PHIS Pharma Profile

SPAIN

2010

PHIS Pharma Profile

SPAIN

December 2010

PHIS Representatives
Ministry of Health, Social Affairs and Equality

Mercedes Martínez Vallejo
Piedad Ferré de la Peña
María Jesús Guilló Izquierdo
Carlos Lens Cabrera

Authors
Mercedes Martínez Vallejo
Piedad Ferré de la Peña
María Jesús Guilló Izquierdo

Editors
Ministry of Health, Social Affairs and Equality: Carlos Lens Cabrera, María Jesús Millán Gonzalo
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG): Sabine Vogler

Development of the PHIS Pharma Profile Template
PHIS Project Leader: Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG): Sabine Vogler, Christine Leopold, Simone Morak, Nina Zimmermann
WP 5 (Monitoring) Leader: International Healthcare and Health Insurance Institute BG (IHHII BG): Gergana Andre

Acknowledgements

Our thanks go to:

Dr. Alfonso Jiménez Palacios, Director General for Pharmacy and Healthcare Products

Amparo Montesinos, DGPhHCP

Alicia Benedi, DGPhHCP

Isabel González Gil,DGPhHCP

María de los Santos Ichaso Hernández-Rubio, Health Information Institute, Ministry of Health, Social Affairs and Equality

Jorge Juan Relaño Toledano, Subdirectorate General for Economic Analysis, Ministry of Health, Social Affairs and Equality

Rosario Santolaya, Spanish Association of Hospital Pharmacists

Jesús García Herrero, DGPhHCP

Executive Summary

Health care system

Since the forties of the XX century, Spain has striven in building its health care structure under the public sector. In the sixties, the Social Insurance setup was funded via contribution of employees and employers and health care benefits were provided free of charge to employees and their families. After the Constitution issued on December 1978, health became a fundamental right for Spanish citizens and the funding of health care evolved, as well as benefits provided by public institutions.

The population of Spain amounted to 46.6 million in 2009, with an absolute growth of 8% in the last ten years. This increase is mainly due to immigration, a phenomenon that has also slowed down the aging parameters.

Funding of the Spanish NHS is done via general taxes. Total health care spending amounts to ca. 9% GDP. Public health care means 6.5% GDP and privately-provided health care means 2.5% GDP.

Provision of health care in Spain is performed through the National Health System that covers the vast majority of the population. Though the political aim is the universal coverage, approximately 300,000 Spaniards and residents do not have yet access to NHS. The basic applicable law, other than constitutional principles, is the General Health Care Act, issued on 1984.

Since its beginning, the NHS started building hospitals and primary care centres and hiring its staff. Covenants and contracts with private health care companies have been in place since the sixties.

Health professionals are public employees and their remunerations packages differ to a certain extent but there exist common grounds for all of them (degrees, hierarchy levels, incentives).

Most hospital beds belong to the NHS. Public hospitals are larger than private ones. In-patients in public hospitals are treated free of charge if they have coverage rights. Most private hospitals belong to profit-based organizations.

Traditionally, Spanish universities have generated sufficient outflow of health graduates to cover the needs of the country. However, in the last decade Spanish health professionals are being offered attractive positions in other EU Member States and there exist some shortage of physicians and nurses.

Pharmaceutical system

Since the seventies of the XX century, NHS has been accounting for 75+% of the pharmaceutical market (out-patients) and an even higher percentage of the hospital market. Medi-

cines are provided free of charge in NHS hospitals and to pensioners in the out-patient domain under NHS coverage. Active (working) out-patients under NHS coverage are subject to co-payment of medicines prescribed by a NHS physician.

Medicines are authorized by the European Medicines Agency and/or the Spanish Agency for Medicines and Healthcare Products. Immediately after, they are subject to pricing and reimbursement procedures to the Ministry of Health, Social Affairs and Equality. Only retail pharmacies may dispense medicines to the out-patients but there exist some exceptions of hospital dispensing. The funding of dispensed medicines to NHS beneficiaries is a competence of the regional governments.

Most medicines authorized by EMA are available in Spain. Medicines authorized in other EU Member States may be available after decentralized procedure. All authorized medicines comply with EU provisions. The whole population has access to authorized medicines.

