% of the population.

The funds for this modality of insurance come from different sources: about 50% is paid by the employer and employee according to a flat fee, and a government subsidy

covers about 24%. The rest of the financing comes from various other sources, including public taxes (5.6%), extraordinary payments (5.8%) and voluntary supplements for basic insurance (3%), which are used to cover expenses for services such as dentistry, prosthesis, hearing aids, etc.

4.3.9. Poland

The Polish financing system is a private-public mix. The public financing comes from tax contributions to health insurance, voluntary insurance premiums, the state budget and the regional authorities' budgets. The mandatory insurance is calculated according to income (Kuszewski & Gericke, 2005).

The contribution from the central government is relatively modest and mostly covers public health services and the contributions for specific groups of the population (the unemployed, pensioners, war veterans and others) as well as investment in public health institutions.

All of the funds are managed by the National Health Fund (NHF), and the mandatory contributions make up 80% of its total budget, as compared to 10% from the State. In this respect, service payments still remain an important challenge for the NHF.

4.3.10. Spain

The National Health Service is mainly financed through direct and indirect taxes. The estimated expenditure in 2003 was 7.7% of its GDP, or US\$1,835 PPP. Public expenditure constituted 71.2% of the total health expenditure in that same year.

Health expenditure has been rising significantly over the last few years, with annual increases of close to 10% between 2003 and 2006, reaching a total of 48,650,890€ in 2006 (Martin-Moreno et al, 2009). This increase is partly due to population growth near 5.5% between 1999 and 2005, as well as the ageing of the Spanish population.

Most direct user payments, which account for about 28.1% of total expenditure, were used to buy OTC medicines, to cover co-pays for prescription drugs (0%, 10%, 40% co-payments), to pay for some dental services and to make payments for private insurance.

In January of 2002, the current system of general regional financing took effect, integrating the systems of financing of competencies common to all regions, the system of healthcare financing and the system of devolved social services. This model provides more than 90% of the budgetary resources to the general administrations in the regions referred to as "common regimen" (*regimen común*).

The agreement regarding the system of healthcare financing altered the traditional criteria of resource distribution, with the protected population used as a proxy for the financial need of each region. A distribution formula was introduced which took into account other variables, including the population above the age of 65 and the percentage of the population living in rural areas.

In addition, the system establishes two specific funds:

1. The Healthcare Cohesion Fund, whose goal is to guarantee equal access to public healthcare services in all national territory as well as care to EU citizens and others from countries with reciprocal agreements. This fund receives additional financing apart from that established in the General Fund.

2. The Temporary Disability Savings Programme Fund, which finances the adoption of programmes and measures directed towards cost containment related to temporary disability and the improvement in management of social security healthcare services. It is necessary to note that in reality, this is not additional financing, given that it is integrated into the General Fund, which takes into account the needs of each autonomous community and distributes the financing according to guaranteed minimums.

4.3.11. Sweden

The Swedish health system is mainly financed through taxes. Both counties and municipalities are authorized to levy scaled income taxes on their population. State financing and direct user payments supplement this source (Glennard et al, 2006).

The proportion of the total budget mobilized for the health system has increased significantly over the past twenty years.

4.3.12. United Kingdom

The National Health Service (NHS) is mainly financed through general tax revenue: direct income taxes and indirect taxes, usually from the VAT. The subsequent financing for social services is available by means of local taxes.

Private financing can be divided into: cash payments for prescriptions, ophthalmologic and dentistry services and private healthcare insurance premiums (Robinson et al, 1999).

In 2003, the Government announced its intention to raise 1% more revenue for the NHS by direct tax.

The total public health expenditure in the United Kingdom has remained quite low with respect to the EU-15 average (made up of EU Member States before 2004). In 2002, it stood at 7.7% of GDP, which accounted for 83% of total health costs. In the same year, the total health expenditure was US\$2,160 PPP *per capita*.

In England, healthcare budgets are set every three years, following negotiations between the Treasury and the Health Department. In the rest of the UK's constituent countries, the budgets are determined independently.

The Local Health Boards (LHB) and the Primary Care Trusts (PCT), which cover populations ranging from 50,000 to 250,000 inhabitants, are the main health service purchasers. In order for the central government to equitably allocate resources to these bodies according to need, a capitative formula is calculated by the Resource Allocation Working Party (RAWP), which uses the criteria of Standardized Mortality or Morbidity Rate. This indicator was chosen because it can be adequately assessed by geographical area, diagnosis, age and gender.

Primary care GPs are self-employed. In April of 2004, a change in the remuneration system for these services was introduced. Prior to that date, the system was based on capitation (population assigned to GPs) and fixed concessions, but the reform introduced changes which combined “quality points” (calculated from a performance assessment of specific indicators) and the cited quota of assigned patients. An evaluation on the degree to which this remunerative system is advantageous is still pending. In any case, it is worth remembering that most of the population is concentrated in urban areas; access and sustainability of quality services are reduced in remote and rural areas.

Hospitals, on the other hand, are financed based on framework contracts and services provided. Most hospital staff have permanent contracts and set salaries, but consulting medical specialists are allowed to simultaneously work in the private sector.

4.4 Health services provision

In this section, we will describe the organizational elements of health services provision in the countries selected for this comparative analysis.

4.4.1. Austria

The *länder* are responsible for public health services, which are usually devolved to local and district authorities.

Beneficiaries of the social security system can freely choose outpatient service from the available options (private professionals or clinics).

As a part of the general agreements, a “location” plan is negotiated, whereby each insurer selectively finances a certain number of physicians; this is done to regulate the geographical distribution of service providers according to sociodemographic indicators and the recruitment capacity of area hospitals (Horfmarcher & Rack, 2006).

In 2003, more than 43% of private health professionals had contractual relationships with one or more insurance companies. On the other hand, in 2004, insurers paid for an average of 5.5 visits *per capita* with contracted professionals as opposed to 1.2 cases with other professionals, which were then later reimbursed. Non-contracted physicians are reimbursed at 80% of the rate which a contracted professional is paid for the same service.

About half (49%) of hospital care is provided in public hospitals, while non-profits handle 19% and private companies deliver about 17%.

Since 2006, pharmaceutical products are approved by *PharmMed* Austria. In addition, the Austrian Federation of Social Security makes decisions regarding the reimbursement of pharmaceuticals, in large part based on the counsel received by the Medicines Evaluations Commission.

4.4.2. Bulgaria

Until 1998, the system of contracts between the National Health Insurance Fund (NHIF) and service providers conditioned the healthcare guidelines.

Hospitals receive financing from the NHIF according to the number of cases handled.

Since 1999, new types of outpatient care have been established (primary and outpatient consultation) (Georgieva et al, 2007). Primary care is provided by private doctors, polyclinics or outpatient consultations and is organized on a *per capita* basis. If the patient wants to directly access specialist care, no public money is provided.

Hospital care is provided by public and private entities, and hospitals are divided into multidisciplinary and specialized centres.

4.4.3. Czech Republic

In January of 2003, the regional public health offices were replaced by district offices, responsible for epidemiological vigilance, immunization programmes and health protection measures.

Outpatient care is currently divided between the State, the regions, and insurance entities. Citizens choose their primary care physician, which can be renewed every three months. There is approximately one family doctor per 1,650 adults (older than 15) and one paediatrician per 1,050 children (Rokosová & Háva, 2005).

More than 95% of primary care was privatized in 2002. Most physicians who work with insurance companies do so in an isolated way, in centres run by the municipality, or in polyclinics where they must pay rent for the use of the facilities.

These doctors spend a good portion of their time granting work leave, despite the initiatives being carried out to provide incentives to get involved in other areas, such as the provision of more specialized services.

Reimbursement is mainly calculated on a *per capita* basis.

With respect to specialized/hospital care, this is provided in physicians' consultations, hospitals and other facilities.

Nearly 75% of external consulting services have been privatized and patient access is not restricted by primary care.

Hospitals reflect a public-private mix of regional, district, local and university hospitals. In this sense, the government has 19 hospitals which account for 9.5% of the total and 26.9% of the beds. In turn, private hospitals comprise 31% of the total and 10.6% of the beds.

4.4.4. Estonia

One objective of the reforms begun in 1991 was to establish Family Medicine as a medical specialty. Thus, there is no clear distinction between primary care and outpatient specialized care.

The main services provided by family doctors included diagnostic procedures, treatment of general pathologies, health promotion and disease prevention. The patient

must be referred to a specialist by his or her family doctor, with exceptions in some specialties, such as ophthalmology, gynaecology, psychiatry and dentistry (Koppel et al, 2008).

Each GP has a quota of patients assigned to him or her, and patients can request a change in physician as often as they like.

Specialized care is divided into two modalities: outpatient and hospital care, which are both arranged through contracts with the Estonian Health Insurance Fund (EHIF). The former is provided in polyclinics, health centres and external consultations as well as through independent, private specialists. The latter can be administered in central, regional or local hospitals; these are non-profit entities accredited by the Healthcare Board and subject to private law. While most hospitals are property of the municipal governments, they have considerable freedom to make decisions regarding the renovation of infrastructures, staff contracting, employee labour conditions, etc.

Pharmaceutical services and products have been overseen by the State Agency of Medicines of Estonia (SAM) since 2000. In addition, SAM is responsible for authorizing new products of proven quality, safety and efficacy; approving clinical trials; regulating publicity; and carrying out pharmacovigilance.

The EHIF reimburses medicines included in the resulting positive list.

4.4.5. France

In France, there are approximately 1.6 million health professionals, or roughly 6.2% of the active working population. In 2002, there were 3.3 doctors and 6.9 nurses for every 1,000 inhabitants, situating France below the EU-15 average. The distribution of physicians reveals geographical disparities: a higher density in Paris, in the south of France and in urban (as opposed to rural) areas.

Primary healthcare (and most of what is denominated secondary healthcare) is provided by private doctors, dentists, auxiliary health professionals as well as by about 1,000 health centres under local administration. To a lesser degree, care is also provided by salaried staff in hospitals.

One striking element of French healthcare is the lack of a gate-keeping filter to access the system, and patients can freely choose their doctor. This freedom is one of the most notable aspects of the French system and is highly valued by French citizens. However, it is also a source of complexity for the control of healthcare costs, prompting some to propose restrictions on the free choice in order to “efficiently organize system entrance.” Recent attempts to introduce a gate-keeping function, though, have been unsuccessful so far, despite the financial incentives proposed for doctors and patients alike.

With regard to tertiary or more specialized care, it is necessary to note that most hospitals in France are public (65% of hospital beds). Private hospitals, either non-profits (15%) or for-profit institutions (20%) also exist, although the latter are usually devoted to minor surgeries. Public and non-profit hospitals, on the other hand, focus more on

emergency services and related admissions as well as rehabilitation, chronic (or long term) care and psychiatric treatment.

With 8.4 hospital beds per 1,000 inhabitants (about half of which are acute care beds), France is in line with the average among the EU-15.

The wide range of stakeholders and financial resources implicated in health policy and practise in France result in a lack of cohesion between them and somewhat diffuse demarcations of responsibilities. In March of 2003, a bill was proposed to address this problem. Its goal was to formulate an exhaustive legislative framework to structure an overall health policy with clear objectives and the ability to develop strategic plans in areas of designated priority. However, a law which accomplishes this has yet to materialize.

4.4.6. Germany

Outpatients are cared for by primary care physicians under contract with the sickness funds or, alternatively, by medical specialists with a private practise. Patients are able to freely choose their doctors, psychotherapists, dentists, pharmacists and emergency care.

Until recently, there hasn't been a formal *gate-keeping* mechanism in primary care (which encompasses about half of the physicians who provide outpatient care). However, the responsibilities of these professionals to coordinate with other care sectors were reinforced in January of 2004, with federal and regional (*Länder*) measures obligating sickness funds to implement a gate-keeping function into their primary care services (Busse & Riesberg, 2004).

Care for hospitalized patients (acute hospital care) is carried out by a collective of private and public providers: 53% of available acute beds belong to the public sector, 39% to non-profit organizations, and 8% to the private sector. Although the number of beds and the average duration of stay has decreased considerably (6.3 beds per 1,000 inhabitants and 9.3 days in 2001), Germany still ranks high among the EU-15 countries with respect to these indicators. The separation between outpatient and inpatient care, traditionally strict, has been relaxed in the past few years due to the promotion of clinics for non-hospitalized patients and outpatient consultations in hospitals as well as transectoral disease management programmes and specialized care networks.

From 1990-2002, the number of physicians increased by 20%. Likewise, the number of nurses rose 8% in 2001. Currently, approximately half of hospital personnel have a permanent contract and salary, while the rest are linked through temporary contracts or other temporary employment formulas.

4.4.7. Italy

In Italy there are approximately 6.1 doctors for every 1,000 inhabitants (figures from 2001), one of the highest proportions in Western Europe. By contrast, the ratio of nurses to patients is just 3:1,000, among the lowest in the EU.

GPs and paediatricians who are independently contracted by the National Health Service offer primary care services and act as gatekeepers of specialized secondary care (Donatini et al, 2001).

Local health units are responsible for protecting and promoting public health, mainly through disease prevention (especially by vaccination against infectious diseases), health promotion, food safety and hygiene.

Specialized medical services are provided either directly from the outpatient services of the local health units or through the external consultations of public (61%) or private (usually defined as “non-profits”) hospital facilities, duly accredited by the local health units.

The number of beds per 1,000 inhabitants has fallen from 7.2 in 1990 to 4 in 2001.

4.4.8. Netherlands

Primary care is provided by family doctors, who also represent the gateway to the rest of the Dutch healthcare system. Their importance in this role is evidenced by the low rate of referral to specialists. Indeed, two thirds of outpatient care is handled by primary care physicians (Den Exter et al, 2004).

Family doctors invest a good amount of time in communicating with patients as a part of their global treatment. This fact explains the low rates of prescription—just 66% of patient visits result in a prescription, in contrast to other European countries, where this figure oscillates between 75-95%.

Secondary and tertiary care is administered primarily through hospitals in external and hospital consultations. More than 90% of hospitals are private.

Dutch pharmaceutical policy has three main objectives: high quality, cost control and rational use. Once a medicine is authorized for use in the country, the government determines if it should be reimbursed or not through cost-benefit analyses which examine the new treatment and that which is already available within the system. Reimbursement is based on the average price of pharmaceutical products with a comparable effect (price referencing system). In the case that the price is higher than this calculation, the consumer must pay the difference.

4.4.9. Poland

Primary care and family medicine are relatively novel concepts in Poland, having been seriously devalued until 1991, when the strategy to improve the *status* and quality of primary care was launched under the name “Family Medicine.” Payment is made per person.

There is a pronounced division between inpatients and outpatients in specialized care. Specialists who work with inpatients, according to their contractual agreement with service financiers, cannot work with outpatients (Kuszewski & Gericke, 2005).

Outpatient care, on the other hand, is mainly provided by private practises, except in larger cities where Specialized Care Centres have been built and operate as independent healthcare institutions.

In the year 2003, there were 723 public hospitals in Poland. Hospitals are classified as follows:

- Hospitals at the first level of referral, usually created by regional governments, which offer services in Internal Medicine, Surgery, Obstetrics and Gynaecology and Paediatrics.
- At the second level, other specialties are handled, such as Cardiology, Dermatology, Urology and Neurology.
- The third level provides highly specialized care.

Hospital financing mainly comes from the National Health Fund (NHF).

The Ministry of Health is responsible for authorizing new medicines on the basis of safety, quality and efficacy. To this respect, medicines which are reimbursed are divided into two broad categories: those products made for all patients and those for patients with specific chronic illnesses. Both are subject to a level of co-payment.

Once a certain product is approved, the pharmaceutical industry negotiates its price.

4.4.10. Slovenia

Both public and private centres provide primary care services. Public providers include health centres and health stations; the latter are equipped with emergency services, family medicine, paediatrics and basic diagnostic services, and they are connected to the nearest health centres for treatment of more complex illnesses (Albrecht et al, 2002).

Health centre employees are civil servants, but they can exercise their practise in private care upon authorization.

The protected population has the right to choose their primary care physician each year; this doctor acts as the gateway to the rest of the system.

As far as secondary and tertiary services are concerned, these are carried out in private hospitals or other facilities. Between inpatients and outpatients, hospitals provide approximately 75% of care.

In deciding what pharmaceuticals to cover under the public system, Slovenia uses a "positive," "intermediate" and "negative" list, whose values are reimbursed 75%, 25% and 0%, respectively.

The two most important problems related to pharmaceuticals in Slovenia are also common in the rest of Europe: increase in consumption and increase in price.

4.4.11. Spain

Primary healthcare is considered to be the gateway to the rest of the system. Organized in Basic Health Areas (small territorial units), the Primary Care Centre is the nucleus

of these health care activities. Staff comprises a set of professionals common to each facility (family doctors, paediatricians, nurses, auxiliary staff, and usually social workers), but other professionals may also be incorporated into the Primary Care Team (PCT) or participate in supporting roles; this is the case for dentists, physiotherapists, midwives, veterinarians and pharmacists.

Population coverage in 2001 was about 90% nationally, ranging from 83% to 100% in different regions.

The number of doctors stands at 71 per 100,000 inhabitants; in family medicine, this translates to about 1,900 adults assigned to each GP, 1,080 children per paediatrician and 1,750 patients per nurse.

Specialized care is the second level of healthcare, and it is provided by hospital in-patient care, specialized consultation, emergency services, outpatient hospitals, home care and major surgical units located in hospitals and specialized centres. However, the traditional concept of hospital has been overcome by new structures and organizational models of specialized healthcare.

In this sense, since the 1990s, public specialized care has become more functionally integrated between hospitals and specialized centres, which together form a sole level of specialized care, sharing both human and material resources among different facilities in the same Health Area. There is some regional variation to this new organizational model.

4.4.12. Sweden

Each country has the legal authority to freely decide how to provide primary care services to their inhabitants. Most of the time, these services are provided publicly, and there are private providers who exercise in the local sphere.

In 2003, of the close to 1,100 existing health centres, 300 were private.

With respect to hospital care, services are offered by the country in regional hospitals. Compared to other European countries, Sweden devotes a high amount of resources to hospital care (Glennard et al, 2006). These facilities can be district, central or regional.

Sweden also has 6 health regions which collaborate with the counties to provide highly specialized care.

Pharmaceutical products must be approved by the Medical Products Agency. In turn, the Pharmaceutical Benefits Agency is responsible for determining whether a specific product should be included in the positive list for reimbursement. In that situation, negotiation with the corresponding pharmaceutical company begins.

4.4.13. United Kingdom

In the United Kingdom, primary care is financed through public funds and provided by GPs and basic clinical teams (with an average of 3 GPs per centre). The patient must

be a resident of the designated area of the clinical team in order to register with a GP. In England in the year 2002, each GP was responsible for an average of 1,800 people in the local community where he or she worked.

Although there is a small number of clinics directly open to patients in the NHS, GPs are usually the gatekeepers of specialized care, referring patients as they see fit to these services.

In 2002, the UK had 3.9 acute beds per 1,000 inhabitants. In 2004, NHS secondary care was administered by 209 NHS trusts. Likewise, 23 Mental Health trusts offered psychiatric services to hospitals and specialized consultations (Robinson et al, 1999).

There are about 240 private acute hospitals, although together, they account for less than 5% of all hospital beds in the country.

In 2001, there were 0.6 GPs per 1,000 inhabitants, illustrating the deficit in qualified staff in the NHS. In light of this shortage, the government pledged to increase NHS personnel to certain levels by 2004, aiming to reinforce the primary care workforce by adding 2,000 GPs, among other goals.

The Welsh Government Assembly also set objectives to increase the number of doctors, nurses and dentists in Wales, and similar measures are being undertaken in Scotland and Northern Ireland.

The organizational structures for the administration and distribution of healthcare services differ among the constituent countries of the United Kingdom. In England, for example, public health personnel operate within the Central and Regional Health Departments, the denominated Strategic Health Authorities and the Primary Care Trusts (PCT). In Wales, a National Public Health Service has been established to offer services and support to the Local Health Boards, local authorities and other NHS bodies.

4.5. Cost-control mechanisms and policies

The omnipresent challenge of economic sustainability is a common denominator in most European health systems. The measures aimed at improving the management of available healthcare resources and the initiatives to control cost have been an object of study in the past few years.

As a paradigm of these initiatives, different formulas for cost and consumption control of pharmaceutical products have been established, and we will review some of these from different European health systems.

It has been suggested that the objective pursued initially with Health Technology Assessments (HTA) was to control pharmaceutical expenditure. However, time has shown that "efficiency" is not always synonymous with "savings," and the spending efficiently does not always mean spending less, although it should mean spending *better*.

Most efficient medicines do not save money—let's not forget that a therapeutic option whose incremental cost is 20,000€/QALY compared to another option means that the cost of one QALY increases by 20,000€.

According to a review of HTA carried out worldwide over 25 years, just 19% of health interventions led to directly identifiable net savings in the short-term budget analysis. Thus, we must begin to acknowledge that new health technology (both pharmaceutical drugs and medical instruments) can contribute to the improvement or lengthening of patients' lives, but they will rarely save money in a direct fashion. However, we should remember that the guiding force behind calculating a public system's budget is not to save money, but rather to use it in the best way possible for the benefit of citizens.

The ministerial conference which took place in June, 2008 in Tallinn, Estonia, focused on the importance of health systems and on changing the existing paradigm. Rather than speaking of healthcare *expenditure*, health *investment* was said to be a reflection of a country's investment in its own development (health and wealth).

The existence of segmented budget structures for each of the components of health expenditure is one of the main barriers identified by most experts in formulating good criteria to evaluate efficiency. This problem, which can be considered as endemic throughout Europe, favours the appearance of rigid mentalities that do not take into account the long-term savings not directly reflected in the budget.

It is necessary to note that the root of the problem is not the existence of a pharmaceutical budget, which is the only way that health system managers can track the evolution of pharmaceutical expenditure. Rather, the problem lies in the lack of simultaneous analysis on the impact that these variations (in pharmaceutical expenditure) have on the rest of social and health system budgets (readmittance, temporary disability, social care...).

4.5.1. Austria

Pharmaceutical expenditure has been increasing in Austria since the early 1990s due to demographic changes and the progress achieved in medicine. The disproportionate increase in pharmaceutical expenditure mainly affected insurance companies (especially in the case of recently patented medicines subject to physician supervision).

In comparison to other countries, the proportion of generic medicines on the market is very low (less than 10%). Furthermore, more than 60% of the cost increase is due to medicines which need the authorization of the primary care physician.

Throughout the last few years, more regulations on prices and quantities of pharmaceutical products have been appearing. In 2003, the Federal Health Ministry for Health and Women initiated negotiations with different interest groups (pharmaceutical industry, doctors, pharmacists, etc.) to formulate a package of reforms in that sector. This package focused mainly on cost containment measures, and the result was the presentation in late 2003 of a new "reimbursement code" for the social security system to try to

address the structural defects in the distribution and access to the market of generics and innovative pharmaceutical products. This new code is called the “box system” (Hormarcher & Rack, 2006).