There are solid data on the out-patient market of medicines, whose trend is similar to the ones observed in other EU markets. Notwithstanding, in 2010 the out-patient market has undergone stagnation/decrease due to contention measures within NHS.

The importance of generic medicines in Spain has steadily grown in the last decade and amounted to 30% in volume at the NHS out-patient sector.

Though there are more than 1,000 pharmaceutical companies listed in the Spanish Agency, 200 account for 99% of the out-patient market.

Approximately 100 wholesalers and 22,000 retail pharmacies compose the dispensing network across Spain.

Pharmaceutical expenditure financed by the Spanish Governments has been growing ever since. 2010 is the first year in which pharmaceutical spending has experienced a small decrease in monetary units. Regarding pharmaceutical expenditure, NHS funds 75% of out-patient market and most of the hospital supply of medicines.

The funds come from general taxes.

Pricing, reimbursement and volume control in the out-patient sector

Prices and reimbursement of medicines is regulated in Spain since the seventies. Today's applicable law is Act 29/2006, by virtue of which the Ministry of Health, Social Affairs and Equality is responsible for pricing and reimbursement of medicines.

Applicants (marketing authorization holders, MAH) are requested to submit their pricing and reimbursement dossiers upon approval of their medicines. The submission is assessed by the Directorate-General for Pharmacy and Healthcare Products of the Ministry of Health. A report is brought up to the Interministerial Commission for Pricing of Medicinal Products,

chaired by the Ministry of Health. Representatives of other Ministries are present in the Commission (Industry, Finance).

As per article 89.1 of Act 29/2006, criteria used in the assessment and pricing and reimbursement proposals include severity of indications, usefulness of the medicines, needs of patient groups, rationality of costs, existence of therapeutic options and degree of innovation. Additionally, prices in other Member States are considered for initial pricing and later revisions.

Innovative medicines are priced in alignments with other Member States but budgetary impacts are thoroughly considered. Generics are priced at least 40% below prices of innovators. Non-prescription medicines are neither reimbursed nor subject to pricing decisions. Hospital medicines are subject to pricing and reimbursement procedures.

The regulator sets the ex-factory price after negotiations with the marketing authorization holder (MAH) on the basis of the assessment of the law criteria afore mentioned . Thereupon, mark-ups and VAT are added to obtain the final price. Hospital medicines are directly sold by MAH or distributors to hospitals at ex-factory price plus VAT. Mark-ups or margins are regulated.

Wholesalers and retail pharmacies are remunerated via margins for all medicines. The scale is broken down as follows:

Medicines up to € 91.63 of ex-factory price: 7.6% of the wholesale price for wholesalers, 27.9% on pharmacy retail price for retail pharmacies.

Medicines higher than € 91.63 to equal or inferior to € 200 of ex-factory price: € 7.54 as a flat mark-up for wholesalers, € 38.37 to retail pharmacies.

Medicines higher than € 200 to equal or inferior to € 500 of ex-factory price: € 43.47 to retail pharmacies.

Medicines over € 500 of ex-factory price: € 48.37 to retail pharmacies.

VAT for medicines is 4%.

The State is responsible for decisions on pricing and reimbursement of medicines. Most prescription medicines are subject to reimbursement and only selected categories are excluded from reimbursement. Pricing and reimbursement decisions are linked. Most prescription medicines have a co-payment of 40% if prescribed by a NHS doctor to out-patients. But some medicines in specific therapeutic sub-groups –aimed at chronic, severe diseases - have a reduced co-payment (10% on the final pharmacy retail price with a maximum of € 2.64). Pensioners receive all reimbursable medicines free of charge.

A reference pricing system (RPS) has been in force in Spain since 1999. The reference groups are always based on the same active pharmaceutical ingredient (API) and updated once per year.

The private sector accounts for 25% of the out-patient pharmaceutical market. As a general rule, patients pay the whole price of medicines prescribed by doctors in private practice but there are some health insurance systems that start to cover pharmaceuticals.

Volume control of pharmaceuticals is performed by regional governments, ultimate payers for the pharmaceutical bill of the Spanish NHS. Since the seventies, prescribing doctors have been subject to control by local authorities since they are mostly public employees. Recently, some regions are starting to implement additional controls in order to keep the expenditure under control.