Since 2004, each medicine is assigned a “box” (category), to which different conditions of reimbursement and price regulations are applied. The “Red Box” contains (for a defined and limited time period) all pharmaceutical products with commercial licenses. These must be prescribed by physicians and are subject to control by the insurance entities. These controls refer to the medical requisites of patient groups, special indications and stages of illness, as well as the incidence and prevalence of illness. The remaining medicines are divided into those which have an important added therapeutical value (“Yellow Box”) and those which can be freely prescribed (“Green Box”).

Red Box prices are set according to the EU average, Yellow Box medicines are subject to discounts per acquired quantity, and Green Box generic drugs are the object of promotions.

4.5.2. Belgium

More than 2,500 pharmaceutical products are on the “positive list,” meaning that they are eligible for partial or total reimbursement. The percentage of reimbursement of the costs depends on the therapeutic importance of the drug.

Before 2008, only the patients covered by the mandatory healthcare insurance were reimbursed. For all those who had self-employment insurance, outpatient pharmaceutical expenses had always been covered in their totality by patients. However, mandatory insurance coverage has now been extended to this collective.

In 2005, pharmaceutical expenditure represented 17.6% of healthcare budgets, and costs have been progressively rising, 6.7% from 1990-2000 and 7.5% between 2000 and 2005.

Indeed, Belgium has a relatively high pharmaceutical expenditure, averaging 359€ *per capita* in outpatient drug spending in 2004.

At least 75% of these reimbursable pharmaceuticals were prescribed by GPs.

All of these circumstances have led healthcare managers to pursue more cost-control measures in recent years. The following initiatives were introduced in 2002 to modernize pharmaceutical policy:

- Simplify the processes and structures to approve new pharmaceuticals: effectiveness of those which are already on the market can be scientifically reviewed
- Guarantee the provision of pharmaceutical innovation
- Foster the use of pharmaceuticals based on evidence and the formulation of clinical guidelines which consider the cost-effectiveness ratios of different alternatives
- Implement realistic objectives for expenditure based on healthcare policy
- Introduce recuperation mechanisms when expenditure is excessive

4.5.3. Bulgaria

Until 1991, the production and distribution of pharmaceutical products was centralized under the State Pharmaceutical Company, which performed all the functions related to the pharmaceutical sector. In 1995, the Pharmaceutical and Human Medicine Pharmacies Act became the foundation of the restructuring and privatization of pharmaceutical production and distribution.

Currently, there are about 30 independent pharmaceutical companies which manufacture these products, 330 wholesalers, which import and trade with 4,518 pharmacies, and less than a dozen distributors which maintain 90% of the domestic pharmaceutical market.

In 2004, the wholesaler market became regulated under the authority of the Bulgarian Ministry of Health and the Bulgarian Drug Agency (Georgieva et al, 2007). Local pharmaceutical manufacturers were authorized to distribute their own products (based on licenses) and could directly participate in the pharmaceuticals supplied by the Ministry of Health, the NHIF and the hospitals. Foreign manufacturers could be represented in two ways:

1. By representative offices: they are not legal entities but serve only for promotion and marketing activities. The sale of pharmaceuticals is done directly by a foreign legal body, through an authorized provider, which then sells and distributes to the pharmacies and participates in tenders.
2. By local offices: legal entities owned by foreign companies licensed to distribute pharmaceuticals. These can directly participate in the calls to tender made by the Ministry of Health and the NHIF and legally sell directly to the pharmacies, although from a practical point of view, they do not for lack of their own distribution network. For this reason, they also authorize local wholesalers to handle hospital supply.

The Pharmaceutical and Human Medicine Pharmacies Act explicitly prohibits the sale of prescription drugs by anything other than pharmacies. OTC drugs are sold only in pharmacies and drug stores.

The consumption of pharmaceuticals has been increasing since 1999. While this consumption rises, the number of pharmaceutical packages sold decreased from 2003 to 2004.

The largest client of pharmaceutical products in Bulgaria is the NHIF, which subsidizes economically vulnerable outpatients (low income, unemployed, retired, children and war veterans) as well as 21 university hospitals, 28 multidisciplinary hospitals, clinics and 64 centres of haemodialysis. The NHIF reimburses expenses wholly or partially, prioritizing the following diseases:

- Cardiovascular
- Neurological
- Gastroenterological
- Diabetes
- Sclerosis
- Multiple sclerosis
- Metabolic

In 2003-04, the Bulgarian Ministry of Health and the Parliament approved the Data Exclusivity clause and the Roche-Bolar clause, previously adopted by the EU. For Bulgaria, this translated into the recognition of patent protection for pharmaceutical products for 20 years. In 2003, the government introduced a data-exclusivity period of 6 years to provide additional protection to the market for manufacturers of original pharmaceuticals, thus preventing the authorization of generics during the period of exclusivity.

For new technologies and organic products, the patents last 10 years. In parallel to this process in Europe, the Hatch-Waxman exemption in the USA allows pharmaceutical companies to begin clinical trials and the registry of a drug two years prior to the expiration of the original patent in order to begin manufacturing the corresponding or related drug smoothly.

Bulgaria is introducing clinical good practise standards. Currently, it is trying to create an adequate system of management, structure and control for the harmonization of legislation with the EU. It is also in the process of implementing good information systems to assure strictly regulated access controls. Other recently formulated objectives are: increasing the efficiency and efficacy of the pharmaceutical sector, including assuring a controlled balance between pharmaceutical innovation in industry and policies for generics (and particularly guaranteeing that Bulgarian generics have competitive prices).

4.5.4. Czech Republic

The General Insurance Fund (GIF) pays approximately 80% of healthcare costs, while the rest is shared between the State and by direct payments from patients (approximately 10% of the total). Until 2008, these payments were mainly destined to pay for medicines, without a doubt one of the areas which has seen the greatest increase in costs in the past 15 years. In 1994, *per capita* pharmaceutical expenditure rose by 39%, and in 1995, this percentage reached 45%, clearly a much higher increase than was seen in the total health expenditure in the same periods, 9.4% and 9.1%, respectively. Between 1998 and 2001, annual consumption of pharmaceutical products went from 33.3 billion Czech crowns¹ (CZK) to 44.2 billion. Currently, it represents almost a fourth of all health expenditure, approximately US\$350 PPP *per capita*. The cost of healthcare equipment has risen as well, with significant increases in the number of CAT and MRI machines bought from 1991-2001 (Rokosová & Háva, 2005).

To reduce costs and ensure system sustainability, the authorities have taken diverse measures. The use of reference pricing, together with energetic price negotiations with the pharmaceutical industry, was established in 1995. The Ministry of Finances and the GIF have the role of negotiating the maximum prices of drugs with the manufacturers and importers; they aim to pact a price which is similar to the lowest price paid by other similar European countries.

Since 1997, this system has worked relatively well, helping to limit the rise in pharmaceutical expenditure to 10% or less a year, which is in line with the increases in total healthcare costs. However, the proportion of costs which must be paid directly by pa-

¹ CZK = *Koruna eská* or Czech crown. 1€ = 28.6 CZK

tients has increased rapidly. In 2004, for example, 76.3% of the total pharmaceutical expenditure was public, but in 2006, this proportion had decreased to 70.8%. In January of 2008, more individual co-payments were introduced (30 CZK per prescription or per surgical procedure, 60 CZK per hospitalized day and 90CZK per service outside of the normal schedule).

However, more reforms in efficiency are necessary in order to widen accessibility. With regard to pharmaceuticals, this process is especially slow and inefficient. Although there are virtually no cost-efficiency studies for health technology in this country, uptake of new drugs usually takes upwards of two years following approval by the EMEA (European Medicines Agency), a reflection of the time which is lost in the administrative and bureaucratic process.

This process would need to be more dynamic in order to respond to the growing pressure to expand access to innovative pharmaceuticals. Moreover, the numerous limitations on access to expensive pharmaceuticals (including the requirement of a co-pay from the patient) contribute to the low sales in comparison to the rest of European countries, not only for new formulations, but also for drugs introduced before 1995. In these two aspects, the Czech Republic is trailing the rest of Europe.

4.5.4.1. Main actors and regulations in the access to health technology in the Czech Republic

- The Ministry of Health: sets general priorities, supervises price negotiations and directs State policy on health technology
- Ministry of Finance: consults the Ministry of Health in decision-making with respect to the authorization of medicines for reimbursement
- GIF: advises the Ministry of Health in the authorization of medicines. Releases a list of reimbursable pharmaceuticals and influences their price by negotiating with manufacturers and importers
- Czech Chamber of Pharmaceuticals: also advises the Ministry of Health in the authorization of medicines.
- Categorization Commission (external body constituted by medical and pharmaceutical specialists, economists from insurance companies and employees of the Ministry of Health): formulates recommendations to update the “drug decree” (57/1997), which defines the level of reimbursement for each drug every six months.
- Coordination Committee (constituted by leaders of the Ministry of Health and the GIF): assigns tasks to the Categorization Committee according to the State’s health policy objectives. The aim of this committee is to formulate clear guidelines in pharmaceutical policy, a goal which is still pending.
- Act 48/1997 (on social health insurance): defines 521 pharmaceutical product groups and establishes specific conditions to reimburse the cost of each group (for example, the patient’s diagnosis, the specialist dispensing the prescription, the approval of a revising physician, etc.). Only the cheapest efficacious formulation of essential drugs is totally reimbursed. Frequently, these are manufactured in Czech territory.
- Act 57/1997 (the “drug decree”): defines the level of reimbursement for all drugs on the positive list.

4.5.4.2. Cancer control actions in the Czech Republic

The growing incidence of cancer and the ageing of the European population have underlined the importance of finding effective policies to serve citizens. In the Czech Republic, these circumstances have resulted in independent and public measures which try to tackle distinct dimensions. However, up to now, there hasn't been a national cancer control plan.

However, the official website of the Czech Republic announces that the Ministry of Health is formulating a new National Oncology Programme, a very positive step in the fight against this disease. Three priorities are listed: cancer prevention, improvements in quality of life for patients and cost rationalization. The Czech government, unlike other administrations (according to published studies), values increased access to medications.

The main measures proposed are articulated through primary and secondary prevention activities as well as the concentration of specialized care in twenty centres throughout the country.

At the moment, available information on this plan in English is scant, but we hope that more details are released in the coming months. The few initiatives which were made explicit do not include the importance of research or palliative care, and curiously, the current cost of cancer care is presented as high (at 6.5% of total healthcare costs) even though the website also assures readers that one in three Czechs will eventually develop some form of cancer. In any case, given the rising incidence of this disease and its current protagonism in Europe, the investment seems insufficient.

Among the most relevant programmes currently in operation are the population-based screening programmes formulated by the Ministry of Health. These programmes are well-established for cervical and breast cancer, and a recent initiative for colorectal cancer has achieved a 68% increase in the number of screenings from 2002 to 2005.

Another positive aspect is the information generated by the cancer registries, which have tracked all diagnosed tumours through obligatory reports since the 1950s.

Upon analyzing the situation of oncological treatments in the Czech Republic, we need to be cautious, given that the health system is experiencing profound changes which will transform the panorama in the next months and years. On the other hand, it is apparent that health authorities are taking dramatic measures to reduce costs, frequently transferring the fiscal burden from the State to the patient and imposing a *de facto* tax on the sick.

Before 2008, direct payments were used only to cover non-essential medicines, but now there is a charge per prescription, per surgical operation, per hospitalized day, and per visit outside of the normal schedule. This, combined with the limits imposed on doctors and hospitals to reduce costs, is perhaps an extreme response to an extreme situation (lack of financial sustainability), but for cancer patients, the financial burden on

the patients and the inaccessibility of many medicines does not inspire much hope for improvement in the near future.

4.5.5. Estonia

Since 2002, clearer guidelines have been established regarding the introduction of new services into the existing portfolio as well as the establishment of adequate levels of use.

The Estonian Health Insurance Fund (EHIF) and the Ministry of Social Affairs agree on a package of services, and the government is responsible for the final decision (Koppel et al, 2008).

The criteria used for the inclusion of new benefits are: medical efficacy, cost-effectiveness, concordance with the national health policies and the availability of financial resources.

4.5.6. France

France is the leading European country in pharmaceutical manufacturing as well as the country which most consumes these products (US\$382 *per capita* annually, double that of the UK).

The French health system covers the majority of medical expenses for the entire French population. Due to the high coverage of treatments, incentives exist for doctors and patients to limit their consumption of pharmaceutical drugs. The French government has recently been pressuring doctors to prescribe less and cheaper medicines with the objective of controlling cost. This has favoured the market of generic drugs in France, although these medicines still account for a relatively low proportion of the total.

In 2001, France was the third pharmaceuticals manufacturer worldwide, employing more than 95,000 people in this sector. There are 300 pharmaceutical companies, but less than 40% are backed by a majority of French capital. It is also one of the highest exporting countries. The biggest buyers are Germany, Italy, Belgium, Spain and the United Kingdom.

French companies invest approximately 15% of their profits in R&D (in 2001, this amounted to about US\$4 billion. A growing percentage (45%) of money for R&D is invested by French companies abroad. The French government is trying to increase R&D investment, approving a package of fiscal measures to maintain innovation in this sector in 2003.

With respect to the process of approving pharmaceuticals, for each drug in the French industry which completes all tests and clinical trials, there are ten with a patent applied for and 100,000 molecules which are submitted to preliminary tests. Between the innovation and synthesis of a molecule, it takes an average of 12 years for a new drug to be put onto the market, at a cost of 800 million euros. After obtaining a patent, the drug must be authorized for sale and receive approval from the Transparency Commission.

As far as pricing is concerned, France has one of the strictest systems in the EU. Although the cost of living (as understood as the theoretical concept which represents

the cost of the goods and services that homes consume in order to obtain a certain level of satisfaction) doubled between 1980-2000, pharmaceutical expenditure rose just 34% in the same period.

The government regulates the price of reimbursable pharmaceuticals. The so-called *Code de la sécurité sociale*, or Social Security Code, establishes the procedures, price criteria and list of reimbursable drugs. The decisions about the prices are reached by consensus between the Ministries of Social Affairs and of the Economy. To increase consumption of generics, the French government implemented a new system of margins in pharmaceutical distribution. The generics market represents just 4-6% of total prescriptions.

4.5.7. Germany

The recent reforms of the German health system have been aimed at reducing cost. Other objectives such as effectiveness, appropriateness, quality and cost-effectiveness have also gained ground among health providers.

In addition, other political reforms, such as the reunification of Germany and EU guidelines, have influenced the financing and healthcare service provision in Germany.

The changes introduced between 1989 and 1995 particularly sought cost control in the healthcare sector. In addition to these, regulations to stimulate competition among hospitals were set in place. The following two years (1996-97) saw a reduction of preventive and rehabilitative services and an increase in the co-pay for certain services.

At the beginning of the following decade, during the period between 2000 and 2003, a varied package of small measures were progressively introduced, including price control, price negotiation with the governmental organs of sickness funds and the communication of the prescription volume to physicians.

Since 2003, new pharmaceutical products introduced on the market have been covered by insurance, with the exception of those included on the negative list due to inefficiency or their modest therapeutic value.

Finally, the statute of modernization of health insurance in 2004 introduced an arsenal of cost-containment measures and structural changes in the pharmaceutical sector. Since the reform, levels of co-pay have increased, and benefits of the mandatory insurance have decreased. These measures, together with the lower prices paid to pharmaceutical companies, have resulted in large savings for the insurance funds but have not translated into lower premiums for consumers, as the federal government intended.

4.5.8. Italy

Since the early 1990s, a radical change in pharmaceutical policy has been taking place in Italy, above all due to the scandals which occurred in that period and the pressure exerted to introduce necessary cost-containment measures.

Since 1994, pharmaceuticals have been classified in four categories subject to different conditions of co-payment and different schemes of exception:

- Group A: medicines for serious or chronic diseases
- Group B: medicines of therapeutical importance not included in group A
- Group C: medicines not included in groups A and B
- Group H: medicines used exclusively in hospitals

This classification is carried out according to criteria of documented and evidence-based clinical efficacy, risk-benefit balance of the therapy in question, acceptability of the treatment by the patient and finally, cost.

A large group of products considered to be of limited therapeutic value have been excluded from public financing in Italy (as in most countries in Europe).

Furthermore, in 1994 the Italian government introduced a ceiling for annual pharmaceutical expenditure so that in 1998, pharmaceutical companies and other private enterprises became responsible for part of the public pharmaceutical deficit beyond the stipulated amount, paying for 60% of these costs.

Reference prices were also introduced in 1996, and since 1997, pharmaceutical profits are subject to scale mechanisms in order to provide incentives for the sale of less expensive drugs.

4.5.9. Poland

Universal coverage is one of the characteristics of the Polish health system, and it is defined by a portfolio of services available to all people with the right to coverage.

Certain services, such as alternative therapies (aesthetic surgery, non-standardized treatments, vaccines not included in the calendars, etc) are excluded from the portfolio of services (Kuszewski & Gericke, 2005). Exclusion is determined by the Ministry of Health and is published through successive decrees. In any case, the exclusions have not been an object of reform in the past few years.

Waiting lists and lack of specialists are the prevalent problems in the public healthcare sector in the entire EU. In the case of Poland, this is more accentuated at the time of tackling special therapies or complex interventions such as some surgical operations for cancer. This implies an extra cost for the patient, who must resort to paid services in the private sector.

The reform process begun in 2003 represents an opportunity to modernize healthcare financing in Poland. One illustrative example with regard to the reduction in pharmaceutical expenditure is the reform underway to foster the consumption of generics and to increase electronic prescriptions.

4.5.10. Spain

Public pharmaceutical expenditure in Spain has risen faster than total health expenditure; both of these rate increases are over the growth of GDP. As a consequence of this evolution, a perception exists that the percentage of pharmaceutical expenditure (over total health expenditure) has been constantly growing in the past decade, accounting

for 20% in 2000. However, before drawing precipitated conclusions, it is necessary to examine different aspects related to this issue.

First of all, we must identify the reasons for this differential growth, which lie in the underlying factors in one or more of the following variables: the volume of medication consumed, the prices of pharmaceuticals and/or the mix of prescribed products.

Upon examining this first variable, we find that the average number of prescriptions *per capita* has increased in the last decade in Spain, although this increase is not statistically significant.

It should also be noted that in this period, the Spanish population has grown (mostly due to immigration) as well as aged substantially—the population over 65 has risen from 13.6% of the total in 1990 to 16.8% in 2000. This segment of the population consumes more medicines than any other.

In Spain, the prices of the drugs which are financed in part or in whole by public funds are controlled, and the index of prices on medicines has virtually not increased at all in the past decade. However, this does not mean that the innovative products are not priced higher than those which already exist on the market. In principle, this should translate to a short term increase in expenditure. On the other hand, these medicines tend to replace less effective treatments for the same illnesses, which can result in a medium-term decrease in total health expenditure.

Along with pharmaceutical expenditure, the introduction of new health technology and the expense associated to it has contributed to generating expectations and creating necessities among citizens. Demand for these technologies subsequently rises, and with it, the expenditure.

Among the studies which have shed the most light on this field in Spain is the recent report on "Patient access to anti-cancer drugs in Spain," elaborated by experts of the Karolinska Institute (Bengt Jönsson and Nils Wilking, and on this occasion Ulf Staginnus) and published in a monograph of the *Revista Española de Economía de la Salud* (The Spanish Journal of Health Economics). This report analyzes the situation in the 17 regions, finding "imbalances," "arbitrariness" and "large differences" between regions with respect to the uptake and availability of cancer drugs (Jönsson et al, 2007).

Among the factors which could be at the root of this, the Swedish authors mention the financing of research, the reimbursement process, the price negotiation, the role of HTA, or the hospital budgetary problems. Madrid and Catalonia, followed by the Basque country, carry out the main research activities in the country (59.7% of the national total in R&D). The first two regions also have the best and quickest incorporation of pharmacological innovation.

Despite the effort carried out in the last few years to increase R&D investment from 0.7% of the annual GDP in 1998 to 1.07% in 2004, Spain occupies a discreet 17th place in cancer research in Europe, devoting €18.3 million to that end while the UK, Germany

and France spend more than €100 million annually. In total, Spain spends 92€ *per capita* in cancer care, less than France, Germany, Sweden and the United Kingdom.

From a comparative point of view, the report cited concludes that “the regions of Madrid, Navarra, Catalonia, Asturias, Cantabria, Castille-Leon and Valencia tend to be fundamentally above average in the incorporation of innovative drugs, while other regions, particularly La Rioja, Ceuta and Melilla, Castille-La Manche, Andalusia and the Canary Islands are below the national average with regard to the uptake of the majority of the drugs in this study. Galicia, the Basque Country, Aragon, Extremadura, Murcia and the Balearic Islands generally have an intermediate position in the uptake of innovative cancer drugs” (Jönsson et al, 2007).

In short, although Spain is identified as one of the countries which is most capable of quickly incorporating treatments and novel diagnostic techniques into the system, this incorporation is unequal and tends to be accompanied by user restrictions (by means of internal clinical practice guidelines) in hospitals or health centres. Given that access to diagnostic procedures and drugs depend a great deal on the adequate financing within health systems, in Spain, most cancer drugs are hospital products, and hospitals are subject to a “rigid” budget which is sometimes closed for several years at a time. In this context, hospital managers are faced with the challenge of introducing therapeutic innovations. Apart from the recommendations made by the Health Technology Assessment Agency, cost-containment strategies occasionally displace cost from one area to another, limiting access to innovative treatments (González et al, 2005; Martín-Moreno et al, 2009).

4.5.11. Sweden

All pharmaceutical products in Sweden are distributed and dispensed to the general public by the publicly owned chain called the National Corporation of Swedish Pharmacies, otherwise known as Apoteket AB.

Before a new drug is put on the market, it must be approved and registered by the Swedish Medical Products Agency (MPA), a national authority responsible for regulation, development, manufacture and sales of medicines and other pharmaceutical products. There are approximately 6,000 products registered in Sweden. The three most dispensed therapeutic areas, according to the anatomico-therapeutic classification, are: the central nervous system (19.6%), the cardiovascular system (13.9%) and the digestive tract and metabolism (11.9%). Antipsychotics, anti-asthmatics, and pain-killers follow (Glennard et al, 2006).

The consumption of pharmaceutical products has been increasing in the past few years. Patients pay for all prescriptions costing up to 900 SEK², and after that, a scale of subsidies guides what the patient must pay, which never exceeds 1,800 SEK over a period of 12 months.

The Committee of Pharmaceutical Benefits (LFN in Swedish) decides which drugs should be financed. Decisions are mainly based on existing cost-effectiveness studies.

² 1€ = 10.6 Swedish Kroner (SEK)

4.5.12. United Kingdom

The pharmaceutical industry in the UK ranks fifth in the world after the USA, Japan, France and Germany. However, the expenditure on new treatments is relatively low.

In 2002, less than 16% of spending on pharmaceuticals corresponded to drugs introduced in the five preceding years (compared to 20-25% in the EU and 29% in the USA). At the same time, generics account for 20% of the market, higher than all other European countries except Germany (Robinson et al, 1999).

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the body responsible for authorizing pharmaceutical products in the country. The commissions of the MHRA, in collaboration with the Committee on Pharmaceutical Safety, are in charge of supervising clinical trials.

The practises used in the approval of pharmaceuticals are considered to be some of the most efficient in Europe. The average time taken in approving public financing for new drugs has been decreasing in the last few years.

The NHS pays for the majority of prescribed drugs in the UK, but the government is very interested in strictly controlling pharmaceutical expenditure. Some of the measures taken to contain costs include the following:

- Price controls
- Fostering use of generics and co-payments
- Publication of "negative lists" for inefficient drugs
- Publication of "select lists" of drugs not covered by the NHS
- Campaigns to raise awareness on prescription control

Some patients pay a standard quota for prescribed drugs and others pay an annual quota which covers all prescriptions for a year. However, approximately 90% of patients are exempt from paying prescriptions.

The use of drugs is extremely influenced by recommendations made by the National Institute for Clinical Excellence. NICE is an independent organism responsible for elaborating clinical guidelines, cost-effectiveness studies and recommendations on treatments which should or should not be financed by the NHS.

The Pharmaceutical Price Regulation Scheme (PPRS) regulates the prices of those drugs which are financed by the NHS after negotiating with the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry, and with the Ministry of Health.

The PPRS does not cover generic drugs. The increasing use of these in the UK has led to an increase in price and sales. In response, the government established a maximum price for generic drugs in 2002, to be calculated on a monthly basis but the Prescription Pricing Authority.

5. Specific description of resources and systems dedicated to cancer control in Europe

Evidence shows that access to hospitals with a broad experience in the diagnosis and treatment of cancer patients, to specialized hospitals and to oncology specialists have a positive influence on survival rates and mortality rates in cancer. At the same time, population-based screening programmes have been proven clearly effective in increasing detection rates, decreasing incidence and mortality and increasing survival. In the same way, access to innovative treatments improves patient outcomes.

To improve our response to cancer, it is crucial that patients have quick access to both diagnostic services and treatments. However, studies which have attempted to examine the situation show that in EU Member States, the type of services offered and the quality of the same vary substantially from one country to another. All of this affects survival and contributes to inequalities among European citizens.

The rational and equitable provision of resources based on evidence is currently a challenge for all European healthcare managers. Micheli and colleagues (2003), in their revision of health systems and cancer care in Europe, reveal important differences in the organization and distribution of cancer care. Some studies that explore the relationship between health system characteristics and cancer indicators have been difficult to complete in a satisfactory way, given the difficulties in obtaining quality data.

Not long ago, a cancer diagnosis was perceived as associated with a limited prognosis. However, technological advances have increased treatments, raising success and subsequent survival rates. Nowadays, if we effectively apply knowledge and use the necessary technology, we can prevent a fourth of all cancers and cure at least a third. Applying and improving all of our technological tools and advancing in prevention, diagnosis and treatment, we may be close to converting cancer into a chronic illness (Sikora, 2006).

In Table 2, we can observe comparative data among different countries with regard to the specific resources employed towards cancer control: screening, diagnosis and treatment, palliative care and registers.

Appendix 2: European Health Systems and Cancer Care					
	Predominant financing mode and payment for cancer care and medicines	Screening for cancers of	Diagnosis and treatment	Palliative care	Cancer registry
Austria	Insurance. No co-payment	Breast Cervical Prostate in Tyrol only	In general hospitals, few specialist centres	Hospices. Not country wide	Yes
Czech Republic	Insurance. Co-payment	No data central cancer units	District, regional and	No data	Yes
Denmark*	Tax funded. No co-payment	Breast Cervical	General hospitals and specialist centres	No data	Yes
England*	Tax funded. No co-payment	Breast Cervical Colorectal (pilot)	General hospitals, specialist centres, private sector	Yes	Yes
Estonia	Insurance. Co-payment for some medicines	Not nationwide programmes	General hospitals and specialist centres	No data	Yes
Finland	Insurance. Co-payment for medicines and services	No data	General hospitals and specialist centres	No data	Yes
France	Social security. No co-payment	No data	General hospitals, specialist centres, private sector	No data	Yes
Germany	Insurance. Co-payment for medicines and services	Breast Cervical Prostate Rectal Skin	General hospitals, specialist centres, private sector	No data	Yes
Iceland	Insurance. No co-payment	Breast Cervical	General hospitals and specialist centres	Yes	Yes
Italy	Tax funded. No co-payment	No data	General hospitals and specialist centres	No data	Yes
Malta	Tax funded. No co-payment	No data	Specialist centre	No data	Yes
Netherlands	Insurance. No co-payment	Breast Cervical	General hospitals and specialist centres	No data	Yes
Norway	Tax funded. No co-payment	Breast Cervical	General hospitals and specialist centres	No data	Yes
Poland	Insurance. No co-payment	No data	General hospitals and specialist centres	No data	Yes
Portugal*	Tax and insurance funded. No co-payment	Breast Cervical (Regional programmes)	General hospitals and specialist centres	No data	Yes
Scotland	Tax funded. No co-payment	Breast Cervical Colorectal (pilot)	General hospitals and specialist centres	No data	Yes
Slovakia	Insurance. No co-payment	Breast Cervical	General hospitals and specialist centres	No data	Yes
Slovenia	Insurance. No co-payment	No data	General hospitals and specialist centres	No data	Yes
Spain	Social security and tax. Co-payment for medicines and services	No data	General hospitals and specialist centres	No data	Yes
Sweden	Tax funded. No co-payment	Breast Cervical	General hospitals and specialist centres	No data	Yes
Wales*	Tax funded. No co-payment	Breast Cervical	General hospitals and specialist centres	No data	Yes

* National Cancer Plan

Source: Michell A, Coebergh JW, Mugno E, Massimiliani E, Sant M, Oberaigner W et al. European health systems and cancer care. Annals of Oncology 2003.

Table 2: Comparative table on oncological resources in the EU

5.1 Primary prevention

Cancer prevention is the set of actions which can be carried out with the aim of decreasing incidence and/or mortality due to this disease. Prevention has the following objectives:

- Decreasing incidence: around 75% of cancers can be attributed to external factors which people could modify, thereby decreasing their risk of developing cancer
- Decreasing mortality: this is mainly accomplished if the cancer is detected in its earliest stages and specific treatments, often simpler and more efficacious, are applied

Primary prevention is the set of actions aimed at modifying unhealthy lifestyle habits in the population and fostering other more adequate ones. By doing this, we manage to avoid risk factors which act on a specific organ, causing alterations that could result in cancer. A series of steps are necessary for a person to modify his or her habits:

- Having enough good information about a risk factor
- Being aware of the risk involved in maintaining said habit
- Making the decision to modify or avoid contact with it
- Maintaining the learned behavioural change over time

This is accomplished by offering information to the population through campaigns and carrying out health education programmes to raise awareness and to help people adopt and maintain healthy lifestyle choices.

In a parallel study we are carrying out (Atun et al, 2009), we have new data on primary prevention programmes in Europe, aimed at reducing the risk of cancer in areas such as tobacco control, moderation of alcohol intake, healthy diet, physical activity, exposure to sunlight and occupational and environmental factors.

5.2 Secondary prevention

Secondary prevention refers to the actions directed towards the early detection of certain malignant tumours. This group of actions is denominated “screening programmes.” Each programme is characterized by a series of factors:

- It should be aimed at detecting a specific kind of tumour, which can be diagnosed in the earliest phases of the disease, in premalignant phases or in both circumstances.
- The healthy population which is most likely to develop this cancer should be determined.
- Effective treatment for the earliest phases of the disease must exist.

The main objective of secondary prevention is to decrease the mortality caused by a certain type of cancer, detecting the disease early by screening the population at risk.

Some cancers, such as lung cancer, colon cancer or skin cancer, can be prevented. Others can be detected early by performing simple tests, including breast, cervical and colorectal cancer. Still other groups can be detected early, but the possibility to improve outcomes is not available (we would move the date of diagnosis forward, but not increase the length of life). For this reason, it is important to identify efficacious screening programmes backed up by scientific evidence.

The first logical step consists of identifying the population which may have a premalignant lesion or cancer but which does not present symptoms. These programmes

should be offered and performed on the entire population at risk of a certain cancer. Systematic, quality population-based programmes are the formula advocated for by experts, as opposed to programmes which try to concentrate action on high risk groups.

When the result of the screening test is positive, it is necessary to carry out follow-up tests to confirm the diagnosis. These will vary according to the cancer being screened for.

Early diagnosis of the disease has significant advantages for the patient:

- Generally, he or she can receive less aggressive, more effective treatments than what would be possible if the tumour was in a more advanced phase.
- Side effects of the treatment are not as serious, thus quality of life is maintained.
- If a premalignant lesion is diagnosed, we can avoid its development into cancer, meaning that the patient will not need certain oncological treatments.

Before beginning a population-based screening programme, it is important that both the disease and the test meet a series of criteria:

- Characteristics of the disease: It must be a public health problem, with high incidence and mortality. It is necessary to know the patterns of the disease evolution and how to diagnose it. Treatment prior to the appearance of symptoms must be more effective than treatment afterwards, increasing the chances of patient survival.
- Characteristics of the test: It must be a highly sensitive and specific test: simple, comfortable, safe and accepted by the population. It should also be easily reproducible and able to be interpreted by a range of different professionals.

Two of the most widely used tests for the early detection of cancer in women are the Papanicolaou, or Pap-smear, which detects cervical lesions, and the mammography, which detects breast cancer. Both have led to satisfactory results in the reduction of mortality attributed to these cancers.

Another commonly used screening procedure is the Faecal Occult Blood (FOB) test, used for the early detection of colorectal cancer. A positive result which finds blood in the faeces should be followed by a colonoscopy or other precise confirmation tests, in accordance with the organized integral procedures in the health system.

In the previously cited study we recently completed, we found that screening programmes in Europe are heterogeneous. Thus, the target population and the recommended frequency of screening procedures (breast, cervical and colorectal cancer) vary substantially among EU countries (Atun et al, 2009).

5.3 Criteria for diagnostic techniques and procedures

Cancer diagnosis begins with the patient check-up, including the physical exploration and the interview. Both help the doctor to evaluate the risk of cancer that the patient has and to determine the necessary tests to detect it.

As stated previously, tests for early detection are aimed at finding the cancer before it provokes symptoms. If the tests are positive, we generally need other tests to confirm the

diagnosis. Cancer diagnosis should be made with absolute certainty, which usually requires a biopsy. It is also essential to determine the specific type of cancer. When a cancer is detected, other tests are used to determine what stage it is in as well as its potential extension throughout the body and whether it has invaded other organs. This information helps medical specialists to plan the appropriate treatment and determine the prognosis.

Given that cancer is a complex disease, with more than 200 different forms, and considering that its treatment varies according to the typology of the malignant tumour, it is essential to have an accurate diagnosis and characterization of the tumour. This process requires diagnostic and therapeutic competencies and skills which are well-established by scientific oncology societies; we will not go into great detail here, as this analysis oversteps the boundaries and objectives of this study (more information available upon request to the Spanish Society of Medical Oncology, SEOM).

5.3.1. Analysis of diagnostic techniques in Europe

In a 2007 review entitled "Report on the implementation of the 2003 EU Council recommendation," the MEP (Member of the European Parliament) Adamos Adamou signalled wide variations in the organization of cancer diagnostic services (Adamou, 2007). This is illustrated with analysis of the number of CAT scanning machines per million inhabitants in different European countries, from 28.8 machines in Austria to 6.3 in Poland (Table 3). The same inequality is apparent for MRI units (Table 4).

Austria	28.8
Italy	24
Greece	17.1
Germany	14.2
Finland	14
Czech Republic	12.6
Spain	13
France	8.4
Slovak Republic	8.7
UK	5.8
Poland	6.3

Table 3: CAT machines per million inhabitants (OCDE, 2005)

Austria	13.5
Finland	12.8
Italy	11.6
Spain	7.3
Germany	6.0
UK	5.2
Czech Republic	2.4
Greece	2.3
France	2.8
Poland	1

Table 4: MRI machines per million inhabitants (OCDE, 2005).

5.4. Pharmacological treatments and surgical and radiotherapeutic procedures

Most cancer treatments can be divided in four categories: surgery, radiotherapy, chemotherapy and immunotherapy. These treatments can be used alone or in combination. The rationale for each of these alternatives must be devised carefully, requiring constant evaluation and professional follow-up by oncologists.

Just as we observed with diagnostic techniques, there are inequalities in the access to pharmacological treatments and surgical procedures in different EU countries.

Beyond the specific conceptual terminology inherent in this subject, here we will focus on the inequalities detected in Europe.

With regards to curative surgery, there is a relationship between the volume of cancer cases diagnosed and treated in hospital centres and the outcomes obtained (Adamou, 2007). Patients who undergo operations for certain cancers have a higher probability of surviving and not experiencing complication if they are cared for in centres with a high case volume. Unfortunately, poor practise continues, and many patients receive surgery in hospitals with a lower case volume and less expert attention (which is conditioned by the learning curve and practical experience in specific techniques).

In the case of access to radiotherapy, the number of existing radiotherapeutic units is not always in line with those considered to be necessary. Bentzen and colleagues (2005) combined the best available evidence on radiotherapy with national epidemiological data, estimating the optimal radiotherapeutic infrastructure in EU Member States. Figure 2 shows that only a minority of European countries has anywhere near the required number of radiotherapeutic units, and many countries do not even have half of those necessary.

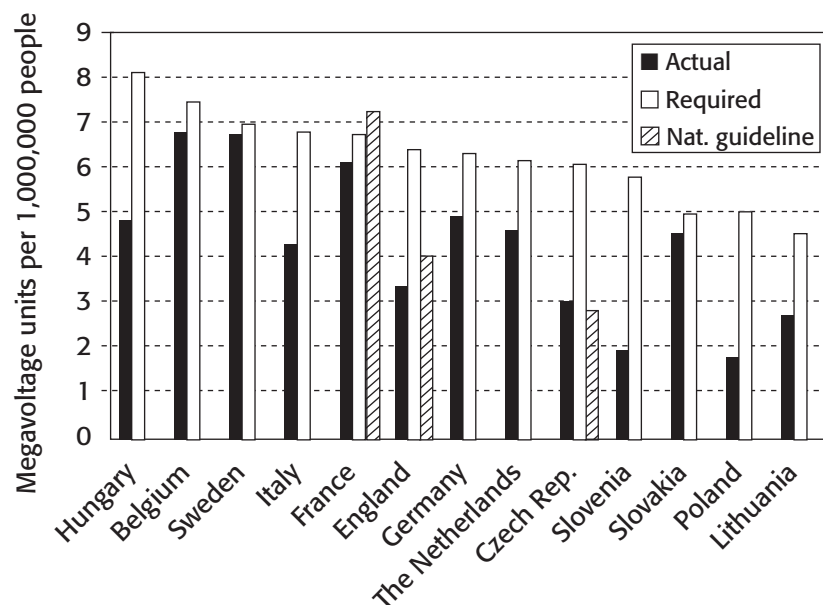


Figure 2. Number of radiotherapeutic units in 13 European countries.

Considerable differences also exist in access to pharmacological treatments in European countries, especially in the availability of innovative drugs. Inequalities are detected in the authorization, approval and commercialization of medicines in different countries.

Many patients are accessing innovative treatments, while other citizens cannot. Furthermore, access to information on clinical trials for many promising molecules is problematic, and in some cases, the recruitment process is less than adequate.

Wilkins and Jönsson (2005) analyzed the incidence of some cancers and the use of certain cancer drugs in different European countries. The study provides evidence on the inequities which exist in access to oncological treatments in Europe. In section 6, we will present additional data and other aspects which characterize this situation.

5.5 Considerations for palliative care

Palliative care is often seen as necessary only in the last phase of the disease, mainly to relieve pain. However, the sphere of this field is much wider, and patients should ideally have access to these services as soon as they begin to experience pain. The field also encompasses psychological and social support for patients and families and care in different settings (home care, hospitals, day care and specialized centres). This should be provided by means of fluid coordination among the multidisciplinary team, which can include doctors (GPs or specialists), nursing staff, psychologists, religious leaders, social workers and volunteers. This modality of care is closely related to cancer, as is reflected by the fact that about 90% of palliative care patients suffer from cancer (Centeno et al, 2007).

This fact helps explain why many countries include palliative care organization within their cancer control structures or programmes. Hungary, Ireland, Latvia, Malta, Poland and Sweden opt for this model, while Austria, Belgium, France, Italy, Portugal, Slovenia, Great Britain and Spain have preferred to formulate an independent national palliative care plan (Martín-Moreno et al, 2008).

In the case of Spain, this plan is articulated through a decentralized strategy led by the National Health System (SNS) and followed at an operative level by the regions. As is the case with overall cancer care, palliative care service provision is highly heterogeneous among and within European countries. On the other hand, the needs of patients are quite similar: a multidisciplinary team with fluid lines of communication open to patients and their families, from diagnosis until after death (in the case of relatives), access to appropriate opioids and other medicines to improve patients' quality of life and services which permit the patient to spend as much time as possible outside the hospital.

The efforts made by patient groups, palliative care associations, and organizations such as the WHO and ESMO (European Society of Medical Oncology) to expand access to the necessary services (including professional multidisciplinary teams and the adequate drugs) should be seconded by relevant politicians and government stakeholders with effective policies. Perhaps the most feasible measures with short- and medium-term improvements are the increased training of GPs in palliative care and a reasonable pol-

icy to regulate access to opioids. Of course, these two measures alone would not be enough to provide quality palliative care to all patients, but they would raise the minimum standard of services dramatically.

5.6. Research

Research on all aspects of cancer is essential to reduce the magnitude of the disease as quickly as possible and for the benefit of generations to come.

Basic research is necessary to understand the genetic and cellular changes which lead to cancer. The genetic revolution provides bigger opportunities to identify people at risk of suffering from cancer and to develop better treatments. Clinical research is also essential to develop better pathways to detect and treat cancer and to improve oncological care (Baselga & Carrato, 2007). Translational research deals with connecting basic research findings to patients' main caretakers; this process is bidirectional, as the clinic can and should orient the issues to resolve through basic research. Epidemiological research is a key complement to the above specialties, as it is used to detect the cancer aetiology. Clinical epidemiological research is used to characterize the prognosis of cases and the effectiveness of interventions (documenting and evaluating the use of new antineoplastic agents), and health services research tackles questions on the most effective organizational model as well as the impact of interventions.

Cancer research is a worldwide responsibility shared by many countries and by some of the best basic, clinical and epidemiological researchers in the world.

However, there are organizational weaknesses in cancer research. High level strategic planning is insufficient, as is the coordination between different financing bodies. The infrastructure for clinical research is inadequate, and there is a lack of support for specific areas of research which could generate significant improvements in service provision.

For the majority of common cancers, the development of the disease depends on complex interactions between genetic variables and environmental factors. Genetic analysis in this area will eventually be able to determine the probability of developing a cancer for individuals, facilitating the introduction of programmes to modify lifestyles and reduce or prevent the disease as well as the adaptation of treatments to personal needs. This approximation to "custom-tailored" medicine would involve the design and application of protocols of prevention and treatment which are best suited to the genetic and molecular singularity of each patient and pathology.

More investigation in each of these areas and a stronger evidence base is important to determine what services will be needed. The type of tests developed and the way that genetic services are developed will vary. Some tests for rare diseases will need a detailed analysis of the genetic structure in specialized laboratories, linked to services with experience in clinical genetics. Tests for the most common tumours may require a high volume of cases and low-cost screening techniques which can be performed in large centralized labs which are close to the patient (with relative considerations for the type of technology which will be developed). It is difficult to accurately predict how genetic services will detect hereditary cancers or how future predisposition tests will be developed.

Despite the lack of some knowledge, patients are already consulting their physicians to try and determine if they have a higher risk of developing cancer due to the presence of a family history. These citizens should have access to the best consultation available as well as to genetic testing (when appropriate) and to vigilance programmes and treatment (if this can reduce any identified risk).

Currently, NICE is developing guides to assist women with a high risk of developing breast cancer. At the moment, these services are poorly articulated. The fact is that genetic services require a strategic framework so that they can be developed in depth. The basis for this framework was recently published by a working group of experts in the *Harper report*, which recommended that genetic cancer services reflect the ideas proposed in the *Calman/Hine report* and that Primary Care be the main sphere of action for the clinical genetics of cancer (Haward, 2006). The report recognized that educational initiatives, development of information technology and referral guides would be necessary to help primary care services in this new and evolving field.

In the study our team carried out with Dr. Rifat Atun (2009), we analyzed different cancer control programmes in Europe. At least nine countries (Belgium, Denmark, England, France, Ireland, Netherlands, Norway, Spain and Switzerland) prioritize and invest in this field of research. England will devote 7 million to implement the National Cancer Research Network in the next five years. In Switzerland, 50 million Swiss francs will be used for cancer research.

Other countries consider specific or sector research actions, with heterogeneous priorities (Atun et al, 2009).

5.7. National cancer plans: outline, principles and organization

Over the course of this study, we were able to identify 17 National Cancer Control Plans (NCCPs) in effect in EU Member States. The four constituent countries of the United Kingdom (England, Scotland, Wales and Northern Ireland) have autonomous plans and were analyzed separately. The other Member States with publicly available plans are Belgium, Denmark, Spain, Estonia, France, the Netherlands, Hungary, Ireland, Italy, Lithuania, Malta, Poland and Portugal.

The differences and idiosyncrasies which make Europe such a heterogeneous continent are also present in the NCCPs. Demographic, epidemiological, political, legal, economic, socio-cultural, ecological and technological (DEPLESET) characteristics have developed independently in each country, where different realities are conditioned by many factors. This makes the comparison of the NCCPs very difficult, although common and disparate features can be identified within a more general context.

NCCPs are multifaceted almost by definition, touching on many areas relevant to the fight against cancer. Service provision aspects affect patients most directly, and these constitute the focus of nearly all the plans: primary and secondary prevention (screening), diagnostic and therapeutic techniques and specialized, palliative and rehabilitative care.

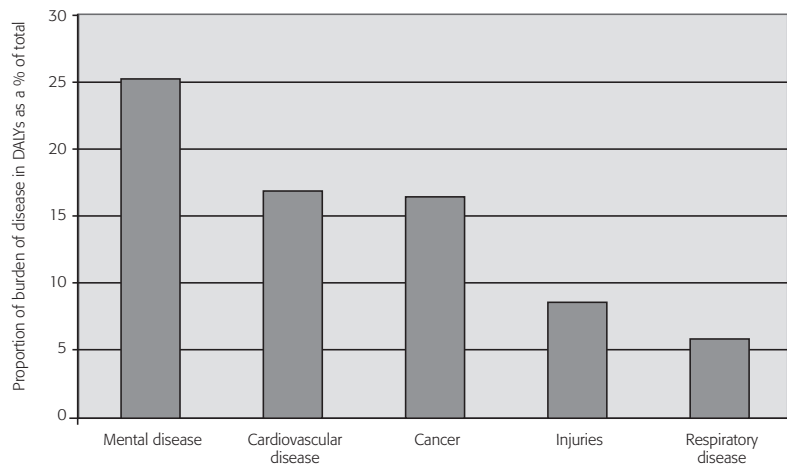
However, the capacity to provide these services also depends on financing, governance (accountability and transparency) and resource generation (financial, material and human). In these aspects, heterogeneity is the rule. An ideal cancer control plan would be capable of channelling state efforts through these three health system functions to guarantee service provision to patients and citizens in a way which is equitable, efficacious, efficient and sensitive to service user needs. By accomplishing this, the ultimate goals of improved health, satisfaction and financial protection would be achieved. In this sense, the model implemented in France is good, as the national cancer control plan is systematically organized, considering not only service provision, but also the financing, resource generation and governance aspects of the plan's execution.