Prescription by INN (international non-proprietary name) shall be encouraged by the public healthcare administrations according to the law and supported by IT systems. In consistency therewith, generics are preferred and prioritized both in prescription and in substitution.

Claw-backs are allowed and performed under legal provisions (Act 29/2006). A general rebate of 2-4% every four months according to the sales plus an additional discount of 7.5% on sales to NHS is applied routinely. Innovative companies may get a reduction of the first pier of rebates up to 25%.

NHS consumption of pharmaceuticals has been monitored since the seventies. Each prescription is processed and a set of data are brought into the IT filing system on a monthly basis. The pharmaceutical bill is thereby paid to associations of retail pharmacies and the data are used afterwards to perform controls both by the regional authorities and by the Ministry of Health.

Pharmaco-economic assessment is performed within the pricing and reimbursement process as a tool to evaluate the usefulness of new medicines and make comparisons.

HTA is performed by specialized entities (Escuela Andaluza de Salud Pública, Agencia d'Avaluació de Tecnologies Sanitàries, Agencia de Evaluación de Tecnologías Sanitarias) with a broader development applicable to health technologies other than medicines. Their reports are used as a tool in the decision making process for public funding and rational use of health technologies including medicines.

Pricing, reimbursement and volume control in the in-patient sector

The legal framework applicable to hospital purchases, whether medicines or other devises, is the Constitutional Law of each region plus the Act 29/2006, previously mentioned. Spanish regional Governments are responsible for the organization and performance of health care and thereby hospital setups differ to some extent among regions.

Notwithstanding, hospitals may buy any medicine that they need and pay no more than prices approved by the Ministry of Health. Purchases are mostly done to pharmaceutical companies and therefore applicable price is ex-factory price.

Big and medium-size hospitals have pharmacy wards that play a key role in the acquisition, stock and dispensing of medicines to in-patients. The bigger the hospital, the more likely a

Pharmaceutical and Therapeutic Committee has been established to decide and/or give advice on selection of medicines. Regional Governments play different roles in this protocol-making activity.

Medicines sold to hospitals are charged the applicable (reduced) VAT rate, namely 4%.

No specific mark-ups are applied to medicines sold to hospitals when they are supplied by MAHs. However, if supplied by a wholesaler or retail pharmacy – usually in emergencies - the margin scheme described to medicines prescribed/sold to out-patients is applied.

There are not mandatory/recommended discounts to sales to hospitals. Suppliers and hospitals are free to negotiate commercial terms.

Tenders can be used for any hospital supply, including medicines. If the Regional Government decides to proceed by tendering, the applicable law is the Public contracting Act that fully complies with EU rules.

Joint procurement is seldom used and, if done, is carried out at regional level. To date, there is no procurement Agency in Spain. Nevertheless, centralized procurement was foreseen in Royal Decree 8/2010 and has been applied to influenza vaccines.

Hospitals may buy reimbursable and non-reimbursable medicines.

The main payer for hospital supplies is the hospital. Public hospitals manage their budgets in accordance with regional provisions. No cooperative funding is applied to hospital medicines but, for management reasons, sometimes hospital managers set limits to the number of treatment to be performed in the year. All medicines bought by a public hospitals are dispensed free of charge to in-patients if they are eligible users of the NHS.

Hospital pharmaceutical formularies are in place.

The role played by hospital pharmacists and Pharmaceutical and Therapeutic Committees is either advisory or binding. It depends on regional provisions but it is frequent to have an advisory committee and a decision-making team composed of the chief hospital pharmacist, the manager and the medical director.

Before finally deciding to introduce a medicine in a hospital pharmaceutical formulary, the overall impact on the budget and health outcomes will be estimated (annual basis). The follow-up is not frequently performed but assessments of the use of selected medicines for in-patients are often done and published.

Most pharmacy wards are computerized. Hospital pharmacists are experts in rational use and monitoring of medicines.

Pharmaco-economic analysis is performed by using cost-effectiveness tools. Since in-patients populations are well known and time series do exist, uncertainty does not have heavy influence. At least, new therapies are subject to budgetary impact assessment and health outcomes.

HTA is routinely performed when considering the introduction of any new therapy or medical intervention. Methodologies do vary depending on the medical specialty.