All of the NCCPs have ambitious goals to improve outcomes for patients, but they do not always explain the requisites of governance, financing and resource allocation. For example, just four countries (Belgium, England, France and Poland) detail how they will fund the programme. With respect to health technology, only two countries (France and England) contain specific provisions on providing extra resources for this purpose. The inconsistencies are clear upon observing that all 17 countries set an objective of improving access to innovative technology. On the other hand, we should note the possibility that some countries may handle the financing through other documents (in the health system budget, for example). Thus, the provision of funds outlined in the plans should be interpreted with caution.

6. Cancer burden and indicators for a comparative analysis

Addressing cancer control is by nature a complex endeavour, requiring multidisciplinary action at different levels of the health system. The achievement of “good” health indicators for this disease requires multiple, interrelated interventions, needing adequate financing which is not available in every country. However, financing and service infrastructure is not enough. It is important that quality be guaranteed and that patients access these services in a timely manner.

In the EU-25, cancer is the third highest disease burden after mental and cardiovascular disease, as measured by Disability Adjusted Life-Years (DALYs) (Figure 3).



Source: WHO, 2004.

Figure 3: Disease burden (DALYs) in EU-25 in 2002.

Between 1994 and 2004, a decrease of 9% in the Standardized Death Rate (SDR) was observed. However, this average rate hides the enormous inequalities existing within Europe.

The incidence of cancer has risen by around 50% since the 1950s, and it remains an important challenge of Public Health in Europe.

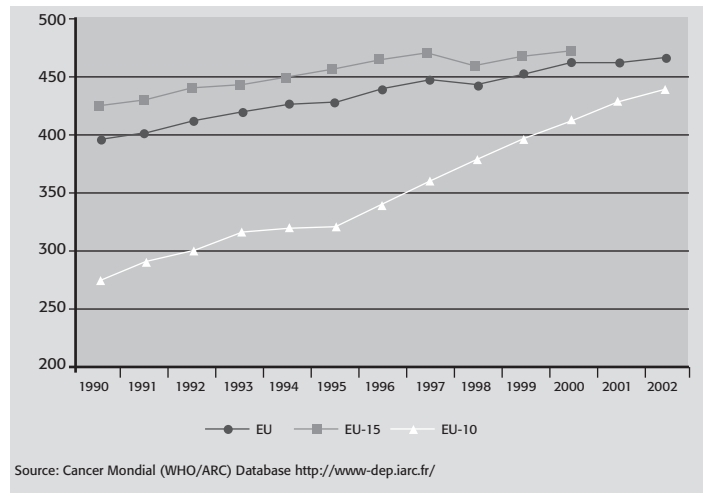


Figure 4: Cancer incidence in the EU-15 and the EU-10.

In 2004, 2.9 new cancers were diagnosed in the EU-25. In the same year, this disease caused 1.7 million deaths, a sharp rise from that observed just four years earlier (1.1 million deaths).

By 2020, WHO predicts, the number of cases may rise up to 25%, reaching 3.4 million new diagnoses. Likewise, the number of deaths is expected to rise by 23%. However, despite the magnitude of the problem, cancer still does not receive the attention it deserves.

For example, the SDR in the EU-15 has fallen 10% (from 196 to 178 per 100,000 inhabitants), but in the same period (1994-2004), only a slight decrease is observed in the EU-10 (3%, from 227 to 221 per 100,000 inhabitants) (Figure 5).

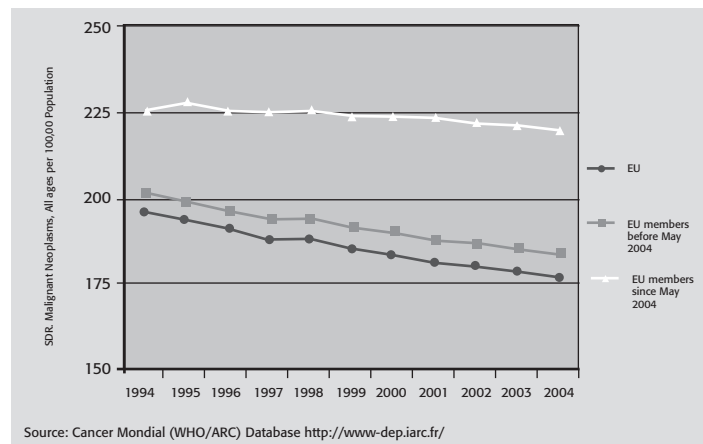


Figure 5: Age standardized death rate due to malignant tumours in the EU

This difference in rates between the EU-15 and the EU-10 reflects a great difference between countries (figures 6 and 7). In 2004, the disparity in SDR was around 25%.

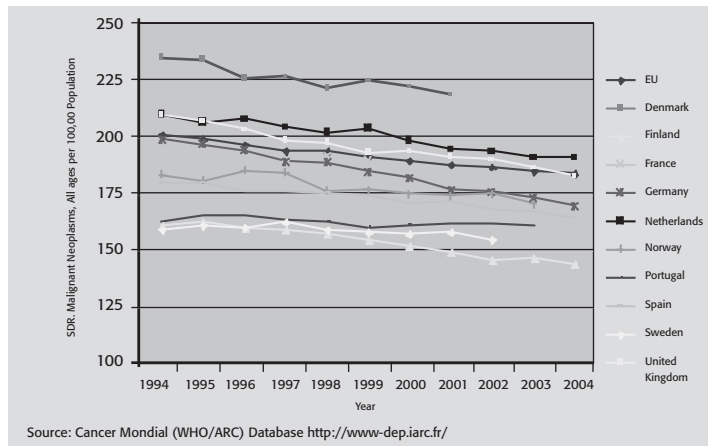


Figure 6: SDR, malignant tumours in the EU-15

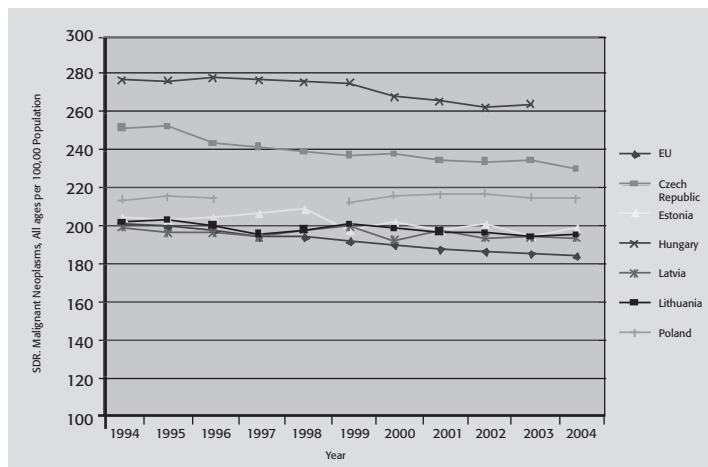


Figure 7: SDR, malignant tumours in the EU-10

Although there have been objective improvements in cancer care in Europe over the last decade, with greater availability of new treatments, SDR figures show that Europe is still lagging behind the USA (Figure 8). While SDR between men and women is converging in the USA, there is still a 12% difference between genders in Europe.

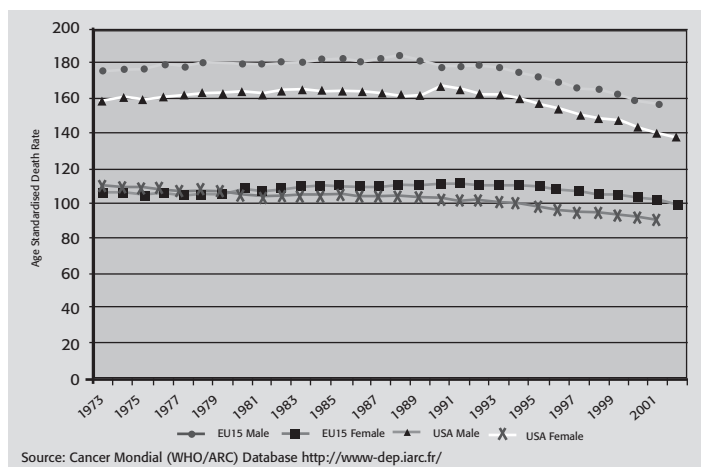


Figure 8: Standardized death rate attributed to cancer in Europe and the USA

6.1. Comparing indicators among EU Member States

The EUROCARE-3 study analyzes the five year survival rates of 1.8 million adults and 24,000 children in 20 European countries who were diagnosed with cancer between 1990 and 1994. The results reveal sharp differences in survival for different types of tumours in different countries: for example, five year survival is 94% for lip cancer, but just 4% for pancreatic cancer. Table 5 summarizes 5-year survival data for European adults.

Five Year Survival	Men		Women		Total
	Types of Cancer	Percentage of all cancers	Types of Cancer	Percentage of all cancers	
≤80%	2	2	4	5	4
60-79%	9	31	7	45	38
40-59%	10	25	13	23	24
20-39%	9	10	7	12	11
<20%	8	32	8	14	23
Total	38	100	39	100	100

Source: EUROCARE-3 Study

Table 5: Five-year survival according to cancer type in European adults

For all types of cancer, the survival rate worsens with age: mortality rates for adults over 75 are twice those of adults aged 15-44. Women also present better survival rates than men for comparable cancers.

Across Europe, the differences in survival rates are evident, with a clear gradient from north to south and east to west (Figure 9).

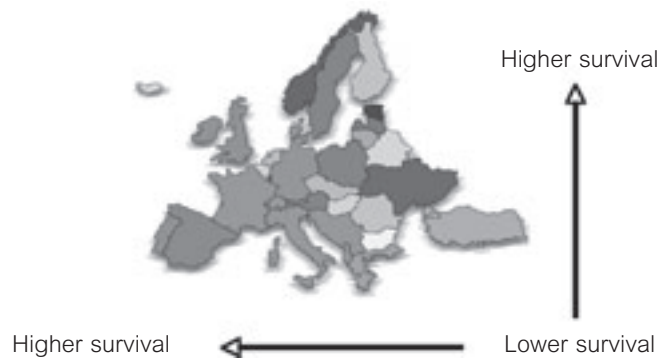


Figure 9. Comparative map of the survival gradient of cancer patients in the European Union

Compared to the five most western European countries, survival is low in the five most eastern countries. This statement holds true for both men and women.

Atun and colleagues (2009) highlight the current imbalances in the overall cancer burden between European countries (Tables 6-8). For example, while the standardized incidence rate for colorectal cancer in European men is 55.4 per 100,000 inhabitants, this figure varies from 13.6 in Albania to 106 in Hungary. Similarly, overall incidence for breast cancer in Europe is 94.3 per 100,000 inhabitants, but this ranges from 51.6 in the Republic of Moldova to 137.8 in Belgium (Ferlay et al, 2007).

	Stomach (C16)		Colon and rectum (C18-21)		Lung (C33-34)		Breast (C50)	Uterus (C53-55)	Prostate (C61)	All cancers (C00-97/C44)	
	M	F	M	F	M	F				M	F
Austria	14.3	8.8	57.6	30.9	54	22.3	91.5	29.1	134.6	444.6	294.6
Belgium	10.3	3.8	53.3	34.3	93	22.9	137.8	32.7	160.8	543.3	343.1
Cyprus	16.2	8.7	41.2	29	66.1	9.5	88.4	23.3	74.6	373.3	269.6
Czech Republic	17	8.2	94.4	46	78.9	22.9	84.8	44.8	76.1	484	346
Denmark	9.1	4.5	61	48	65	48.7	122.6	28.7	80.3	442	413.6
Estonia	33.4	17.5	50	33.9	80.3	13.2	71.1	40.5	65.3	411.1	298.5
Finland	11.8	6.8	39.2	29.4	45.8	14.7	119.8	25.4	149.7	406	314
France	12	4.5	59.8	36.8	75.5	15	127.4	22.2	133.5	527.5	329
Germany	17.6	8.5	70.2	45.1	61.2	20.8	121.2	26.4	113	451.4	333.7
Greece	18.9	8.9	31	21.3	88.7	12.7	81.8	21.3	81	423.9	259.5
Hungary	26.6	10.9	106	50.6	119.3	42.4	118	51.6	85.6	598.8	408.7
Ireland	14.7	7.6	65.2	36.9	60.2	34.1	131.4	28.8	182	513.6	382.2
Italy	22.1	11.1	52	30.3	84.7	15.6	105.3	25.1	108.4	499.7	323.6
Latvia	28.6	14.6	47	28.7	82.5	10.2	64.8	39.7	85.7	419.4	265.2
Lithuania	36.8	17.9	53.1	32.5	91.9	9.9	68.7	63.4	109.7	500.1	320.5
Luxembourg	14.8	5.4	61.9	36.1	69.8	16.3	116.9	20	93.6	440	312.5
Malta	13.7	7.7	51.5	36.2	43.9	6.5	94.5	25.7	68.8	322.8	279.5
The Netherlands	13.4	6.3	61.2	43.9	63.4	32.5	128	22.1	98.4	435	355.4
Poland	34.8	8.8	43.1	27.7	103	28.6	74.1	37.9	51	443.2	311.9
Portugal	28.9	15.4	58.9	30.9	44.5	11.7	103.5	33.1	101.2	427.8	289.4
Slovakia	25.2	10.3	87.1	42.6	71.7	11.6	69.7	40	51.2	434.4	288.4
Slovenia	27.5	11	69	36.3	75.6	22.9	87.5	42.8	70.2	438.5	319
Spain	15.9	8.4	54.4	25.4	68.3	13.8	93.6	24.5	77.2	416.9	263.4
Sweden	9.2	4.9	49.2	37.4	28.6	23.8	125.8	31.7	157.2	418.2	361.3
United Kingdom	14.3	5.7	54.9	34.8	57.1	34.6	122.2	25.2	107.3	410.5	348.9
European Union (EU25)	18.2	8.1	59	35.6	71.8	21.7	110.3	28.3	106.2	463	325.5
Iceland	14.1	6.4	50.2	36.8	40.6	45.6	121.6	27.3	140.5	429.2	383.6
Norway	11.2	5.4	66.4	51.2	53.8	33.7	109.1	34.1	133.2	458.7	381.5
Switzerland	16.4	3.9	79.1	55.6	52.7	26.2	126.5	29.2	137	493.6	369
EEA and Switzerland	18.1	8	59.4	36.1	71.3	21.9	110.5	28.3	106.9	463.4	326.7
Bulgaria	25.5	13.6	49.6	31.3	67.3	11.5	74	53	36	336.6	269
Romania	30.6	13	40.7	25.1	81	15.4	61.2	64.1	32.2	371.8	279.1
Albania	59.4	21.5	13.6	21.4	95	26.2	82.4	22.2	62.1	444.7	312.1
Belarus	45.1	20.4	42.8	29	86.5	6.7	55.5	39.3	38	380.7	251.4
Bosnia Herzegovina	37.8	14.4	34.6	27.3	76	17.5	79	43.8	42	369.4	287
Croatia	27.5	8.6	57	36.9	69.3	13.9	79.4	25.9	67.8	421.3	244.4
Macedonia	37.3	16	49.4	30	71.8	8.9	85.4	49.1	31.9	363	280.2
Republic of Moldova	28.3	14.4	38.7	26.7	63.7	12.5	51.6	45	18.7	331.2	238.3
Russian Federation	47.8	21.1	46.5	33.9	92.7	11.2	67.3	39.2	30.1	389	261.9
Serbia and Montenegro	16.9	5.9	41	30.4	61.5	17.3	69.2	60	32.3	300.10	268.5
Ukraine	37.1	15.4	41.7	27	74.6	9.5	53.3	40.9	26.7	333.6	227.4
Europe	24.8	11.6	55.4	34.6	75.3	18.3	94.3	33.5	86.7	439.7	303

Table 6: Estimated incidence rate by cancer type, country and gender.

	Stomach		Colorectum		Lung		Soft-tissue		Skin melanoma		Breast		Cervix		Corpus uteri		Prostate	
	RS	95% CI	RS	95% CI	RS	95% CI	RS	95% CI	RS	95% CI	RS	95% CI	RS	95% CI	RS	95% CI	RS	95% CI
Austria	29.2	26.9-31.6	59.3	57.8-60.9	14.1	13.0-15.3	57.5	51.1-64.7	83.3	80.8-85.9	81.4	79.9-82.8	64.2	60.4-68.2	76.1	73.1-79.2	88.9	87.6-90.3
Belgium	32.7	30.2-35.4	60.7	59.5-62.0	16.3	15.4-17.2	65.3	59.5-71.7	81.4	78.8-84.2	79.7	78.6-80.9	66	62.6-69.6	79.5	76.9-82.1	NA	NA
Czech Republic	NA	NA	45.2	41.0-49.9	NA	NA	NA	NA	75.1	66.6-84.7	68.9	62.9-75.4	59.8	53.0-69.6	79.5	76.9-82.1	NA	NA
England	16.9	16.3-17.6	51.8	51.4-52.2	8.4	8.1-8.6	57.5	55.4-59.6	84.8	84.0-85.5	77.8	77.4-78.2	58.6	57.3-59.9	75.7	74.7-76.8	NA	NA
Finland	27.3	24.8-29.4	59.4	57.8-61.1	9.2	8.2-10.3	58.5	53.1-64.4	84.8	82.0-87.1	85.7	84.4-87.0	65.8	60.9-71.0	79.8	77.3-82.4	84.3	82.7-85.9
France*	20.7	13.9-30.9	59.9	55.5-64.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Germany	31.4	25.3-39.1	62.2	57.7-65.0	14.7	12.1-17.7	NA	NA	89.4	82.1-97.3	78.2	74.5-82.1	55.5	47.4-65.1	82.7	75.0-89.1	85.3	80.7-90.2
Iceland	NA	NA	58.9	52.6-65.9	16.8	12.8-22.2	NA	NA	83.6	72.1-96.9	93.4	87.4-99.8	70.6	61.1-81.6	69.7	56.5-86.1	84.4	79.6-89.4
Italy	33.2	32.1-34.3	59.4	58.6-60.1	13.4	12.8-14.0	61.8	58.3-65.6	85.3	84.0-86.6	83.7	83.1-84.4	67	64.7-69.4	77.4	75.7-79.0	84	83.5-86.4
Malta	NA	NA	51.5	45.8-57.9	4.6	2.7-7.8	61	49.3-75.5	94.8	84.5-106.4	76	70.7-81.8	46.5	32.5-66.6	76.5	66.7-87.7	NA	NA
The Netherlands	20.1	18.1-22.4	58.5	57.1-57.9	12.9	12.1-13.8	59.8	54.4-65.6	90	87.9-92.1	83.1	81.8-84.4	69.2	64.7-73.9	79.3	76.2-82.6	81.7	79.3-84.2
Northern Ireland	18.9	15.6-22.8	54.5	52.1-57.0	10.7	NA	59.2	49.2-71.3	91.4	87.5-95.5	79.5	77.0-82.1	63.5	56.6-71.2	70.2	64.4-76.6	NA	NA
Norway	24.7	22.1-27.5	59.5	58.2-60.9	11.2	10.3-12.3	61.8	54.2-70.6	86.8	85.0-88.6	84.1	82.6-85.5	67.5	63.7-71.4	86.1	83.2-89.1	79	77.5-80.6
Poland	20	17.7-22.6	46	44.0-48.0	14	12.8-15.3	60.4	51.3-70.8	65.8	61.5-70.4	73.9	71.7-76.1	56	52.6-59.5	74.5	70.3-78.8	70.7	66.5-75.2
Scotland	16.6	14.9-18.6	54.1	52.8-55.4	8.2	7.5-8.9	55.9	49.3-63.3	90.7	88.6-93.0	77.3	76.0-78.6	61	57.3-65.0	76.6	73.1-80.1	71	68.8-73.5
Slovenia	23.2	20.5-26.2	50.5	48.2-53.0	9.9	8.6-11.3	64	53.7-76.2	79.2	75.0-83.2	75.3	72.7-78.1	65.2	60.8-69.9	78.7	74.3-83.3	63.3	59.2-67.6
Spain	31.8	25.9-39.2	61.5	57.7-65.5	12.2	10.1-14.8	50.7	35.0-73.5	85.9	79.0-93.5	82.8	79.8-85.8	60.4	48.6-75.0	73.6	66.4-81.5	NA	NA
Sweden	21.5	19.8-23.5	59.8	58.8-60.9	13.9	13.0-14.9	62.1	59.2-66.3	90.3	89.1-91.5	86.3	85.4-87.2	66.7	63.8-69.6	83.9	82.2-85.7	82.5	81.5-83.6
Switzerland	25.6	15.8-29.8	63.8	61.4-66.2	15.3	13.6-17.2	72	61.9-83.7	89.7	87.1-92.4	84.5	82.6-80.5	66.8	60.0-74.5	79.2	74.5-84.3	87.3	84.6-90.1
Wales	18.3	15.8-21.1	53.3	51.6-55.1	10.4	9.1-11.8	58.6	51.4-66.8	78.3	74.8-81.9	78.4	79.7-80.0	52.6	47.8-57.8	75.7	71.7-79.9	71.8	69.1-74.5
EUROCARE-4 mean	24.9	23.7-26.2	56.2	55.3-57.2	10.9	10.5-11.4	61.2	58.3-64.2	86.1	84.3-88.0	79	78.1-80.0	60.4	57.7-63.2	78	76.2-79.9	77.5	76.5-78.6
USE SEER-13 registres	25	23.8-26.2	65.5	64.9-66.1	15.7	13.3-16.1	65.1	62.8-67.5	92.3	91.5-93.1	90.1	89.6-90.5	65.8	64.1-67.6	82.3	81.2-83.4	99.3	98.9-99.8

RS: relative survival. NA: not available (due to missing data in one or more age classes impeding the age standardisation). SEER: Surveillance, Epidemiology and End Results.
 * Data from France was represented by the digestive cancer registry of Cote d'Or.

Table 7: Five-year relative survival (%) by type of cancer diagnosed (2000-02) and country.