Interface management and developments

There are solid links between both sectors. Most hospital physicians spend some time in out-patient care and follow up patients discharged from their hospital. Medical treatment established during hospital stays are afterwards followed up and monitored by family physicians.

The greatest changes expected both in in-patient and out-patient care are the ones to be brought about by the implementation of new technologies. Computerized hospital records and e-prescription are underway and the process speed is fast.

Table of content

List of tables

List of figures

List of abbreviations

AEMPS	Agencia Española de Medicamentos y Productos Sanitarios/Spanish Medicines Agency
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ATC	Anatomic therapeutic chemical classification
BMG	Bundesministerium für Gesundheit / Austrian Ministry of Health
CISNS	Consejo Interterritorial del Sistema Nacional de Salud/Interterritorial Board of the National Health System
CIVAS	Centralized Intravenous Admixtures Service
CNO	Clasificación Nacional de Ocupaciones/National Occupations Classifications
CPD	Cupón precinto diferenciado
DCP	Decentralised procedure
DDD	Defined daily doses
DG SANCO	Health and Consumer Protection Directorate General
DGPhHCP	Directorate General for Pharmacy and Healthcare Products
DH	Diagnóstico Hospitalario / Hospital diagnosis
DRG	Diagnosis related group
EAHC	Executive Agency for Health and Consumers
ECM	Especial control medico / Special medical control
IHHII	International Healthcare and Health Insurance Institute
INE	Instituto Nacional de Estadística/National Statistics Institute
INN	International Non-proprietary Name
IPC	Interministerial Pricing Committee
ISCO	International Standard Classification of Occupations
GDP	Gross domestic product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute

GP	General practitioner
HTA	Health technology assessment
HE	Health expenditure
HiT	Health systems in transition
HOM	Hospital-only medicine
HPF	Hospital pharmaceutical formularies
MAH	Marketing authorization holders
MoH	Ministry of Health
MSPSI	Ministerio de Sanidad, Política Social e Igualdad de España/Spanish Ministry of Health, Social Affairs and Equality
NHS	National health service / National health system
NMEs	New molecular entities
Mio.	Million
OECD	Organisation for Economic Co-operation and Development
OPD	Out-patient departments
OPP	Out-of-pocket payment
OTC	Over-the-counter medicine
PHIS	Pharmaceutical Health Information System
PE	Pharmaceutical expenditure
POM	Prescription-only medicine
PPP	Purchasing power parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price
PTC	Pharmaceutical and Therapeutic Committee
QALY	Quality adjusted life year
RPS	Reference pricing system

SCP	Sin cupón precinto
SIAP	Sistema de Información de Atención Primaria/Primary Care Information System
SNHS	Spanish National Health System
SD	Standard deviation
SHI	Social health insurance
SUKL	Štátny ústav pre kontrolu liečiv / State Institute for Drug Control
SOGETI	SOGETI Luxembourg SA
TFEU	Treaty on the Functioning of the European Union
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
VHI	Voluntary health insurance
WHO	World Health Organisation
WP	Work package

Introduction

The Pharmaceutical Health Information System (PHIS) project is a research project commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project management is a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) a research institute situated in Vienna, Austria, and four associated partners: the Italian Medicines Agency (AIFA), Italy, the International Healthcare and Health Insurance Institute - (IHHII), Bulgaria, SOGETI Luxembourg SA., Luxembourg and the State Institute for Drug Control (SUKL), Slovakia. Further key stakeholders of the PHIS project management are the PHIS advisory board covering EU Commission services and agencies and international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project aims to increase the level of knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union. This will be achieved by surveying and monitoring pharmaceutical health system information in the in-patient and out-patient sector from a public health perspective, and by developing key pharmaceutical health indicators which may be included in a European Health Information System.

The PHIS project runs from September 2008 to April 2011 (32 months). Further information and all deliverables are made available at the PHIS project website http://phis.goeg.at.

PHIS Monitoring

The aim of the work package “Monitoring” is to provide up-to-date country-specific information on out-patient and in-patient pharmaceutical systems in the EU Member States.

The country-specific information is compiled in different sets and for different purposes based on different templates taking into consideration a common terminology (PHIS Glossary) and a set of indicators (PHIS Indicators): e.g.

- Country reports covering information on the pharmaceutical system in the in- and out-patient sector written by country representatives of the PHIS network (PHIS Pharma Profiles)
- Integrated flowchart of the pharmaceutical system in the in- and out-patient sector (also part of the PHIS Pharma Profile)
- Country reports with a focus on the pharmaceutical system in the in-patient sector (national PHIS Hospital Pharma Report) and a compilation of the information in a benchmarking report (PHIS Hospital Pharma Report)

All documents together represent the PHIS Library, which has to be understood as an on-line documentation system containing up-to-date information on the pharmaceutical in- and out-patient sectors. The PHIS Library is accessible at the website of the PHIS project (http://phis.goeg.at) and is constantly updated.

PHIS Pharma Profile

The production of the country-specific PHIS Pharma Profiles is based on three steps:

1. Development of a uniform PHIS Pharma Report Template

The PHIS Pharma Profile offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in- and out-patient sector of a country. The Template provides detailed guidelines and specific questions, definitions and examples needed to compile the PHIS Pharma Profile. It consists of six chapters, referring to the regulatory situation in 2010 or 2011. Three of the chapters (chapter 1 Health care system, chapter 2 Pharmaceutical system and chapter 5 Interface management and developments) are covering integrated information on the in- and out-patient sector. Chapters 3 and 4 are dedicated entirely to the pricing, reimbursement and volume control in out-patient sector and respectively to the in-patient sector.

The methodology for developing the PHIS Pharma Profile Template is based on the review of existing surveys – country profiles developed in the PPRI project (Pharmaceutical Pricing and Reimbursement Information) and the PHIS Hospital Pharma report – and by using the common terminology (glossary) developed in Work Package 4 (Terminology) and the pharmaceutical indicators (PHIS indicators) developed in Work Package 6 (Indicators) of the PHIS project. The PHIS Pharma Profile Template was developed by the leader of work package Monitoring Ms. Gergana Andre (IHHII, Bulgaria[1]) in collaboration with the PHIS main partner (GÖG/ÖBIG). The Template was kindly reviewed by the PHIS Advisory Board. Members of the PHIS network received the draft Template for feed-back, and had the opportunity to discuss and provide personal feed-back during a meeting.

[1] IHHII BG is a 10 years old Bulgarian think tank, independent non-governmental organisation, which provides information and analysis in health policy, healthcare management and organisation in Bulgaria. Through its network of consultants and independent research work it provides reports, early warning statements, organises debates, engages non-governmental stakeholders in health to perform proper government monitoring and enforce civic participation in the development and implementation of health policy. A significant part of the research work of IHHII is dedicated to the pharmaceutical system and market in Bulgaria. Through its reports and analyses the Institute is a reliable partner to many professional organisations in health and the public institutions. IHHII maintains the largest and the oldest health web portal in the country – www.zdrave.net – which is an online arena of information exchange and debates in health reaching at daily average 5, 000 people acting in health and pharmaceutical system.

2. Collecting information and data and drafting the PHIS Pharma Profiles

The country-specific PHIS Pharma Profiles were written by members of the PHIS network. In order to get the needed information and data, experts of the in- and out-patient sectors were contacted and involved in several countries. They provided information and data in written form and during telephone conservations and personal talks. In several countries, the preparatory work for drafting the PHIS Pharma Profiles also included study visits of the authors e.g. to hospital pharmacies. Information on persons and institutions involved can be found in the “Acknowledgements” at the beginning of this PHIS Pharma Profiles. For some countries (out-dated) information on the pharmaceutical system in the in- and out-patient sectors was already available but in form of separated reports (e.g. for the out-patient sector: PPRI report; for the in-patient sector: PHIS Hospital Pharma Report). It was a challenge to integrate the two separated reports into one updated integrated description of the pharmaceutical system. The main partner (GÖG/ÖBIG) of the PHIS project offered PHIS network members to pre-fill the template with already existing information and delivered pre-filled templates for 13 countries.

3. Editorial process

The drafts of PHIS Pharma Profiles were submitted to the project management for review, which was undertaken by IHHII, Bulgaria (Work Package leader of “Monitoring”) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template, terminology (PHIS Glossary) and data provision for filling PHIS Indicators (to be filled in the PHIS database). In the course of the editorial process, the reviewers contacted the authors for providing feedback on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

1 Health care system

This chapter provides an overview of Spain's health care system as of 2010.