		Breast (95% CI)	Colon			Rectum		Colorectum		Prostate 95% CI)
			Women	Men	Women	Men	Women	Men	Women	
Africa	Algeria (Sétif)	38.8 (31.4-46.2)R	11.4 (0.7-40.9) R	30.6 (9.5-56.1) R	25.9 (11.4-43.7)R	18.2 (6.6-34.6) R	22.5 (10.6-37.7) R	22.6 (11.2-36.7)R	21.4 (8.7-38.9) R	
America (Central and South)	Brazilian registries	58.4 (52.7-64.6)	33.1 (24.2-45.3)	32.7 (26.1-40.8)	49.3 (34.8-69.8)	38.4 (27.3-53.9)	47.5 (37.5-59.6)	43.5 (35.7-53.1)	49.3 (43.6-55.8)	
	Cuba	84.0 (82.9-85.2)	59.3 (55.8-63.1)	61.4 (58.3-64.5)	59.2 (55.1-63.7)	62.8 (58.6-67.4)	59.5 (56.8-62.5)	62.0 (59.5-64.6)	69.7 (67.1-72.3)	
America (North)	Canadian registries	82.5 (81.9-83.0)	56.1 (55.8-57.2)	58.7 (57.7-59.7)	53.1 (51.5-54.6)	58.7 (57.0-60.4)	55.3 (54.4-56.2)	58.9 (58.0-59.8)	85.1 (84.4-85.7)	
	US registries	83.9 (93.7-84.1)	60.1 (59.6-60.5)	60.1 (56.3-60.5)	56.9 (56.3-57.5)	59.8 (59.2-60.4)	59.1 (58.8-59.5)	60.2 (59.8-60.5)	91.9 (91.7-92.1)	
Asia	Japanese registries	81.6 (79.7-83.5)	63.0 (61.3-64.8)	57.1 (55.5-58.8)	58.2 (55.9-60.5)	57.6 (55.2-60.1)	61.1 (59.7-62.5)	57.3 (55.9-58.6)	50.4 (46.3-54.9)	
Europe	European registries	73.1 (72.9-73.4)	46.8 (46.3-47.2)	48.4 (48.0-48.8)	43.2 (42.7-43.7)	47.4 (46.9-48.0)	45.5 (45.0-45.7)	48.1 (47.7-48.4)	57.1 (56.7-57.6)	
	Austria (Tirol)	74.9 (71.9-78.1)	57.0 (51.5-63.0)	59.3 (54.3-64.7)	45.8 (39.1-53.8)	45.2 (37.6-52.8)R	52.7 (48.2-57.6)	55.1 (50.8-59.7)	86.1 (82.9-89.4)	
	Czech Republic (West Bohemia)	62.9 (58.9-67.1)	37.7 (33.0-43.0)	37.6 (33.3-42.5)	29.3 (25.2-31.1)	39.1 (33.8-45.2)	38.3 (30.5-37.6)	38.3 (34.9-42.0)	50.7 (44.4-58.0)	
	Denmark	73.6 (72.5-74.7)	44.7 (42.7-46.7)	48.6 (46.8-50.4)	43.4 (41.2-45.6)	45.9 (43.6-48.3)	44.2 (42.7-45.7)	47.7 (46.3-49.2)	38.4 (36.3-40.6)	
	Estonia	61.3 (57.9-64.8)	38.5 (33.7-44.1)	39.1 (35.3-43.2)	33.6 (28.4-39.7)	30.2 (26.0-35.1)	36.4 (32.8-40.8)	35.5 (32.6-38.6)	56.5 (52.3-60.9)	
	Finland	80.2 (79.0-81.4)	54.6 (51.6-57.8)	54.7 (52.5-57.1)	49.8 (46.8-53.0)	52.6 (49.7-55.6)	52.5 (50.4-54.7)	54.0 (52.2-55.8)	62.9 (60.6-65.2)	
	French registries	79.8 (78.2-81.4)	57.4 (54.4-60.7)	60.1 (57.2-63.2)	52.8 (49.3-56.7)	63.9 (60.1-67.8)	55.6 (53.3-58.1)	61.5 (59.2-64.0)	73.7 (70.5-77.1)	
	Germany (Saarland)	75.5 (73.3-77.8)	52.0 (48.2-56.0)	56.2 (52.9-59.7)	47.8 (43.0-53.1)	52.5 (48.1-57.3)	50.1 (47.2-53.2)	55.0 (52.3-57.9)	76.4 (72.7-80.4)	
	Iceland	79.0 (73.3-85.0)	48.1 (39.0-59.3)	54.9 (45.2-66.6)	52.1 (45.2-71.4)R	48.4 (31.9-64.6)R	49.5 (41.0-59.9)	54.0 (45.9-63.6)	69.7 (62.2-78.1)	
	Ireland	69.6 (66.1-73.3)	49.1 (44.0-54.8)	48.5 (43.7-53.8)	41.1 (35.0-48.2)R	52.5 (44.6-60.3)R	46.0 (42.0-50.8)	50.0 (45.9-54.5)	62.8 (58.0-68.0)	
	Italian registries	79.5 (78.8-80.3)	52.4 (51.1-53.8)	53.8 (52.6-55.0)	47.4 (45.7-49.2)	50.4 (48.6-52.3)	50.7 (49.7-51.8)	52.7 (51.7-53.8)	65.4 (63.7-67.2)	
	Malta	73.5 (66.7-81.1)	38.0 (25.9-50.7)R	58.0 (46.5-72.4)	34.7 (20.8-49.9)R	52.5 (31.9-71.4)R	35.7 (27.0-47.1)	55.5 (46.1-66.8)	44.3 (32.3-56.9)R	
	The Netherlands registries	77.6 (76.6-78.6)	52.7 (50.1-55.4)	55.4 (53.2-57.7)	55.0 (51.6-58.6)	54.5 (51.3-57.9)	53.6 (51.5-55.7)	55.1 (53.3-57.0)	69.5 (67.2-71.9)	
	Norway	76.3 (75.1-77.6)	50.8 (48.7-53.0)	54.4 (52.5-56.3)	51.3 (48.9-53.9)	56.9 (54.3-59.6)	51.1 (49.5-52.8)	55.3 (53.8-56.9)	63.0 (60.9-65.1)	
	Polish registries	62.9 (60.6-65.3)	28.5 (25.3-32.1)	30.9 (28.0-34.2)	28.4 (24.7-32.7)	30.2 (26.7-34.1)	28.6 (26.1-31.5)	30.6 (28.3-33.0)	37.1 (33.0-41.6)	
	Slovakia	57.9 (55.9-59.9)	40.1 (41.7-42.7)	27.6 (41.7-46.7)	27.6 (25.5-29.8)	32.3 (29.9-34.8)	34.0 (32.3-35.8)	38.7 (37.0-40.5)	45.7 (42.7-49.0)	
	Slovenia	66.3 (63.8-68.9)	37.3 (33.5-41.5)	39.8 (36.3-43.6)	34.0 (30.5-38.0)	35.6 (32.1-39.5)	35.7 (33.1-38.5)	37.7 (35.3-40.4)	43.7 (39.4-48.4)	
	Spanish registries	77.7 (76.4-79.0)	54.2 (52.2-56.3)	56.3 (54.2-58.4)	50.0 (47.7-52.4)	51.8 (49.1-54.6)	52.5 (51.0-54.1)	54.7 (53.1-56.4)	60.5 (57.6-63.6)	
	Sweden	82.0 (81.2-82.7)	52.5 (50.9-54.2)	54.8 (53.3-56.3)	53.0 (51.2-55.0)	58.2 (56.3-60.2)	52.8 (51.6-54.1)	56.2 (55.0-57.4)	66.0 (64.7-67.3)	
	Swiss registries	76.0 (74.3-77.7)	-	-	-	-	-	-	-	
	UK	69.7 (69.4-70.1)	43.5 (42.9-44.1)	44.4 (43.8-45.0)	40.6 (39.9-41.3)	45.3 (44.5-46.1)	42.3 (41.8-42.8)	44.7 (44.3-45.2)	51.1 (50.4-51.8)	
	UK - England (national)	69.8 (69.5-70.2)	43.4 (42.8-44.1)	44.3 (43.7-45.0)	40.4 (39.6-41.2)	45.4 (44.6-46.3)	42.2 (41.7-42.7)	44.7 (44.2-45.3)	50.9 (50.1-51.7)	
	UK - Northern Ireland	72.0 (68.9-75.3)	47.3 (42.8-53.0)	49.0 (44.3-54.3)	48.2 (41.6-55.8)	43.8 (37.0-51.9)	47.8 (43.7-52.3)	47.8 (43.8-52.2)	54.0 (48.7-59.9)	
	UK - Scotland	70.6 (69.5-71.8)	45.9 (44.0-47.9)	47.8 (46.1-49.6)	42.3 (39.9-44.9)	46.9 (44.4-49.6)	44.6 (43.1-46.2)	47.7 (46.2-49.2)	54.2 (52.0-56.3)	
	UK - Wales	67.1 (65.8-68.4)	39.9 (37.5-42.6)	38.0 (35.7-40.4)	39.5 (36.8-42.3)	41.9 (38.0-45.2)	39.8 (38.0-41.8)	39.3 (37.5-41.3)	47.9 (44.9-51.1)	
	Oceania	Australia (national)	80.7 (80.1-81.3)	57.8 (56.8-58.8)	57.7 (56.7-58.6)	54.8 (53.6-56.1)	59.2 (57.8-60.6)	56.7 (55.9-57.5)	77.4 (74.7-81.9)	77.4 (76.6-78.2)

R: raw (not age-standardised) survival estimate.

Table 8: Five-year relative survival (%) for certain cancers, by different countries worldwide

6.2. Comparison of expenditure in health and specifically in cancer care

Current, reliable information on the resources dedicated to cancer control in each country (such as the percentage of health expenditure devoted to cancer, number of specialists and facilities for treatment) are not available. This is one of the pending challenges emerging from this project: the need to obtain objective data in this field. Wilking and Jönsson (2005) calculated the percentage of resources devoted to cancer care by extrapolating data from total health system expenditure for 19 European countries belonging to the OECD (Organization for Economic Co-operation and Development). They estimated that in a one year period from 2002-2003, a total of 54 billion euros was used on cancer control in those countries. The overall *per capita* expenditure was 120€, although this ranged from 34€/person in Poland to 191€/person in Norway.

In Europe, between 4.1-10.6% of total health resources are devoted to cancer (Figure 10).

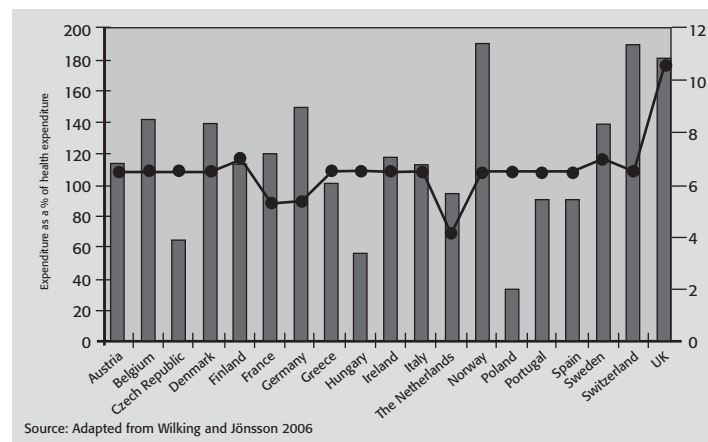


Figure 10: Percentage of health expenditure devoted to cancer care

Studies in different European countries show that care for hospitalized patients account for around 60-83% of total cancer care costs, while outpatient care consumes 7-16% of the resources and 4-11% is spent on treatment. In 2002-03, the *per capita* expense of antineoplastic drugs ranged from 4€ in Poland to 16€ in France, with the European average standing at 11€. In absolute terms, this represents a total annual cost of 5.1 million euros, or 3-4% of the total cost of pharmaceuticals in Europe.

There is an asymmetry between the resources dedicated to cancer care and those which are really required. While cancer represents 16.7% of the total disease burden, just 4.1-10.6% of resources are directed to that end.

As explained earlier in this report, cancer management is complex, and many factors influence survival rates and hence, the management of the disease. Socio-economic differences are among the factors which have been documented the most (Kogevinas & Porta, 1997), inspiring many theories on how these differences influence cancer survival and mortality, examining, for example, the tumour itself (stage, diagnosis and aggressiveness), the patient (educational level) and the health system (possible de-

lays in diagnosis and treatment). Reviews (Woods et al, 2006) on the origins of socio-economic inequalities in cancer conclude that although tumour stage at diagnosis is an important variable, differences in what treatment is received according to social group also influences the evolution of the disease. Evidence shows that the socio-economic level of patients influences their access to the health system and the treatment they receive. For example, patients in southwest England have higher empirical possibilities of receiving oncological surgery for liver, colorectal and breast cancer (Pollock & Vickers, 1998). In the UK, breast cancer patients who live in economically depressed areas are more likely to receive a mastectomy (as opposed to a more conservative surgery) than women living in wealthier areas.

A recent study analyzed the relationship between cancer survival and inputs such as health system expenditure, availability of new technologies (such as CAT or MRI) and human resources (total number of specialized doctors). The study found a strong relationship between total health expenditure in a given country and cancer survival rates for many types of cancers (with the exception of liver, cervical and lung cancer). The same relationship was observed for GDP. There is also a positive correlation between the number of CAT units and survival (although the number of CAT units is not related to total health expenditure). The number of MRIs in use was also found to be significant, although to a lesser degree. Interestingly, there was not a significant relationship between the number of oncologists and cancer survival (Quaglia et al, 2005).

Other studies which examine the connection between survival and the percentage of GDP devoted to health care have demonstrated a statistically positive relationship for the 5-10 year survival for 14 types of cancer in men and women. (Evans & Pritchard, 2000; Micheli et al., 2003).

The picture which emerges seems to point to an apparently positive relationship between total health expenditure (including expenditure in public health) and survival at all levels studied.

6.3. Criteria for decision-making in the allocation of resources for cancer control in different health systems: description of criteria and organization of the approval process for new pharmaceuticals according to country

Total sales in oncological pharmaceuticals have been increasing, from 840 million euros in 1993 to 6.17 billion euros in 2004, and much of this rise was caused by the purchase of innovative drugs. However, once again, the uptake of these drugs varied by country.

For example, Figure 11 shows how Trastuzumab (which has become an important drug for treating advanced breast cancer) was introduced in Norway in 1998, but it took two years to be authorized in the UK and three in Poland.

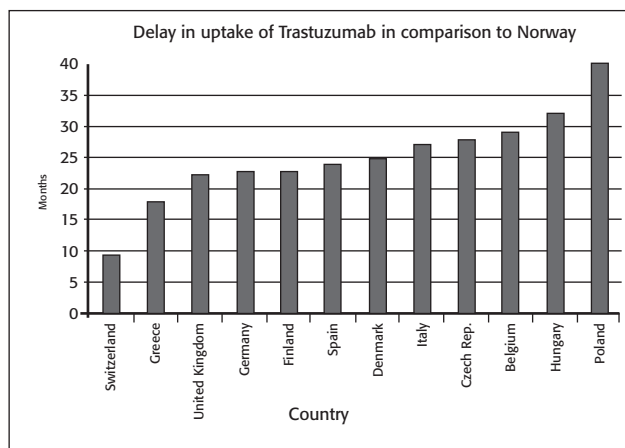


Figure 11. Elaborated from data in the report *A pan-European comparison regarding patient access to cancer drugs* (Karolinska Institutet).

A similar situation occurred in the case of colorectal cancer, where the introduction of an innovative drug (Oxaliplatin as an adjuvant to 5-Fluorouracil) was delayed by up to 7 years (Figure 12).

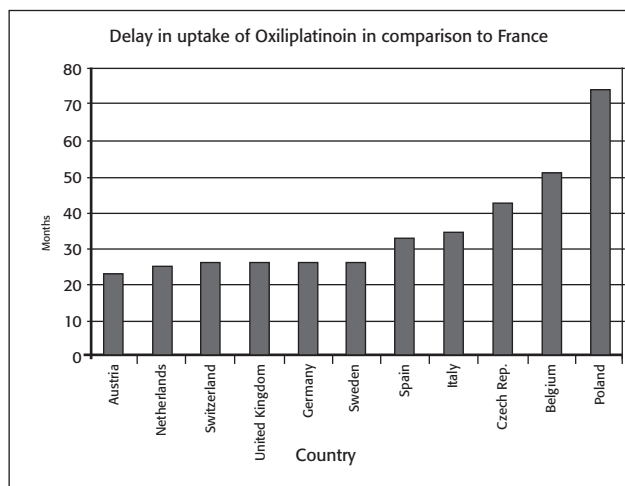


Figure 12. Elaborated from data in the report *A pan-European comparison regarding patient access to cancer drugs* (Karolinska Institutet).

The same situation occurred for Gemcitabin, which treats liver cancer: the uptake in different countries ranged from four months to three years (Figure 13). Similar examples exist for drugs used to treat leukaemia, lymphoma and gastrointestinal tumours. In general, Austria and Spain tend to introduce these drugs the fastest, followed by Finland, France, Germany, Ireland, Italy and Switzerland. At the other end of the spectrum are the Czech Republic, Hungary, Norway, Poland, and the UK, countries which tend to lag behind other Member States in the uptake of innovative cancer drugs.

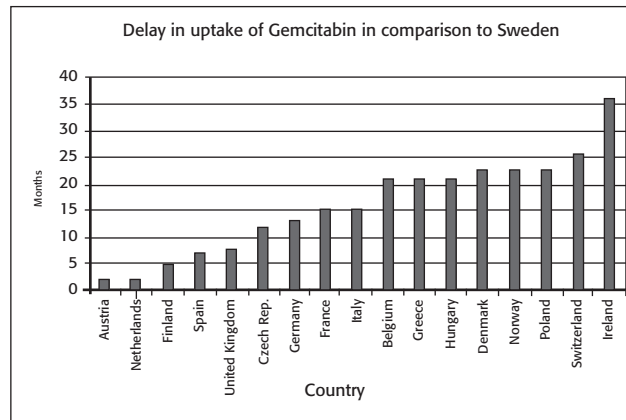


Figure 13. Elaborated from data in the report *A pan-European comparison regarding patient access to cancer drugs* (Karolinska Institutet).

These delays are usually due to the time needed by health authorities to approve the reimbursement of new drugs, a process which might include health technology assessments, cost-effectiveness studies and administrative procedures.

Currently, many public health systems decide which drugs to reimburse by using analyses to determine the relative utility or performance of an innovative drug versus another which is already in the system. In the UK, the National Institute for Clinical Excellence (NICE) is an independent organism which makes recommendations to the NHS regarding the best and most cost-effective methods available. Their decisions are often used as references in this type of evaluation.

For most health technologies, there is no ideal evidence generated by randomized clinical trials. To date, such trials are not common for non-pharmacological therapies. In the case of pharmaceuticals, the trials carried out for licensing are subject to significant restrictions with regard to supporting decisions on reimbursement.

Two ways to tackle this challenge can be identified:

- a) Present a methodology which provides an explicit method to integrate decisions made regarding the incorporation of a certain technology as well as a channel to demand more information from additional investigations. It is important to stipulate how to deal with the inevitable uncertainty in the data used in the analysis and when additional investigations should be requested.
- b) Consider the analysis of decisions as a tool which can be used to respond to the parameters that determine the reimbursement of a treatment, establishing which data is appropriate for decision-making and how these decisions should be made.

One possible model is that in which the appropriateness of each alternative intervention is calculated according to information with some degree of uncertainty, such as the clinical effects, health-related quality of life and the use of resources. Each *input* can present a distinct degree of volume and quality of information, which is reflected in the probability distributions assigned to each estimate in accordance with what is called the fuzzy distribution

model. A computer simulation is carried out to reflect the uncertainty implicated in adopting a particular decision, and this results in an “appropriateness” value.

When a technology with uncertain results is adopted based on the existing information, there may be concrete cases in which the decision is made is incorrect. Because there are costs associated with this error, the expected cost of uncertainty is usually determined by the probability that a decision based on the information will be erroneous or partially so, with the corresponding consequences. The information is valuable because it reduces the chances of error and therefore, the expected costs of uncertainty which surround the decision decrease. The expected costs of uncertainty are denominated the Expected Value of Perfect Information (EVPI). Summarizing the algorithm, if the EVPI for the current population and future patients exceeds the expected costs implied in further research, we consider that more information is needed to make the decision.

These considerations on the appropriateness of a particular treatment for reimbursement first appeared in Australia and Canada before spreading to the USA and other Western nations.

In the UK, these evaluations of technology are carried out by NICE, whose activities stand out as a reference in Europe. Their studies are often used as tools to justify the lack of reimbursement for a drug, and their proponents cite the need to control health system expenditure.

The importance of a controlled randomized clinical trial as a source of data for decision-making has been widely accepted. However, for many technologies, these data are scarce or non-existent. Until now, most trials have been carried out because of regulatory and registry demands, and the main criteria tested have been safety and efficacy. However, the design of these trials often does not allow us to evaluate the profitability of the potential adoption of the treatment, a criteria which is fundamental when making a decision on reimbursement.

In synthesis, there is in fact a certain technical consensus on the need to compare new technology with that which already exists, with results for the general population and taking into account factors that allow analysis of the profitability (over an extended period of time). In this sense, the methodological line emerging with regard to establishing a framework for action, which facilitates objectivity in decision-making, is important.

By analyzing decisions, we can establish a relationship between inputs and degrees of uncertainty and thus, the profitability resulting from the decision, identifying all the variables and comparing costs and benefits of different treatment alternatives for patients. The concept of EVPI is important to quantify costs, given that perfect information will eliminate the possibility of making the wrong decision of generating costs.

The EVPI is also the maximum sum that the health system should be willing to pay for additional information to underwrite the decision in the future; therefore a monetary limit is implicitly imposed on any necessary additional research.

Analytical models on decision-making have become a fundamental part of the NICE evaluation process. The types of models include decision trees with simple initial inputs

or models based on the progression of the disease. In any case, they consist of generating an explicit framework that recognizes that all decisions are made despite the existence of uncertainty about costs and effects, and that research and health services are ultimately financed with the same resources.

Economic Evaluations of Medicines (EEM) have seen pronounced growth in the past few years, due to the progressive application of efficiency as a criterion of prioritization in an environment in which available resources do not meet the rising demand. The first countries to use EEM in their decisions on pharmaceutical policy were Australia and Canada, followed by about a dozen other countries, mostly in Europe, which have begun to formally require an EEM evaluation from pharmaceutical companies before a public price is set for their products.

Spain is following this example, so it is convenient to identify the main challenges involved in the use of efficiency criteria in decision-making on pharmaceutical policy.

6.3.1. Health Technology Assessment agencies and institutions

Health Technology Assessment (HTA) provides (at least conceptually) a structured, systematic, multidisciplinary process of analysis based on scientific evidence, which supports the decision-making process in the field of health. This begins by identifying areas needing information and formulating questions compatible with scientific research. A report is then elaborated, synthesizing the systematic analysis of relevant information.

Health technologies are defined as the set of medical and surgical drugs, instruments and procedures used in healthcare as well as the organization and integration which facilitate their use.

HTA rigorously and comprehensively reports the effects, both beneficial and adverse, that health technology has when used in healthcare for prevention, diagnosis, treatment, palliation and rehabilitation of concrete clinical conditions. It analyzes the economic, organizational, normative, ethical and social impact that a certain technology has on individuals and collectives. Its ultimate objective is to contribute to the improvement of the decision-making process at different levels of the health system: policy and planning, management and clinical practise (professionals and patients).

The design of reforms and operative interventions in health systems represent a complex challenge which must be adapted to each scenario (whose context also varies in genesis and development).

As explained in previous sections, there are different ways to generate and distribute resources as well as to organize and provide services. Other variations exist with respect to what services are offered and which professionals are responsible.

Making decisions about health technology requires reliable and objective information which considers all of the related factors. In short, the process should integrate other evidence into the result of the assessment.

The organization and provision of health services is a complex issue requiring different types of decisions at different levels of management (macro, meso and micro).

Health technologies, in the measure that they are interventions in the health system, require an analysis of how to make them available (approval for commercialization and degree of extension), how to organize them and how to manage their provision.

The approval for commercialization of a health product, whether it is a medicine or an instrument, is mandatory. This is usually handled at a macro level, and at times even by supranational authorities, such as the European Medicines Agency (EMA). This process is clearly standardized, with the only actors being the manufacturer and the agency emitting the license.

In addition to evaluating the efficacy and safety of a product, HTA evaluates whether the introduction of a certain technology can produce an added clinical or benefit to the system which is not available with the existing processes or products.

In European countries, decisions on organization and management are usually made directly by governments or by the health authorities in charge of developing health services guidelines.

Another important complementary aspect which must be considered regarding the inclusion of a service or product in the portfolio or services is the degree of coverage offered. Many European countries provide only partial coverage for some services in the portfolio. On occasions, decision-making is conditioned by the definition of the technology/service to be offered and the conditions of co-pay in the case that it is applied.

In the case of pharmaceutical products, most EU countries control prices directly or indirectly. In these health systems, pricing decisions are closely related to the degree of coverage offered. For example, in France, price negotiations depend on the added value (in terms of effectiveness) that the product provides.

While the above considerations already make this process enormously complex, there are still other issues to be taken into account.

Terms such as effectiveness, cost and cost-effectiveness are broadly defined in the legal framework of European health systems.

The difficulty lies in making these values and criteria explicit. It is not enough to assume that the incorporation of new technologies is done according to utility, effectiveness, appropriateness or benefit. The definition of the decision-making criteria should be the first step for transparent and accountable policies.

The pharmaceutical sector is among those with the highest number of specific criteria. Countries such as Austria, Belgium, Denmark, Finland, the Netherlands, Norway, Sweden and the UK have defined cost-effectiveness as one of the most relevant criteria to make decisions regarding medicines. (Table 9).

Type of service	Germany	Denmark	Spain	France	Hungary	Italy	Holland	Poland	UK
Curative care	P, CE, CV, N	B, N	C, E, N, S	N, E, S	C, E	P, N, B	C, E, N	-	B, C, N
Rehabilitative care	CE, CV, N	B, N	N	N	-	P	P	-	E, N
Pharmaceuticals	E, N	B, CE, N	B, N, U	C, E, I, S	B, CE, E, N, S	C, E	B, CE, I	C	B, CE, E, N, S

Criteria: C: Cost, CE: Cost-effectiveness, CV: Convenience, E: Effectiveness, I: Degree of innovation, N: Need, P: Pertinence, B: Budget, S: Safety, U: Utility

Table 9: Criteria used in decision-making

In short, there are numerous institutions, organizations and professional groups around the world which dedicate some or all of their efforts to the evaluation of medicines or technology in general. Their main mission is to contribute to the decision-making process and promote the efficient use of economic resources. Unsurprisingly, the spheres of action vary in each case, leading to the emergence of different models (Velasco et al, 2008).

In the next section, we will systematically revise the conceptual and instrumental elements habitually used by these institutions and agencies to make decisions.

6.3.2 Efficiency and equity

Perhaps the largest danger presented by the adoption of efficiency criteria is the temptation to make it the only criteria. The risk is even greater if the results of cost-effectiveness (CE) analysis are expressed as numeric figures, facilitating a mechanical function that recommends reimbursement only if the CE is below a limit established *a priori*.

This is the case in the UK, where the limit has been established at £ 30,000 per DALY. In any case, and although the utilization of simple and objective criteria is attractive, in practise there are other criteria beyond efficiency which decision-makers cannot ignore. Returning to the UK, top administrators at NICE have explicitly declared that they do not want to make decisions exclusively on the basis of cost-effectiveness. In part, this is due to an unavoidable degree of uncertainty in the economic evaluations of medicines (EEM), which require judgements on value to be assigned based on purely scientific aspects. However, judgements on social values, among other things, are necessary in order to balance the tensions between efficiency and equity. The creation of a Citizen Council, with patient representatives is a good example of the influence that “social factors” have on their decisions.

In practise, NICE has elaborated its recommendations without information on CE on a number of occasions, and at times their advice has contradicted the numeric result that the evaluation would have reflected. That is, some interventions with a CE exceeding £ 30,000/DALY have been recommended for reimbursement, while others with a value below that threshold have been denied.

Upon reviewing experiences in other countries worldwide, we can cite Australia, where the Pharmaceutical Benefits Advisory Committee recognizes that cost-efficiency is just one of the factors considered in decision-making. Others include the severity of the disease, the availability of alternatives, the implications of including new technology on the list and aspects

related to investments in research. In Ontario, Canada, the effectiveness of new treatments continues to be the decisive factor in decisions made by the Drug Quality Therapeutics Committee, which belongs to the Ontario Ministry of Health and Long Term Care.

Sweden and the Netherlands are other countries which also take into account elements such as equity, the demands of specific collectives or the necessity of supporting research.

In health systems such as the Spanish or British ones, it is essential to consider elements such as equity. Therefore, it seems reasonable that if the EEM were implemented in Spain, efficiency should not be the only criteria used in financing, pricing, and medicine selection decisions. Likewise, we would have to open a channel for the opinions of health professionals and patients with regard to the processes of prioritization in the evaluation and, indeed, to the evaluation itself.

6.3.3 Healthcare expenditure

It has been suggested that the objective initially pursued with the economic evaluation of medicines (EEM) was to contain pharmaceutical costs. However, time has demonstrated that efficiency is not always synonymous with savings, and that spending efficiently does not necessarily mean spending less. Most efficient medicines do not save money in a simple accounting analysis (let's not forget that an option whose incremental CE is 20,000€/QALY in comparison with another, means that an additional 20,000€ will have to be paid for every QALY obtained).

According to a review of the EEMs carried out all over the world in the last 25 years, just 19% of all health interventions produced net savings. Thus, we must begin to acknowledge that new medical drugs and instruments may contribute to a higher quality or longer life for patients, but they will rarely save money. Again, we must place this debate within the context of the opinions and quality of life of citizens (including patients and their relatives).

6.3.4 Budget rigidity

Most experts cite the existence of segmented budget structures for each of the components of healthcare expenditure as one of the main barriers to adopting efficiency criteria. This problem, which can be considered endemic in Europe, favours the appearance of fixed, rigid mentalities which translate (in practise) to a lack of awareness about the savings that a certain intervention can generate, if that savings is not perceived in the segment's budget.

The root of the problem is not the existence of a pharmaceutical budget, which is the only way for the health services manager to track the evolution of pharmaceutical expenditure. Rather, the problem lies in not analyzing the effects that this spending has on other budgets; as mentioned previously, an inadequate or incomplete treatment will have repercussions on admittance or readmittance to hospitals, occupational disability, or many other health and social dimensions.

Budget rigidity usually leads to inefficiency in the allocation of resources and to ineffective cost containment policies. If we want a more efficient health system, efficiency criteria must

be applied to all of its components. It would be beneficial to implement health policies that foster more integral management of all health system components. Resources should be allocated according to diseases or programmes rather than types of services.

This integration could be carried out at different levels, which would allow the health system manager to decide which the most efficient combination of elements is; in this way, both patient outcomes and the budgetary bottom line would improve.

6.3.5 Conflicts of interest in the economic evaluation of medicines

The results of the economic evaluation of medicines (EEM) can have a high impact on the use of a particular drug. Conflicts of interest and the potential appearance of biases in the studies sponsored by the pharmaceutical industry are often an issue. However, the same precautions should be in place for evaluations carried out by organisms directly or indirectly linked to the financing of pharmaceuticals.

With this in mind, it would be recommendable to have independent experts carry out these types of evaluations, following a methodology similar to that adhered to in rigorous, peer-reviewed scientific journals. It does not seem reasonable that the articles published in scientific journals are reviewed by at least two external experts, while pharmaceutical guidelines and bulletins, which have a much greater impact, are not revised according to any explicit criteria or procedure. The standardization of evaluation methods and the transparency in the analyses are elements which should contribute to achieving more credibility for EEMs, independently of who elaborates the report.

6.3.6 Continuous analysis of efficiency

Re-evaluation is necessary because efficiency of medicines can vary with time, and the circumstances of their application can change. In order to be able to decide on the financing of a new medicine, we have no choice but to use information obtained from clinical trials, even though we know that this is not the ideal source to use while elaborating EEMs. On the other hand, the efficiency cannot be calculated until the drug or procedure is used in daily clinical practise. Therefore it is necessary to re-evaluate the efficiency and the objective therapeutic impact once new data emerges on effectiveness and cost in real conditions.

At times, cost-efficiency analyses of a particular intervention can improve with time, for example due to more experience with the medicine, leading to lower dosage or more narrowly selected patient populations.

With respect to these issues, the shared risk contracts signed by public administrations and pharmaceutical companies can be especially useful in situations in which the key parameters to set prices for public financing of the drug are unknown.

Later, when the drug has already been commercialized, and new results, derived from real practise, are available, a new economic evaluation would help to calculate the value which the medicine provides to the society, helping to establish its price and conditions for reimbursement.

6.3.7. Innovation and efficiency

Currently, the process of regulatory approval (based on efficacy, quality and safety) is formally separated from the process of pricing, reimbursement and access to innovation. In the same way, the evaluation of innovation should be independent of the evaluation on efficiency. It could happen that a medicine is sufficiently innovative but initially demonstrates scant objective efficiency. A drug could also be very efficient but not very innovative, or neither very innovative nor very efficient, etc. It would be worthwhile to reorient the debate on innovation, finding the true added value of a particular drug for the patient.

A new drug constitutes an innovation if it really contributes to a therapeutic advance. Perhaps the most difficult thing is to forge a consensus on how to objectively define when and whether a new drug contributes to said advance. We must also acknowledge that incremental innovation is the main way to progress in any industrial sector, and the pharmaceutical sector should not be an exception. On very few occasions does a drug represent an enormous innovation. A recent report reveals that 63% of the drugs on the WHO list of essential medicines were initially considered to be “me-too” drugs, with limited added value. Most of the time, medical progress and benefits for patients are obtained from small and painstaking improvements which could be the first steps to achieve more dramatic improvements in the future.

If a health system does not have enough resources to pay for a particular innovation, the solution is not to deny its value, but rather to recognize that it is not willing to pay a certain cost for the benefits achieved, or conversely, to obtain more resources. Efficiency analyses are adequate tools to explain the rationale of a decision to the society. Faced with limited resources, it may be simpler for health system managers to publicly question the efficacy, safety or degree of innovation of a new drug, but the most coherent approach is to separate the evaluation of these aspects from the evaluation of efficiency.

6.3.8. Budgetary impact

The concepts of EEMs and budget-based management should be understood as complementary, although sometimes the use of CE analysis and budget management together can give rise to conflicts in the algorithm of decisions in real practise. For example, a new intervention may be considered efficient (if its incremental CE is less than the predetermined threshold), but its budgetary impact could be so high that it could not be financed with the existing budget. It could also be the case that the CE is too high (which would be the case for many orphan drugs), but the budgetary impact is small.

The recent recommendation in favour of a chemotherapy drug, made by NICE in the UK, did not consider the budgetary impact nor who would finance the drug and how, reopening this debate. In theory, not financing or restricting the use of an efficient medicine because of its high budgetary impact would lead to a label as an inefficient use of resources. If we intend to finance interventions with an “acceptable” CE, without raising the budget, it is necessary to obtain the resources from another part of the system, suspending the financing of another intervention with a less favourable CE. In order to do this, we would have to have more complete information on the collection of health interventions.

Some authors signal that only in this way can we adequately employ cost-effectiveness analyses. If health system managers cannot make decisions which imply the transfer of resources from one budgetary item to another, reducing expenditure for policies and treatments with a high CE and increasing spending on treatments with a lower CE, the utility that CE analyses have is limited. Once again, more integral management of the health system and services would help to resolve this problem.

6.4. Satisfaction indicators

Patient satisfaction has become one of the cornerstones of the systems of progressive quality improvement in hospitals. Satisfaction will influence the choices that patients (and others close to them) make in the future when a health problem appears as well as when it comes to adhering to prescribed therapeutic measures. The adoption of quality indicators to measure satisfaction can contribute to a gradual improvement in this area.

In this context, it is worth highlighting that we are undergoing profound transformations with regard to demographic and epidemiological patterns, and few sectors are as complex and dynamic, supporting as much tension, as health systems.

Several factors inevitably imply greater demand for services. Among others, these variables include: the growing complexity of medicine; the development of patient associations; and the progressive establishment of mechanisms which guarantee the effective exercising of citizen rights and make the system and the centres which comprise it accountable.

We live in an EU which is trying to eliminate borders, and healthcare is one area in which borders persist. In contrast to technical and objective quality which is fundamentally based on the human and material resources available, quality as perceived by patients also exists, and their needs and expectations must necessarily be taken into account.

Upon consulting the Euro Health Consumer Index Report 2008 (Björnberg & Uhliir, 2008), where the indicators for patient satisfaction in health services are reflected, we can observe the existing inequalities among European countries. This scope of the document includes the 27 Member States as well as Norway, Switzerland, Croatia and Macedonia, and reports on 20 indicators. The countries included are:

Austria	Latvia
Belgium	Lithuania
Bulgaria	Luxembourg
Croatia	Macedonia
Cyprus	Malta
Czech Republic	Netherlands
Denmark	Norway
Spain	Poland
Estonia	Portugal
Finland	Romania
France	Slovakia
Germany	Slovenia
Greece	Sweden
Hungary	Switzerland
Ireland	United Kingdom
Italy	

The 2008 Euro Health Consumer Report shows a ranking of countries according to service users' self-reported health status. The ranking is led by the Netherlands (with 839 points out of 1000), Denmark and Austria (Figure 14).

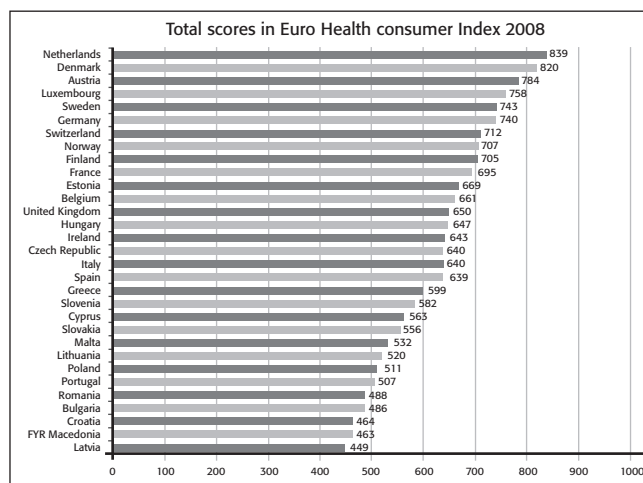


Figure 14: Ranking of European countries according to service users' self-reported health status. (2008 Euro Health Consumer Report)

Among the countries which stand out in this Index Report with regards to accessibility of health services, Austria, Luxembourg and Germany receive the highest score from service users.

6.5. The point of view of ministries, patient associations, professionals and scientific societies. Country specific experiences.

6.5.1. Patient and professional perspectives

The most important primary data from this study come from surveys sent to societies of medical oncology, cancer patient associations and national health authorities (see section 1.1 Methodology). Due to the limited period of time permitted to gather data, the number of responses received is also limited: 12 patient associations in 6 countries and 4 medical societies in 4 countries responded to our request for information. Below, we will summarize the main conclusions gathered from the surveys. The opinions detailed below do not represent the opinions of the research team, but rather the perspectives of the national organisms.

6.5.2. Opinions from patient associations

Belgium

The overall assessment of cancer care is very positive; patients have rapid and generally equitable access to high quality treatments, and a National Cancer Control Plan (NCCP) has existed since 2008. Among the favourable elements of the NCCP is the requirement (since 2009) of a multidisciplinary team for each patient. Although there is no institutional structure obligating the authorities to consult patient associations, the

Fondation contre le Cancer (FCC) has collaborated with authorities in the elaboration of the NCCP and in other important decisions.

However, there are other areas which need improvement. The two most serious concerns are the accessibility of treatments and the availability of information about them. In the case of accessibility, the FCC perceives inequalities between urban and rural areas in addition to differences between the elderly and the rest of the population. Unfortunately, there are no current studies to confirm or refute these perceptions.

The channels of communication could improve notably as well. Oncologists are often not aware of all of the protocols of the ongoing trials in their region, city, and even hospital; subsequently they cannot share this important information with patients. Furthermore, physicians could offer more and better information on the diagnosis and treatment. Other causes for concern include the lack of coordination between the regions (which manage disease prevention and health promotion) and the central government (which manages treatment) and the lack of objective criteria in negotiating the prices of new medicines with the pharmaceutical industry.

Denmark

The Danish Cancer Society (DCS) sees most aspects of cancer care in Denmark in a positive light. The Society is an integral part of the decision-making process for cancer policy, with a seat on the managing board of the national cancer control plan. Access to treatments and new drugs is considered to be relatively equitable, and the DCS is not aware of whether the cost of the most efficacious treatments plays an important role in cancer control planning. The most important area in need of improvement are the waiting lists; patients need quicker access to treatment. Access to innovative pharmaceuticals is generally good, although at times there are “unreasonable” delays caused by administrative inefficiency. Finally, the DCS states that while there is reliable information about clinical trials available, its dissemination among patients could improve.

Spain

So far, we have received a response from three Spanish patient associations: the Spanish Federation of Breast Cancer (FECMA), Europacolón Spain, and the Spanish Association of people affected by Lymphoma, Myeloma, Leukaemia and Myelodysplastic Syndromes (AEAL).

The general impression gleaned from the statements of these associations is of satisfaction with the public health system in Spain. In this way, they observe a marked improvement in the last few years with regard to strategies to palliate the progression of certain tumours (colon, breast). Above all, the associations posit themselves as defenders of the constitutional right to universal healthcare coverage based on the principles of quality, safety and equity. Still, the system is not perfect, and they signal that one of the main pending challenges is to improve the doctor-patient relationship, especially with respect to the information provided to patients and their relatives.

The NCCP is viewed positively by two of the associations questioned (FECMA and Europacolón); they point out the importance of this instrument at a national level to co-

ordinate all 17 autonomous regions through national recommendations. The third association, AEAL, notes that specific strategies for onco-hematological patients are not being carried out.

In general, the associations are satisfied with the degree of consultation they observe in the decisions on national cancer policy, having had the opportunity to actively work on the documents and in the decisions linked to cancer policies. Despite the fact that there is no official channel of communication between authorities and patient associations, the associations refer to having participated in consensus documents. In the case of AEAL, they have had meetings with the Ministry of Health, where they have had the opportunity to express their ideas and suggestions orally and in writing.

The associations emphasize that the regions control and manage health services and therefore they are the ones that should agree on a global portfolio of services to avoid discrimination between patients due to the coincidental location of the patient. To accomplish this, the Ministry of Health and Consumption must guarantee equity among regions and coordinate the necessary flow of information to advance in an organized way, both in terms of research and patient treatment.

The associations consider that the Interterritorial Council of the National Health System should tackle the study of the reduction of inequalities, with a stronger commitment to co responsibility and territorial cohesion in the field of health and healthcare policies.

As far as the economic implications of implementing new treatments are concerned, patients do not see this as an essential criterion. The associations are aware of the limitations on public resources and of the need to manage these rigorously. They agree that health policy cannot be solely guided by economic criteria:

- "...each hospital facility tries to handle this circumstance in the most positive way..." (Europacolón España)
- "Patients demand access to the most innovative methods, but it should be the policy-makers who define spending priorities ..." (FECMA)

Likewise, AEAL indicates that economic criteria should not be the only measure used to set treatment paths—questions such as quality of life, possibility of reincorporation at work and long term benefits should also be considered.

With respect to the overall health expenditure and the conditions of reimbursement for pharmaceuticals and expensive technologies, patient associations do not see themselves as responsible for the pact of reimbursement mechanisms. Rather, they see the Interterritorial Council of the National Health System as responsible for tackling inequalities and overall cohesion among regions.

The three associations do not consider that the potential differences between healthcare schemes in the private and public sector are important, given that most citizens (95%) are treated within the system. However, they do point out that for those treatments not included in the protocols, there are differences between one region and another, and even between one healthcare facility and another in the same region.

The patient perspective on personal care is generally positive, with high levels of patient satisfaction. The same is true for access to medicines and diagnostic procedures employed, although logically, everything can be further improved and perfected. The associations are aware that if they emphasize patient rights and needs, care will evolve in a more humanized way. In this sense, the associations acknowledge that more and more patients are adopting an active role in the decisions which affect their health:

“...as organized patients, what we ask for is that there is no delay in authorizing medicines which have been sufficiently tested, and that there is no discrimination in the supply of these medicines, once they have been authorized by the competent organisms...” (FECMA).

The main source of information on innovative treatments identified by the patient associations are healthcare professionals. However, they also highlight the role that they themselves can play as disseminators of reliable information.

The associations do not consider that they have much information on clinical trials in their communities, but they do believe that these investigations are the only way to advance their knowledge in new therapies.

Finally, and with regard to personalized care (concerns such as quality of life, possibility of palliative treatments, psychosocial care, etc.), the associations stress that this aspect is one of the most deficient. They emphasize the need to continue working on personalized therapeutic plans, paediatric care and care for the young in general, multidisciplinary teams, palliative care for patients with advanced cancer, the defence of safety as a priority in all policies for quality health services, integral healthcare coverage, the right to objective and reliable information, the right to a second opinion and the right to make an informed decision about treatment alternatives.

United Kingdom

In general, British patients are reasonably satisfied with the cancer care services they receive from the NHS, and they consider them to be better than the care they receive from private providers. The four countries which make up Great Britain (England, Scotland, Northern Ireland and Wales) each have their own plan to deal with cancer control, and investments and public commitments to this end have increased dramatically in this field in the past few years. Patients are important actors in the formulation of these plans, participating at all levels in the decision-making process. Information on all clinical trials can be found in the national database (with mandatory registry), although opinions on the availability vary, a sign that this aspect could be improved.

There are other areas in which improvements are imperative, and one of these is the access to innovative drugs and diagnostic techniques. The three British associations who responded agree that this is one of the areas needing most improvement in the NHS. First, the emphasis that the NHS puts on cost-efficiency is, according to the associations, too rigid and not apt for many situations, including rare cancers and other uncommon diseases. Moreover, and reflecting what Roger Wilson, of the National Cancer Research Institute, says, “EuroQoL methodology to measure quality of life is weak and inappropriate for the case of cancer; in addition, the way which these measures are applied in not

transparent.” The slowness of the process, especially in England, is another cause for concern: innovative drugs may be available in the private system, but without approval from NICE (which may take months, if approval is actually granted), reimbursement from the NHS depends on local authorities, and there are no systematic or equitable local criteria.

Access to diagnostic techniques is viewed more positively. There is more and more cutting edge technology available, including positron emission tomography (PET). The NCCP, currently in its second phase, aims to further broaden access to this type of technique. However, at the moment there is concern about long waiting lists, particularly for the diagnosis of recurring cases, but also for physiotherapy and pain management.

The associations recognize the complexity of the problem, understanding that politicians and health authorities are accountable to the taxpayer, and they advocate creative solutions.

Sarah Ritchie, of Myeloma UK, states:

In some instances the manufacturer of a drug may agree with the government to implement a reimbursement or price reduction scheme for an expensive drug. The aim of this is to enable the drug to be made available on the NHS where there may be concerns over cost and for the government and the manufacturer to share the financial risk that it does not work. . . . The Department of Health (England) has recently asked the drugs industry to consider supplying treatments at a discount price until they are proved to have significant benefits, or to cap costs, with the NHS paying only for a set number of doses.