1.1 Demography

In the last decade, the population in Spain has considerably increased. In the same period of time, life expectancy has risen. Demographic indicators are provided in Table 1.1.

Table 1.1: Spain – Demographic indicators 2000, 2005–2009

Demography	2000	2005	2006	2007	2008	2009
Total population	40,264,162	43,398,190	44,068,244	44,873,567	45,593,385	45,929,432
Population aged 0-14	5,951,897	6,291,077	6,393,446	6,535,014	6,695,663	6,815,069
Population aged 15-64	27,540,048	29,838,672	30,318,423	30,873,346	31,321,413	31,427,791
Population aged > 64	6,772,217	7,268,441	7,356,375	7,465,207	7,576,309	7,686,572
Life expectancy at birth	79.3	80.3	80.9	80.9	81.2	81.6
Life expectancy at age 65	18.8	19.3	19.9	19.8	20.0	20.2

Data as of 31 December

Source: Instituto Nacional de Estadística (Statistical National Institute)

1.2 Organisation

The Spanish National Health System integrates all public structures and health services, including Mutual funds for civil servants: Muface, Mugeju e Isfas).The Spanish National Health System provides universal coverage and free healthcare services at the time of use via public funding. The Spanish Constitution of 1978 establishes the right to health protection and healthcare for all citizens. The fundamental principles and criteria enabling the access are provided for in Act 14/1986, April 25th, on General Health, and Act 16/2003, May 28th, on the Cohesion and Quality of the National Health System.

The Spanish National Health System - SNHS - is comprised by both the Central Government Administration and the autonomous regions public healthcare managements working in coordination to cover all the healthcare duties and benefits for which public authorities are legally responsible.

The Central Government responsibilities on health are:

- Health basic principles and general coordination.
- Foreign health affairs and international relations and agreements.
- Legislation on pharmaceutical products.

The Ministry of Health, Social Policy and Equality is the body entrusted with proposing and implementing Government health policy, health planning and care and consumer affairs, as well as with the exercise of the powers and responsibilities of the Central Government to ensure citizens' right to health protection. It is also in charge of proposing and implementing the Government policy on cohesion and social inclusion of families, child protection and care and support to dependent or disabled people, as well as promotion of equality, non-discrimination and universal accessibility policies.

The Ministry of Health, Social Policy and Equality is responsible for the coordination of pharmaceutical policy and pharmaceuticals financing, a task performed through the General Directorate for Pharmacy and Medical Products, and for the processes of assessment and authorisation of medicines and medical devices a responsibility exercised through the Spanish Agency for Medicines and Medical Devices.

The Interterritorial Board of the National Health System (CISNS, from its Spanish abbreviation), is the body responsible for the coordination, cooperation and liaison among the central and autonomous region public health administrations. The Minister for Health, Social Policy and Equality acts as Chairman of the Interterritorial Board. The Deputy Chairman is held by one of the directors of the Health Departments of the autonomous regions, elected by and among the Department directors comprising the Board. The CISNS operates through its Plenary Meeting, an Executive Committee, technical committees and working groups.

Each autonomous region has its own Health Service, which is the administrative and management body responsible for all the health centres, services and facilities in its region, provincial administrations, town councils and any other intra-community administration.

Under constitutional provisions and their respective autonomy statutes, the autonomous regions have taken up responsibilities with respect to healthcare. The taking-up of responsibilities in the field of health by the autonomous regions brings the management of healthcare closer to citizens and guarantees: equity in access to the benefits and the right to health protection under conditions of effective equality throughout the country and free movement of all citizens, quality and participation of citizens.

1.3 Funding

This section gives an overview of the health care expenditure and the sources of funding health care.

1.3.1 Health expenditure

In the last decade, total health expenditure has nearly doubled. Table 1.2 provides an overview about the development of health expenditure, also with regard to sources of funds and sector.