In an effort, increasingly stronger, to control prices and also satisfy the demands of patients and citizens, health systems and pharmaceutical companies will have to find new formulas to establish a balance between cost-efficiency and innovation.

Portugal

Two informal opinions from members of breast cancer patient support groups, *Laço* and *Viva Mulher Viva*, agree that the problems in the Portuguese health system are profound and generalized, and this evaluation includes cancer care. There are inequalities in access and quality of services between urban and rural areas, between public and private services, between regions and between different ages. Waiting time for surgery can last up to three months, and hospitals are generally inefficient, using inadequate medicines, tests and treatments for the patient or for the disease. The system needs more doctors (especially in primary care), but these are abandoning the public system to work in the private sector, which is better equipped and has more resources. Little is done in terms of prevention, and the quality of screening is not assured nor audited. There are no basic guidelines on best practises. For the most part, patients do not have access to second opinions on the possible results of their treatment, nor to a multidisciplinary team. Furthermore, the process of approval for innovative medicines is extremely slow and not very transparent.

Indeed, many problems can be attributed to the lack of transparency and the weight of vested interests. Moreover, the Ministry of Health, the College of Physicians and In-

farmed (the national authority for medicines and health products) are very influential, but they have little responsibility. Likewise, the respondents allege that the National Cancer Control Plan is not worth the paper it is written on, given that the new National Cancer Coordinator has orders to maintain the *status quo* rather than advancing the plan.

This criticism from patient associations helps explain why both the mortality and incidence rates are very high (1,500 deaths and 4,500 new cases every year). Less than half of women at risk age participate in breast cancer screening programmes. Therefore, all of these negative results signal the urgent need to systematically reform the cancer care structures and, indeed, the entire Portuguese health system.

Romania

The situation for cancer patients in Romania is desperate. The most important obstacle hindering the development of a national strategy against cancer is the lack of any registry for patient data (not only cancer, but all diseases). Without this vital tool, it is impossible to calculate the real necessities of the population and to raise awareness among the public regarding the extension of the epidemic.

Investment in the health system is insignificant, more so given the dire problems in the infrastructure. Much of the diagnostic equipment (such as CAT or MRI) is obsolete, and there are not enough beds for patients. There is also a shortage of doctors, who seek better salaries and conditions outside Romania's borders, and the multidisciplinary team does not exist. There is no appreciable access to information on clinical trials or innovative medicines—myeloma patients, for example, are treated with VAD rather than products such as Revlimid or other substances recently approved by the EMEA.

Inequity is the norm, a situation reinforced by national health policy, which reimburses patient care according to the payments previously as taxpayers. The rural population is marginalized: for example, people often have to travel for hours to go to a pharmacy, and the medicine they need may be out of stock. There are also severe inequities between those who have private insurance (which is very expensive) and those who are cared for within the public system.

Without strong pressure from service users and/or the EU, it is improbable that this situation changes in the short- or medium-term. The relationship between health authorities and patient associations are “cynical” and antagonistic. Meanwhile, patients suffer the consequences.

6.5.3. Oncologists' perspectives

Among the positive aspects that the Spanish Society of Medical Oncology (*Sociedad Española de Oncología Médica*, SEOM) finds about cancer care in Spain is the universal access to services, the multidisciplinary focus on patient care and the speed with which new medicines and innovative technology are incorporated into the system. SEOM has a fluid and communicative relationship with the Ministry of Health, and the two bodies collaborated closely to elaborate the National Cancer Strategy. Oncologists are satisfied with the treatment options they can offer to patients, signalling few economic limitations imposed by regional health authorities. Given that the public health system is highly decentralized, there

are some regional variations in specific services offered and the budgetary distribution, but SEOM feels that equity is gradually extending throughout the territory.

The new areas most in need of new investment are clinical research and human resources. Currently, there is little public clinical research. The Ministry made a call for tender for independent research in 2006, but most clinical research is still undertaken by the private sector. Human resources are also important: SEOM believes that oncologists do not have enough time to dedicate to each patient, which may provoke anxiety and feelings of dissatisfaction among patients and stress among physicians. Waiting lists are another problem, slowing quick access to treatments.

In the White Book of Medical Oncology, edited recently by SEOM, the care planning in medical oncology was analyzed. SEOM has calculated the demand for specialists in order to evaluate the need for resources in Medical Oncology, basing their study on the most recent population data on cancer incidence. This data was gathered from the National Institute of Statistics (*Instituto Nacional de Estadística*, INE, at www.ine.es) and the Spanish cancer registry, which published data in the IARC (International Agency for Research on Cancer) study entitled *Cancer Incidence in the Five Continents* (Curado et al, 2007). According to the estimation made by SEOM, the number of oncologists needed in Spain stands at 23.5 per million inhabitants, or 1,064 specialists across the country.

Currently, however, there are just 800 active medical oncologists, according to data from SEOM and the Ministry of Health and Consumption (González & Barber, 2007). The calls for training medical specialists in the next few years—more than 100 specialists annually—would allow a full roster of oncologists to be assembled in the next 4 years.

United Kingdom

The President of the National Association of Cancer Physicians in the UK responded briefly to our request for information, expressing his general satisfaction with the conditions of cancer care in the UK but also recognizing that there are areas in need of improvement, especially with respect to access to innovative drugs, which is inequitable. Oncologists are not satisfied with the available treatment, and they face pressures from health authorities to limit costs. The medicines evaluation process could be quicker and more transparent, and economic considerations are judged to be too decisive in policies on what the most adequate treatments are. Finally, and although there is good care continuity and a multidisciplinary focus for patients, contracting more primary physicians would be a positive measure, as would allowing more “medical time” with patients.

Lithuania

According to the Lithuanian Society of Medical Oncology (LSMO), the situation for cancer patients is improving notably, and the NCCP is seen as an effective tool which helps bring about these changes. The most positive measures mentioned are the generalized access to modern diagnostic equipment and screening programmes for the early detection of cervical, breast and prostate cancer.

On the other hand, practically all other elements have important qualifications. There are several ongoing clinical trials sponsored by pharmaceutical companies, but the popula-

tions studied do not tend to be representative of the population in general. In addition, the growing costs of treatment are not very directly correlated with better outcomes for patients. Oncologists also feel pressure from health authorities to limit costs; although Dr. Alvydas Cesas, president of the LSMO, assures that cost-efficiency is a secondary factor, the availability of resources continues to restrict the treatments that patients can receive.

In fact, the lack of financial resources is the factor which most conditions patient care. Other problems include: insufficient consideration of research evidence in the formulation of health policy, the inexistence of palliative care, and the short time that Lithuanian doctors have to spend with each patient.

Luxembourg

The President of the *Société Luxembourgeoise d'Oncologie* is generally very pleased with cancer care in Luxembourg. There are some deficiencies, for example, the lack of a registry which tracks mortality rates, but many of these defects will be corrected by the time the NCCP is fully implemented. Other areas needing further development include psychological support, better information on clinical trials, and mandatory tumour board discussions to decide what treatment is best for each patient.

Some issues which are problematic for some countries are managed very well in Luxembourg. At the moment, there are few examples of limitations due to health expenditure, physicians feel free to prescribe the most adequate medicines they choose, and they are capable of treating all patients in an individualized way.

7. Conclusions: possible “model practises” in Europe

One of the basic conclusions emerging from this study, based mostly on secondary data, is precisely the shortage of information and transparency regarding the criteria and decision-making processes in the EU Member States, and the need to carry out more studies with primary data which permit an objective comparison of the *ad hoc* solutions reached in each country.

In any case, for now we can identify two models which are particularly noteworthy: the UK (because of the transparency and clarity in the formulation of criteria, although the decisions can be debated), and France (because of the systematic, integrated character of its national cancer control plan within the larger health system).

In the case of the United Kingdom, the documents released by NICE and complementary organisms reveal a commitment to pursuing an explicit methodology to integrate decisions on the incorporation of a certain technology into the public system. The method includes the consideration of a variety of data to help make decisions, including the inevitable uncertainty in the data used and protocols to establish when to request additional research.

On the other hand, we should avoid simplifying the analysis by only adopting criteria of efficiency to make the decision. In a field in which we must take into account feelings, suffering, family and social repercussions, the risk of oversimplification increases if we consider that cost-effectiveness (CE) criteria are expressed numerically. Even NICE itself has explicitly declared that it does not wish to make decisions based exclusively on CE criteria, as, apart from the uncertainty in the results of the economic evaluations of medicines, it is necessary to make subjective judgements on purely scientific aspects in order to balance the tension between efficiency and equity. In any case, both patients and professionals believe that there are serious limitations in the access to innovative treatments, mainly because of the pressure to control spending.

To make decisions more impartial and respectful of all, the creation of a Citizen Council, with patient representatives, is a good example of how “social factors” can influence decisions, and a possible model to follow. In the same line, the Pharmaceutical Benefits Advisory Committee of Australia recognizes that CE criteria is just one of the factors considered in their decisions, and there are other factors which are just as important or more so, such as the severity of the disease, the availability of alternatives, the implications of including a new technology in the portfolio of services offered and the aspects related to investments in privately (or company) funded research. Sweden and the Netherlands are other countries in which aspects such as equity, the needs of specific patient collectives, and the need to support innovation are also taken into account.

In health systems such as the Spanish or British ones, it is essential to consider elements such as equity. Therefore, it seems reasonable that if the EEM model was implemented in Spain, efficiency should not be the only criteria used in financing, pricing,

and medicine selection decisions. Likewise, we would have to open a channel for the opinions of health professionals and patients with regard to the processes of prioritization in the evaluation and, indeed, to the evaluation itself.

As far as the good example which France offers, its virtue lies in the fact that the National Cancer Control Plan (NCCP) is not limited to enumerating the provision of services. Rather, it recognizes that the ability to supply these services also depends on the financing, the quality of governance/stewardship (transparency and accountability) and the generation of resources. From the point of view of a model NCCP, any plan should be able to channel the state's efforts through these three elements in order to guarantee service provision to citizens in an equitable, efficacious and efficient way which is sensitive to patients' needs. Only by doing this can the ultimate goals of health, patient satisfaction and financial protection be achieved.

We should keep in mind that the debate on the innovation necessary to respond to patient needs is set among the coordinates of innovative effort in the long term and cost control in the short term. In order to solidly respond to this challenge, it is necessary to work within a stable framework. However, currently the situation is the opposite: the health technology and pharmaceutical sector have been evolving within an extremely complex and controversial context (López-Casasnovas, 2008).

In light of the information presented in the present report, we believe it is necessary to make the following recommendations explicit in order to increase equity in the access to innovative diagnostics and treatments in the field of oncology, and to work for the establishment of transparent criteria.

1. Considering the intra- and inter-country differences we observed with regards to the regulation and implementation of innovative treatments, we propose the development of national and European initiatives which establish reference criteria for these processes. The development of explicit ground rules is essential to ensure ethical principles and transparent, open relationships between authorities, medical professionals, specialists and industry, which would favour optimal planning of research and development for the future.
2. It is necessary to establish information systems capable of providing reliable and comparable information in order to accurately contrast the degree of development and implementation of resources destined to cancer control in Europe.
3. Lacking these, it is vital to pursue studies which generate primary information, based on systematic questionnaires to patients' organizations, health administrations and scientific and professional societies of oncology, in addition to considering the perspective of the industry which provides diagnostic and pharmaco-therapeutic tools.
4. To enable research, development and innovation, it would be beneficial to define a stable framework which allows a certain degree of prediction regarding the evolution of health policies on investments, human and material costs, facilities and biomedical investigation.

5. It is necessary to evolve towards a debate which recognizes the necessity of overcoming the short-term vision of initial cost, and evaluating the long-term impact in terms of the cost-effectiveness of anti-cancer diagnostics and treatments. An integrated vision of the health system as a whole must recognize the role that technology and medicines have in meeting the goals of the system (such as better health) and in influencing other segments of the health budget. We must take into account not only what a certain technology or medicine costs in the pharmaceutical budget, but also what that intervention will save in other areas in the future.
6. Currently, many diagnostic and therapeutic procedures are focused on “caring” rather than “curing,” responding to a new way of dealing with disease which seeks quality of life and individual welfare. In order to develop more personal treatments, and indeed to further humanize medicine, it will be necessary to invest more in research and development.
7. The goal we must pursue is that of promoting coordinated health policies for cancer and a relatively homogeneous catalogue of offered services to decrease health inequity. This coordination, which is basic at a national level, should be extended into the sphere of the EU.

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ANNEX

INDICATORS AUSTRIA

Demographic indicators	Population	8,175,000
	Population between 0-14 years old (%)	16.22
	Population over 65 years old (%)	15.74
	% of urban population	65.9
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	79
	Number of live births per 1000 inhabitants	9.66
	Fertility rate	4.42
	Gross mortality rate per 100,000 inhabitants	620.1
	Infant mortality per 1000 live births	3.14
	Unemployment rate (%)	7.1
	Gross National Product (US\$ per capita)	32,590
	Gross Domestic Product (US\$ per capita)	35,663
	Real Gross Domestic Product (\$ PPP per cápita)	32,276
Health indicators	No. of hospitals per 100,000 inhabitants	3.2
	Hospital beds per 100,000 inhabitants	773.2
	No. of doctors per 100,000 inhabitants	345.3
	Total health expenditure (%GDP) [WHO estimate]	10.3
	Total health expenditure (\$ PPP per capita) [WHO estimate]	3,398
	Public health expenditure (% total health expenditure)	75.6
	Total pharmaceutical expenditure (% total health expenditure)	12.2
	Pharmaceutical expenditure (\$ PPP per capita)	413
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	70.4

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS BELGIUM

Demographic indicators	Population	10,421,000
	Population between 0-14 years old (%)	not available (na)
	Population over 65 years old (%)	na
	% of urban population	97.2
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	78
	Number of live births per 1000 inhabitants	11.09
	Fertility rate	1.68
	Gross mortality rate per 100,000 inhabitants	na
	Infant mortality per 1000 live births	na
	Unemployment rate (%)	8.5
	Gross National Product (US\$ per capita)	31,630
	Gross Domestic Product (US\$ per capita)	34,319
Health indicators	Real Gross Domestic Product (\$ PPP per cápita)	31,096
	No. of hospitals per 100,000 inhabitants	2.1
	Hospital beds per 100,000 inhabitants	535.6
	No. of doctors per 100,000 inhabitants	418.4
	Total health expenditure (%GDP) [WHO estimate]	9.7
	Total health expenditure (\$ PPP per capita) [WHO estimate]	3006
	Public health expenditure (% total health expenditure)	72.3
	Total pharmaceutical expenditure (% total health expenditure)	19.4
	Pharmaceutical expenditure (\$ PPP per capita)	na
Public pharmaceutical expenditure (% total pharmaceutical expenditure)	52.4	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS BULGARIA

Demographic indicators	Population	7,781,000
	Population between 0-14 years old (%)	14
	Population over 65 years old (%)	17.12
	% of urban population	69.8
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	72.5
	Number of live births per 1000 inhabitants	8.98
	Fertility rate	1.29
	Gross mortality rate per 100,000 inhabitants	1056.4
	Infant mortality per 1000 live births	6.57
	Unemployment rate (%)	12
	Gross National Product (US\$ per capita)	2,830
	Gross Domestic Product (US\$ per capita)	3,109
	Real Gross Domestic Product (\$ PPP per cápita)	8,078
Health indicators	No. of hospitals per 100,000 inhabitants	3.9
	Hospital beds per 100,000 inhabitants	613.1
	No. of doctors per 100,000 inhabitants	352.4
	Total health expenditure (%GDP) [WHO estimate]	7.5
	Total health expenditure (\$ PPP per capita) [WHO estimate]	655
	Public health expenditure (% total health expenditure)	60.5
	Total pharmaceutical expenditure (% total health expenditure)	na
	Pharmaceutical expenditure (\$ PPP per capita)	na
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	na

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS CYPRUS

Demographic indicators	Population	737,000
	Population between 0-14 years old (%)	19.19
	Population over 65 years old (%)	11.93
	% of urban population	69.2
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	79.5
	Number of live births per 1000 inhabitants	11.27
	Fertility rate	1.49
	Gross mortality rate per 100,000 inhabitants	636.4
	Infant mortality per 1000 live births	na
	Unemployment rate (%)	4.7
	Gross National Product (US\$ per capita)	18,430
	Gross Domestic Product (US\$ per capita)	18,668
	Real Gross Domestic Product (\$ PPP per cápita)	22,805
Health indicators	No. of hospitals per 100,000 inhabitants	na
	Hospital beds per 100,000 inhabitants	417.2
	No. of doctors per 100,000 inhabitants	266.6
	Total health expenditure (%GDP) [WHO estimate]	6.3
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,355
	Public health expenditure (% total health expenditure)	44.6
	Total pharmaceutical expenditure (% total health expenditure)	na
	Pharmaceutical expenditure (\$ PPP per capita)	na
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	na

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS CZECH REPUBLIC

Demographic indicators	Population	10,207,000
	Population between 0-14 years old (%)	15.08
	Population over 65 years old (%)	14
	% of urban population	73.6
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	76
	Number of live births per 1000 inhabitants	9.57
	Fertility rate	1.23
	Gross mortality rate per 1000 inhabitants	851.9
	Infant mortality per 1000 live births	2.3
	Unemployment rate (%)	8.3
	Gross National Product (US\$ per capita)	9,200
	Gross Domestic Product (US\$ per capita)	10,730
	Real Gross Domestic Product (\$ PPP per cápita)	19,400
Health indicators	No. of hospitals per 100,000 inhabitants	3.6
	Hospital beds per 100,000 inhabitants	847.4
	No. of doctors per 100,000 inhabitants	347.6
	Total health expenditure (%GDP) [WHO estimate]	7.2
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,388
	Public health expenditure (% total health expenditure)	89.2
	Total pharmaceutical expenditure (% total health expenditure)	24.8
	Pharmaceutical expenditure (\$ PPP per capita)	345
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	76.3

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS DENMARK

Demographic indicators	Population	5,401,000
	Population between 0-14 years old (%)	na
	Population over 65 years old (%)	na
	% of urban population	85.5
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	77.5
	Number of live births per 1000 inhabitants	11.92
	Fertility rate	1.78
	Gross mortality rate per 100,000 inhabitants	na
	Infant mortality per 1000 live births	na
	Unemployment rate (%)	6.4
	Gross National Product (US\$ per capita)	41,280
	Gross Domestic Product (US\$ per capita)	45,320
	Real Gross Domestic Product (\$ PPP per cápita)	31,914
Health indicators	No. of hospitals per 100,000 inhabitants	na
	Hospital beds per 100,000 inhabitants	382.3
	No. of doctors per 100,000 inhabitants	357.1
	Total health expenditure (%GDP) [WHO estimate]	9.4
	Total health expenditure (\$ PPP per capita) [WHO estimate]	3,030
	Public health expenditure (% total health expenditure)	83.5
	Total pharmaceutical expenditure (% total health expenditure)	8.5
	Pharmaceutical expenditure (\$ PPP per capita)	258
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	54.5

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS ESTONIA

Demographic indicators	Population	1,349,000
	Population between 0-14 years old (%)	16
	Population over 65 years old (%)	16
	% of urban population	69
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	72
	Number of live births per 1000 inhabitants	10,4
	Fertility rate	1.5
	Gross mortality rate per 100,000 inhabitants	1028
	Infant mortality per 1000 live births	4.15
	Unemployment rate (%)	9.7
	Gross National Product (US\$ per capita)	7,130
	Gross Domestic Product (US\$ per capita)	8,330
	Real Gross Domestic Product (\$ PPP per cápita)	14,550
Health indicators	No. of hospitals per 100,000 inhabitants	3.8
	Hospital beds per 100,000 inhabitants	581.8
	No. of doctors per 100,000 inhabitants	320.9
	Total health expenditure (%GDP) [WHO estimate]	5.2
	Total health expenditure (\$ PPP per capita) [WHO estimate]	740
	Public health expenditure (% total health expenditure)	76
	Total pharmaceutical expenditure (% total health expenditure)	27.8
	Pharmaceutical expenditure (\$ PPP per capita)	na
Public pharmaceutical expenditure (% total pharmaceutical expenditure)	45.4	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS FINLAND

Demographic indicators	Population	5,228,000
	Population between 0-14 years old (%)	17.55
	Population over 65 years old (%)	15.72
	% of urban population	61.1
Development indicators	Estimated life expectancy (World Health Report)	78.5
	Number of live births per 1000 inhabitants	11.05
	Fertility rate	1.8
	Gross mortality rate per 1000 inhabitants	636.82
	Infant mortality per 1000 live births	2.46
	Unemployment rate (%)	8.8
	Gross National Product (US\$ per capita)	33,010
	Gross Domestic Product (US\$ per capita)	35,976
	Real Gross Domestic Product (\$ PPP per cápita)	29,951
Health indicators	No. of hospitals per 100,000 inhabitants	7.1
	Hospital beds per 100,000 inhabitants	690.2
	No. of doctors per 100,000 inhabitants	319.2
	Total health expenditure (%GDP) [WHO estimate]	7.4
	Total health expenditure (\$ PPP per capita) [WHO estimate]	2,203
	Public health expenditure (% total health expenditure)	77.2
	Total pharmaceutical expenditure (% total health expenditure)	15.8
	Pharmaceutical expenditure (\$ PPP per capita)	382
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	52.2

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS FRANCE

Demographic indicators	Population	60,144,000	
		Number of men	29,299,000
		Number of women	30,845,000
	Population between 0-14 years old (%)	18.83	
	Population over 65 years old (%)	16.08	
	Area (km ²)	551,500	
	Average population density per km ²	108.2	
	% of urban population	75.5	
Development indicators	Estimated life expectancy (World Health Report)	79.7	
	Number of live births per 1000 inhabitants	13.16	
	Fertility rate	1.8	
	Gross mortality rate per 1000 inhabitants	9.01	
	Infant mortality per 1000 live births	4.38	
	Unemployment rate (%)	8.7	
	Gross National Product (US\$ per capita)	22,690	
	Gross Domestic Product (US\$ per capita)	23,400	
	Real Gross Domestic Product (\$ PPP per cápita)	27,200	
Health indicators	No. of hospitals per 100,000 inhabitants	5.22	
	Total no. of hospitals	3076	
	Hospital beds per 100,000 inhabitants	793.17	
	Total no. of hospital beds	471,561	
	No. of doctors per 100,000 inhabitants	333	
	Total health expenditure (% GDP)	9.7	
	Total health expenditure (%GDP) [WHO estimate]	9.6	
	Total health expenditure (\$ PPP per capita)	2,736	
	Total health expenditure (\$ PPP per capita) [WHO estimate]	2,567	
	Public health expenditure (% total health expenditure)	76	
	Total pharmaceutical expenditure (% total health expenditure)	20.8	
	Pharmaceutical expenditure (\$ PPP per capita)	537	
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	67	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS GERMANY

Demographic indicators	Population	82,476,000	
		Number of men	40,299,000
		Number of women	42,177,000
	Population between 0-14 years old (%)	15.42	
	Population over 65 years old (%)	16.85	
	Area (km ²)	357,030	
	Average population density per km ²	229.64	
	% of urban population	87.7	
Development indicators	Estimated life expectancy (World Health Report)	78.7	
	Number of live births per 1000 inhabitants	8.92	
	Fertility rate	1.35	
	Gross mortality rate per 1000 inhabitants	10.06	
	Infant mortality per 1000 live births	4.31	
	Unemployment rate (%)	8.5	
	Gross National Product (US\$ per capita)	23,700	
	Gross Domestic Product (US\$ per capita)	24,100	
	Real Gross Domestic Product (\$ PPP per cápita)	26,350	
Health indicators	No. of hospitals per 100,000 inhabitants	4.41	
	Total no. of hospitals	3,628	
	Hospital beds per 100,000 inhabitants	901.06	
	Total no. of hospital beds	741,933	
	No. of doctors per 100,000 inhabitants	335.61	
	Total health expenditure (% GDP)	10.9	
	Total health expenditure (%GDP) [WHO estimate]	10.8	
	Total health expenditure (\$ PPP per capita)	2,817	
	Total health expenditure (\$ PPP per capita) [WHO estimate]	2,820	
	Public health expenditure (% total health expenditure)	78.5 (74.9)	
	Total pharmaceutical expenditure (% total health expenditure)	14.5	
	Pharmaceutical expenditure (\$ PPP per capita)	402	
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	74.8	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS GREECE

Demographic indicators	Population	11,064,000
	Population between 0-14 years old (%)	14.45
	Population over 65 years old (%)	17.98
	% of urban population	58.9
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	79.5
	Number of live births per 1000 inhabitants	9.55
	Fertility rate	1.31
	Gross mortality rate per 1000 inhabitants	662.8
	Infant mortality per 1000 live births	2.62
	Unemployment rate (%)	10.2
	Gross National Product (US\$ per capita)	16,890
	Gross Domestic Product (US\$ per capita)	20,672
	Real Gross Domestic Product (\$ PPP per cápita)	22,205
Health indicators	No. of hospitals per 100,000 inhabitants	2.9
	Hospital beds per 100,000 inhabitants	468.8
	No. of doctors per 100,000 inhabitants	487.5
	Total health expenditure (%GDP) [WHO estimate]	9.6
	Total health expenditure (\$ PPP per capita) [WHO estimate]	2667
	Public health expenditure (% total health expenditure)	44.6
	Total pharmaceutical expenditure (% total health expenditure)	19.7
	Pharmaceutical expenditure (\$ PPP per capita)	393
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	82.1

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS HUNGARY

Demographic indicators	Population	10,107,000
	Population between 0-14 years old (%)	15.76
	Population over 65 years old (%)	15.56
	% of urban population	65.9
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	73
	Number of live births per 1000 inhabitants	9.41
	Fertility rate	1.28
	Gross mortality rate per 1000 inhabitants	1009.8
	Infant mortality per 1000 live births	4.45
	Unemployment rate (%)	6.1
	Gross National Product (US\$ per capita)	8,400
	Gross Domestic Product (US\$ per capita)	10,110
	Real Gross Domestic Product (\$ PPP per cápita)	16,814
Health indicators	No. of hospitals per 100,000 inhabitants	1.8
	Hospital beds per 100,000 inhabitants	782.8
	No. of doctors per 100,000 inhabitants	333.7
	Total health expenditure (%GDP) [WHO estimate]	8.1
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,315
	Public health expenditure (% total health expenditure)	70.5
	Total pharmaceutical expenditure (% total health expenditure)	28.3
	Pharmaceutical expenditure (\$ PPP per capita)	376
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	64

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS IRELAND

Demographic indicators	Population	4,044,000
	Population between 0-14 years old (%)	20.85
	Population over 65 years old (%)	11.15
	% of urban population	60.2
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	78
	Number of live births per 1000 inhabitants	15.25
	Fertility rate	1.99
	Gross mortality rate per 1000 inhabitants	651.6
	Infant mortality per 1000 live births	3.47
	Unemployment rate (%)	4.4
	Gross National Product (US\$ per capita)	35,010
	Gross Domestic Product (US\$ per capita)	45,337
	Real Gross Domestic Product (\$ PPP per cápita)	38,827
Health indicators	No. of hospitals per 100,000 inhabitants	4.4
	Hospital beds per 100,000 inhabitants	572.1
	No. of doctors per 100,000 inhabitants	275.5
	Total health expenditure (%GDP) [WHO estimate]	7.5
	Total health expenditure (\$ PPP per capita) [WHO estimate]	2,723
	Public health expenditure (% total health expenditure)	78.6
	Total pharmaceutical expenditure (% total health expenditure)	11.8
	Pharmaceutical expenditure (\$ PPP per capita)	325
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	88.7

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS ITALY

Demographic indicators	Population	57,423,000	
		Number of men	27,845,000
		Number of women	29,578,000
	Population between 0-14 years old (%)	14.22	
	Population over 65 years old (%)	18.68	
	Area (km ²)	301,340	
	Average population density per km ²	190.65	
	% of urban population	67.1	
Development indicators	Estimated life expectancy (World Health Report)	79.7	
	Number of live births per 1000 inhabitants	9.32	
	Fertility rate	1.2	
	Gross mortality rate per 1000 inhabitants	9.77	
	Infant mortality per 1000 live births	4.67	
	Unemployment rate (%)	9.5	
	Gross National Product (US\$ per capita)	19,740	
	Gross Domestic Product (US\$ per capita)	20,400	
	Real Gross Domestic Product (\$ PPP per cápita)	26,350	
Health indicators	No. of hospitals per 100,000 inhabitants	2.29	
	Total no. of hospitals	1,307	
	Hospital beds per 100,000 inhabitants	446.81	
	Total no. of hospital beds	254,663	
	No. of doctors per 100,000 inhabitants	612.08	
	Total health expenditure (% GDP)	8.5	
	Total health expenditure (%GDP) [WHO estimate]	8.4	
	Total health expenditure (\$ PPP per capita)	2,239.75	
	Total health expenditure (\$ PPP per capita) [WHO estimate]	2,204	
	Public health expenditure (% total health expenditure)	75.3	
	Total pharmaceutical expenditure (% total health expenditure)	21.9	
	Pharmaceutical expenditure (\$ PPP per capita)	493	
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	52.1	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS LATVIA

Demographic indicators	Population	2,313,000
	Population between 0-14 years old (%)	15.09
	Population over 65 years old (%)	16.36
	% of urban population	67.8
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	71
	Number of live births per 1000 inhabitants	8.8
	Fertility rate	1.24
	Gross mortality rate per 1000 inhabitants	1090.6
	Infant mortality per 1000 live births	5.7
	Unemployment rate (%)	8.5
	Gross National Product (US\$ per capita)	5,470
	Gross Domestic Product (US\$ per capita)	5,868
	Real Gross Domestic Product (\$ PPP per cápita)	11,653
Health indicators	No. of hospitals per 100,000 inhabitants	5,2
	Hospital beds per 100,000 inhabitants	773.6
	No. of doctors per 100,000 inhabitants	311.2
	Total health expenditure (%GDP) [WHO estimate]	6.8
	Total health expenditure (\$ PPP per capita) [WHO estimate]	796
	Public health expenditure (% total health expenditure)	58.6
	Total pharmaceutical expenditure (% total health expenditure)	na
	Pharmaceutical expenditure (\$ PPP per capita)	na
Public pharmaceutical expenditure (% total pharmaceutical expenditure)	na	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS LITHUANIA

Demographic indicators	Population	3,436,000
	Population between 0-14 years old (%)	17.38
	Population over 65 years old (%)	15.06
	% of urban population	66.6
Development indicators	Estimated life expectancy (World Health Report)	72
	Number of live births per 1000 inhabitants	8.85
	Fertility rate	1.26
	Gross mortality rate per 1000 inhabitants	1017.7
	Infant mortality per 1000 live births	4.8
	Unemployment rate (%)	11.4
	Gross National Product (US\$ per capita)	5,840
	Gross Domestic Product (US\$ per capita)	6,480
	Real Gross Domestic Product (\$ PPP per cápita)	13,107
Health indicators	No. of hospitals per 100,000 inhabitants	5.3
	Hospital beds per 100,000 inhabitants	843.3
	No. of doctors per 100,000 inhabitants	390
	Total health expenditure (%GDP) [WHO estimate]	5.7
	Total health expenditure (\$ PPP per capita) [WHO estimate]	756
	Public health expenditure (% total health expenditure)	67.6
	Total pharmaceutical expenditure (% total health expenditure)	na
	Pharmaceutical expenditure (\$ PPP per capita)	na
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	na

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS LUXEMBOURG

Demographic indicators	Population	453,300
	Population between 0-14 years old (%)	18.74
	Population over 65 years old (%)	14.18
	% of urban population	83
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	78.5
	Number of live births per 1000 inhabitants	12.03
	Fertility rate	1.7
	Gross mortality rate per 1000 inhabitants	614.9
	Infant mortality per 1000 live births	2.0
	Unemployment rate (%)	4.2
	Gross National Product (US\$ per capita)	58,050
	Gross Domestic Product (US\$ per capita)	57,140
	Real Gross Domestic Product (\$ PPP per cápita)	70,000
Health indicators	No. of hospitals per 100,000 inhabitants	na
	Hospital beds per 100,000 inhabitants	633.4
	No. of doctors per 100,000 inhabitants	276.9
	Total health expenditure (%GDP) [WHO estimate]	8.1
	Total health expenditure (\$ PPP per capita) [WHO estimate]	5,317
	Public health expenditure (% total health expenditure)	90.6
	Total pharmaceutical expenditure (% total health expenditure)	8.9
	Pharmaceutical expenditure (\$ PPP per capita)	364
Public pharmaceutical expenditure (% total pharmaceutical expenditure)	84.2	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS MALTA

Demographic indicators	Population	401,300
	Population between 0-14 years old (%)	17.94
	Population over 65 years old (%)	13.17
	% of urban population	95
Development indicators	Estimated life expectancy (World Health Report)	78.5
	Number of live births per 1000 inhabitants	9.69
	Fertility rate	1.37
	Gross mortality rate per 1000 inhabitants	628.2
	Infant mortality per 1000 live births	4.4
	Unemployment rate (%)	7.2
	Gross National Product (US\$ per capita)	12,250
	Gross Domestic Product (US\$ per capita)	13,300
	Real Gross Domestic Product (\$ PPP per cápita)	18,900
Health indicators	No. of hospitals per 100,000 inhabitants	2.5
	Hospital beds per 100,000 inhabitants	464.3
	No. of doctors per 100,000 inhabitants	324.5
	Total health expenditure (%GDP) [WHO estimate]	8.2
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,608
	Public health expenditure (% total health expenditure)	75.8
	Total pharmaceutical expenditure (% total health expenditure)	22.7
	Pharmaceutical expenditure (\$ PPP per capita)	na
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	56.7

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS NETHERLANDS

Demographic indicators	Population	16,282,000
	Population between 0-14 years old (%)	18.5
	Population over 65 years old (%)	13.94
	% of urban population	79.6
Development indicators	Estimated life expectancy (World Health Report)	79
	Number of live births per 1000 inhabitants	11.92
	Fertility rate	1.73
	Gross mortality rate per 1000 inhabitants	630.6
	Infant mortality per 1000 live births	3.36
	Unemployment rate (%)	5.1
	Gross National Product (US\$ per capita)	34,340
	Gross Domestic Product (US\$ per capita)	37,240
	Real Gross Domestic Product (\$ PPP per cápita)	31,800
Health indicators	No. of hospitals per 100,000 inhabitants	1.2
	Hospital beds per 100,000 inhabitants	na
	No. of doctors per 100,000 inhabitants	360.4
	Total health expenditure (%GDP) [WHO estimate]	9
	Total health expenditure (\$ PPP per capita) [WHO estimate]	3,002
	Public health expenditure (% total health expenditure)	64.5
	Total pharmaceutical expenditure (% total health expenditure)	14.1
	Pharmaceutical expenditure (\$ PPP per capita)	na
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	na

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS POLAND

Demographic indicators	Population	38,181,000
	Population between 0-14 years old (%)	16.97
	Population over 65 years old (%)	13.05
	% of urban population	62
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	75
	Number of live births per 1000 inhabitants	9.33
	Fertility rate	1.23
	Gross mortality rate per 1000 inhabitants	872
	Infant mortality per 1000 live births	4.9
	Unemployment rate (%)	19
	Gross National Product (US\$ per capita)	6,150
	Gross Domestic Product (US\$ per capita)	6,620
	Real Gross Domestic Product (\$ PPP per cápita)	12,970
Health indicators	No. of hospitals per 100,000 inhabitants	2.2
	Hospital beds per 100,000 inhabitants	534.8
	No. of doctors per 100,000 inhabitants	224.3
	Total health expenditure (%GDP) [WHO estimate]	6.2
	Total health expenditure (\$ PPP per capita) [WHO estimate]	808
	Public health expenditure (% total health expenditure)	68.6
	Total pharmaceutical expenditure (% total health expenditure)	29.6
	Pharmaceutical expenditure (\$ PPP per capita)	239
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	36.5

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS PORTUGAL

Demographic indicators	Population	10,502,000
	Population between 0-14 years old (%)	15.69
	Population over 65 years old (%)	16.91
	% of urban population	57
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	77.5
	Number of live births per 1000 inhabitants	10.41
	Fertility rate	1.42
	Gross mortality rate per 1000 inhabitants	674.1
	Infant mortality per 1000 live births	na
	Unemployment rate (%)	6.7
	Gross National Product (US\$ per capita)	15,150
	Gross Domestic Product (US\$ per capita)	16,900
	Real Gross Domestic Product (\$ PPP per capita)	19,600
Health indicators	No. of hospitals per 100,000 inhabitants	2
	Hospital beds per 100,000 inhabitants	374.6
	No. of doctors per 100,000 inhabitants	335.3
	Total health expenditure (%GDP) [WHO estimate]	10
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,913
	Public health expenditure (% total health expenditure)	72
	Total pharmaceutical expenditure (% total health expenditure)	21.8
	Pharmaceutical expenditure (\$ PPP per capita)	418
Public pharmaceutical expenditure (% total pharmaceutical expenditure)	58	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per capita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS ROMANIA

Demographic indicators	Population	21,674,000
	Population between 0-14 years old (%)	16.15
	Population over 65 years old (%)	14.53
	% of urban population	53.5
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	72
	Number of live births per 1000 inhabitants	9.98
	Fertility rate	1.29
	Gross mortality rate per 1000 inhabitants	1076.4
	Infant mortality per 1000 live births	9.6
	Unemployment rate (%)	8
	Gross National Product (US\$ per capita)	3,030
	Gross Domestic Product (US\$ per capita)	3,370
	Real Gross Domestic Product (\$ PPP per cápita)	8,480
Health indicators	No. of hospitals per 100,000 inhabitants	1.9
	Hospital beds per 100,000 inhabitants	655.3
	No. of doctors per 100,000 inhabitants	198.2
	Total health expenditure (%GDP) [WHO estimate]	4.9
	Total health expenditure (\$ PPP per capita) [WHO estimate]	427
	Public health expenditure (% total health expenditure)	71.5
	Total pharmaceutical expenditure (% total health expenditure)	na
	Pharmaceutical expenditure (\$ PPP per capita)	na
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	na

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS SLOVAKIA

Demographic indicators	Population	5,385,000
	Population between 0-14 years old (%)	17.06
	Population over 65 years old (%)	11.62
	% of urban population	56.2
Development indicators	Estimated life expectancy (World Health Report)	74
	Number of live births per 1000 inhabitants	9.98
	Fertility rate	1.24
	Gross mortality rate per 100,000 inhabitants	932.9
	Infant mortality per 1000 live births	3.93
	Unemployment rate (%)	18.1
	Gross National Product (US\$ per capita)	6,480
	Gross Domestic Product (US\$ per capita)	7,806
	Real Gross Domestic Product (\$ PPP per capita)	14,623
Health indicators	No. of hospitals per 100,000 inhabitants	2.7
	Hospital beds per 100,000 inhabitants	700.8
	No. of doctors per 100,000 inhabitants	313.3
	Total health expenditure (%GDP) [WHO estimate]	7.2
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,058
	Public health expenditure (% total health expenditure)	73.8
	Total pharmaceutical expenditure (% total health expenditure)	31.4
	Pharmaceutical expenditure (\$ PPP per capita)	332
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	76.1

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per capita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS SLOVENIA

Demographic indicators	Population	1,997,000
	Population between 0-14 years old (%)	14.17
	Population over 65 years old (%)	15.17
	% of urban population	50.9
Development indicators	Estimated life expectancy (<i>World Health Report</i>)	77
	Number of live births per 1000 inhabitants	8.91
	Fertility rate	1.25
	Gross mortality rate per 100,000 inhabitants	738.6
	Infant mortality per 1000 live births	2.58
	Unemployment rate (%)	10.6
	Gross National Product (US\$ per capita)	14,860
	Gross Domestic Product (US\$ per capita)	16,115
	Real Gross Domestic Product (\$ PPP per cápita)	20,939
Health indicators	No. of hospitals per 100,000 inhabitants	1.5
	Hospital beds per 100,000 inhabitants	479.9
	No. of doctors per 100,000 inhabitants	231.2
	Total health expenditure (%GDP) [WHO estimate]	8.5
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,863
	Public health expenditure (% total health expenditure)	73.5
	Total pharmaceutical expenditure (% total health expenditure)	na
	Pharmaceutical expenditure (\$ PPP per capita)	na
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	na

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS SPAIN

Demographic indicators	Population	41,061,000	
		Number of men	20,133,000
		Number of women	20,928,000
	Population between 0-14 years old (%)	14.6	
	Population over 65 years old (%)	16.96	
	Area (km ²)	505,990	
	Average population density per km ²	78.9	
	% of urban population	77.8	
Development indicators	Estimated life expectancy (World Health Report)	79.6	
	Number of live births per 1000 inhabitants	10.01	
	Fertility rate	1.24	
	Gross mortality rate per 1000 inhabitants	8.87	
	Infant mortality per 1000 live births	4.08	
	Unemployment rate (%)	14.9	
	Gross National Product (US\$ per capita)	14,860	
	Gross Domestic Product (US\$ per capita)	16,200	
	Real Gross Domestic Product (\$ PPP per cápita)	23,200	
Health indicators	No. of hospitals per 100,000 inhabitants	1.96	
	Total no. of hospitals	798	
	Hospital beds per 100,000 inhabitants	394.35	
	Total no. of hospital beds	160,162	
	No. of doctors per 100,000 inhabitants	324.34	
	Total health expenditure (% GDP)	7.6	
	Total health expenditure (%GDP) [WHO estimate]	7.5	
	Total health expenditure (\$ PPP per capita)	1,646	
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,607	
	Public health expenditure (% total health expenditure)	71.4	
	Total pharmaceutical expenditure (% total health expenditure)	21.5	
	Pharmaceutical expenditure (\$ PPP per capita)	145	
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	73.6	

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS SWEDEN

Demographic indicators	Population	8,994,000
	Population between 0-14 years old (%)	17.69
	Population over 65 years old (%)	17.21
	% of urban population	84.1
Development indicators	Estimated life expectancy (World Health Report)	80.5
	Number of live births per 1000 inhabitants	11.22
	Fertility rate	1.75
	Gross mortality rate per 1000 inhabitants	567.9
	Infant mortality per 1000 live births	2.3
	Unemployment rate (%)	5.5
	Gross National Product (US\$ per capita)	35,740
	Gross Domestic Product (US\$ per capita)	39,700
	Real Gross Domestic Product (\$ PPP per cápita)	29,540
Health indicators	No. of hospitals per 100,000 inhabitants	na
	Hospital beds per 100,000 inhabitants	na
	No. of doctors per 100,000 inhabitants	324.6
	Total health expenditure (%GDP) [WHO estimate]	9.2
	Total health expenditure (\$ PPP per capita) [WHO estimate]	2,964
	Public health expenditure (% total health expenditure)	81.8
	Total pharmaceutical expenditure (% total health expenditure)	13.8
	Pharmaceutical expenditure (\$ PPP per capita)	410
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	60.9

Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.

INDICATORS UNITED KINGDOM

Demographic indicators	Population	59,251,000	
		Number of men	28,863,000
		Number of women	30,388,000
	Population between 0-14 years old (%)	18.56	
	Population over 65 years old (%)	15.92	
	Area (km ²)	243,480	
	Average population density per km ²	243.26	
	% of urban population	89.5	
Development indicators	Estimated life expectancy (World Health Report)	78.2	
	Number of live births per 1000 inhabitants	11.29	
	Fertility rate	1.63	
	Gross mortality rate per 1000 inhabitants	10.24	
	Infant mortality per 1000 live births	5.23	
	Unemployment rate (%)	5.5	
	Gross National Product (US\$ per capita)	24,230	
	Gross Domestic Product (US\$ per capita)	26,400	
	Real Gross Domestic Product (\$ PPP per cápita)	29,000	
Health indicators	No. of hospitals per 100,000 inhabitants	2.71	
	Total no. of hospitals	1,564	
	Hospital beds per 100,000 inhabitants	417.1	
	Total no. of hospital beds	245,984	
	No. of doctors per 100,000 inhabitants	163.99	
	Total health expenditure (% GDP)	7.7	
	Total health expenditure (%GDP) [WHO estimate]	7.6	
	Total health expenditure (\$ PPP per capita)	2,160	
	Total health expenditure (\$ PPP per capita) [WHO estimate]	1,989	
	Public health expenditure (% total health expenditure)	83.4 (82.2)	
	Total pharmaceutical expenditure (% total health expenditure)	15.8	
	Pharmaceutical expenditure (\$ PPP per capita)	240	
	Public pharmaceutical expenditure (% total pharmaceutical expenditure)	64.2	

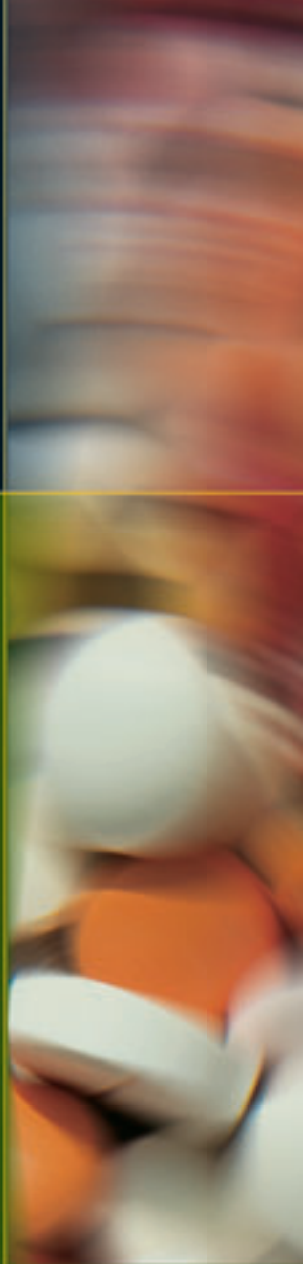
Source: WHO Europe. HFA database, 2004 and OCDE, Health Data (1st ed.), 2004.

Note: \$ PPP per cápita = amount expressed in US dollars adjusted for purchasing power parity.



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