Table 1.2: Spain – Health expenditure 2000, 2005–2009

Health expenditure in millions of Euro	2000	2005	2006	2007	2008	2009
GDP	630,263	908,792	984,284	1,053,537	1,088,124	1,053,914
THE	45,446	75,289	82,250	88,914	97,614	n.a.
- thereof public HE	32,550	53,145	58,652	63,854	7,0799	n.a.
- thereof private HE	12,896	22,144	23,598	25,060	26,815	n.a.
HE in the out-patient sector	17,994	22,291	24,264	26,200	28,753	n.a.
- thereof public	11,286	12,064	13,336	14,682	16,416	n.a.
- thereof private	6,708	10,227	10,928	11,518	12,338	n.a.
HE in the in-patient sector	12,799	20,317	22,423	24,573	27,481	n.a.
- thereof public	11,122	17,489	19,437	21,316	24,126	n.a.
- thereof private	1,677	2,827	2,986	3,257	3,355	n.a.

GDP = gross domestic product, HE = health expenditure, n.a. = not available, THE = total health expenditure

Note: Data of out-patient and in-patient health expenditure does add up to the total health expenditure due to the methodology applied.

Source: OECD Health Data 2010.
National Statistics Institute. Spanish National Accounts.

1.3.2 Sources of funds

The Spanish National Health System provides universal coverage and free healthcare services at the time of use via public funding. 72.5 per cent of total health expenditure in Spain corresponds to National Health System and so is publicly funded. 27.5 per cent of health expenditure corresponds to private sector. To our knowledge, informal payments do not play a role in health care.

1.3.3 Out-patient care

Out-patient physicians – whether general practitioners (GP) or specialists – are paid a salary including a small capitation component, as well as a performance-based remuneration considering the extent to which objectives have been achieved according to financial incentive schemes, including items related to the rational use of medicines. As mentioned before, there are no OPP within in the SNHS. The Spanish National Health System provides universal coverage and free healthcare services at the point of care via public funding.

1.3.4 In-patient care

The main payer of funding in the in-patient sector is the Spanish National Health System. Hospitals are financed by global budgeting. There are no OPP in hospitals. The Spanish National Health System provides universal coverage and free healthcare services at the point of care via public funding.

1.4 Access to health care

1.4.1 Health care professions

Table 1.3 provides an overview about the development of health professionals like doctors and pharmacists in Spain. The numbers have risen.

Table 1.3: Spain – Doctors and pharmacists development 2000, 2005–2009

Health professionals	2000	2005	2006	2007	2008	2009
Total no. of doctors[1]	132,900	163,500	159,900	163,800	159,500	162,600
- of which GPs	n.a.	31,210	32,001	31,590	33,349	n.a.
- of which work in the out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- of which work in the in-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of pharmacists	30,000	35,500	34,200	42,400	40,000	46,800
- of which work in community pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- of which work in hospital pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

GP = general practitioner, n.a. = not available

Notes and source:

Total number of doctors: National Statistics Institute (INE). Labour Force Survey (several issues).
http://www.ine.es/jaxi/menu.do?type=pcaxis&path=/t22/e308_mnu&file=inebase&N=&L=0
Reference period: annual average.
Coverage:
- 2000 data are based on the Labour Force Survey. Data include "physicians and odontologists" from the National Occupations Classification (CNO-94 Spain, code 212) on 3 digit level. The information on 4 digit level is not available. The CNO-94 is the Spanish equivalence of ISCO-88. It is not possible to separate "physicians and odontologists" on 3 digit level.
- Practising physicians include physicians providing services directly to patients working in the sector "Health and Social Services" of ISIC.
- Data with ISCO-08 definitions are not yet available.

Break in time series: In the year 2005 there is a break in the series due to a "new methodology" in the Labour Force Survey.

GPs: Ministry of Health and Social Policy. From Primary Care Information System (SIAP)
http://www.msc.es/estadEstudios/estadisticas/estadisticas/estMinisterio/siap.htm.
Reference Period: 31st December.
Coverage:
- Data include number of persons who work in Health care centres of National Health System at the end of the calendar year. Data for private sector are not available.
- Included: interns and residents who are training to become GPs (3 years is required to qualify as GP; before 2005/2006, it used to be 4 years).

No. of pharmacists: National Statistics Institute (INE). Labour Force Survey (several issues).
http://www.ine.es/jaxi/menu.do?type=pcaxis&path=/t22/e308_mnu&file=inebase&N=&L=0
Reference period: annual average.
Coverage:

- Data are based on the Labour Force Survey. Data include practising pharmacists (2224 ISCO-88 code).
- The data by occupation is classified according the National Occupations Classification (CNO-94 Spain, code 214), the Spanish equivalence of ISCO-88. Data with ISCO-08 definitions are not yet available.

1.4.2 Out-patient care

Primary out-patient care is provided by the National Health System in healthcare centers and surgeries. Primary Health Care makes basic health care services available within a 15-minute radius from any place of residence. The main facilities are the Health care centres, staffed by multidisciplinary teams comprising general practitioners, paediatricians, nurses and administrative staff, and, in some cases, social workers, midwives and physiotherapists. Primary health care includes service provided either on-demand, scheduled, or urgently, both in the centres as well as in the patient's home.

There is free choice of out-patient doctors, but the procedure varies for each autonomous region, according to the management rules of each Regional Health Service. Out-patient doctors practise publicly when provided by National Health System. They act as a gate-keeper for access to specialists and in-patient care. Thus, secondary care is provided at the request of primary care physicians. Hospital-based emergency care (available twenty-four hours a day for patients with acute medical conditions requiring urgent hospital care) is provided to patients referred by their primary care or specialist care doctor, or to patients who have suffered an accident or presented with a sudden life-threatening condition requiring treatment available only in a hospital setting.

Secondary care is also delivered by the National Health System. Specialist Care is provided in Specialist care centres and hospitals in the form of out-patient and in-patient care. Patients having received specialist care and treatment are expected to be referred back to their primary health care doctor, who, based on the patient’s full medical history, including the medical notes issued by the specialist, assumes responsibility for any necessary follow-up treatment and care. This ensures the provision of continuous care under equitable conditions, irrespective of the patient’s place of residence and individual circumstances, with care provided even in the patient’s home if necessary.

Health care services are distributed following a region-based organisation of health areas and basic health zones. Each autonomous region defines its own health areas according to various demographic and geographic criteria, but above all aiming to guarantee service proximity to users.

1.4.3 In-patient care

Hospitals (in-patient healthcare centres) are healthcare centres destined to specialized and continued care of patients provided in the form of in-patient care (minimum one night), whose main purpose is the diagnosis or treatment of the in-patients, and also with the possibility to provide specialized and continued care in the form of out-patient care.

There are 804 hospitals operating in Spain. The National Health System has 315 hospitals, equipped with 105,505 beds, and 4 Defense Ministry's hospitals contributing with 995 beds. There are also 20 hospital facilities owned by the occupational accident and work-related illnesses mutual societies, with 1,468 beds. The remainder, 465 hospitals, are privately run and have 53,013 beds.

According to the kind of care provided, from the total of 160,981 beds installed in Spain's hospitals, 131,445 are located in 589 hospitals concerned with acute care, 72.9% of which are managed by the National Health System. 37.2% of the 16,111 beds available in psychiatric care hospitals and 35.1% of the 13,365 beds for geriatric and long-term care are managed by the National Health System. The National Health System provides in-patient care in public hospitals.

Table 1.4: Spain – In-patient care 2000, 2005–2009

In-patient care	2000	2005	2006	2007	2008	2009
No. of hospitals	771	751	746	764	767	n.a.
Classified according to ownership						
– thereof public hospitals	356	330	325	335	345	n.a.
– thereof not-for-profit privately owned hospitals	133	121	120	121	121	n.a.
– thereof for-profit private hospitals	282	300	301	308	301	n.a.
Classified according to subtypes[1]						
– thereof general hospitals	586	544	548	559	557	n.a.
No. of acute care beds	119,328	116,629	117.429	118,971	118,871	n.a.
– thereof in the public sector	94,904	93,863	94,728	95,714	95,875	n.a.
– thereof in not-for-profit privately owned hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof in for-profit private hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Average length of stay (acute care) in days	7.1	6.7	6.6	6.6	6.5	n.a.
No. of hospital pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available, No. = number

[1] according to the OECD definition and its subtypes.

-Reference period: Annual average

Source: Ministry of Health, Social Affairs and Equality data from Statistics on Health Establishments Providing In-patient Care.
http://www.msc.es/estadEstudios/estadisticas/estHospiInternado/inforAnual/homeESCRI.htm

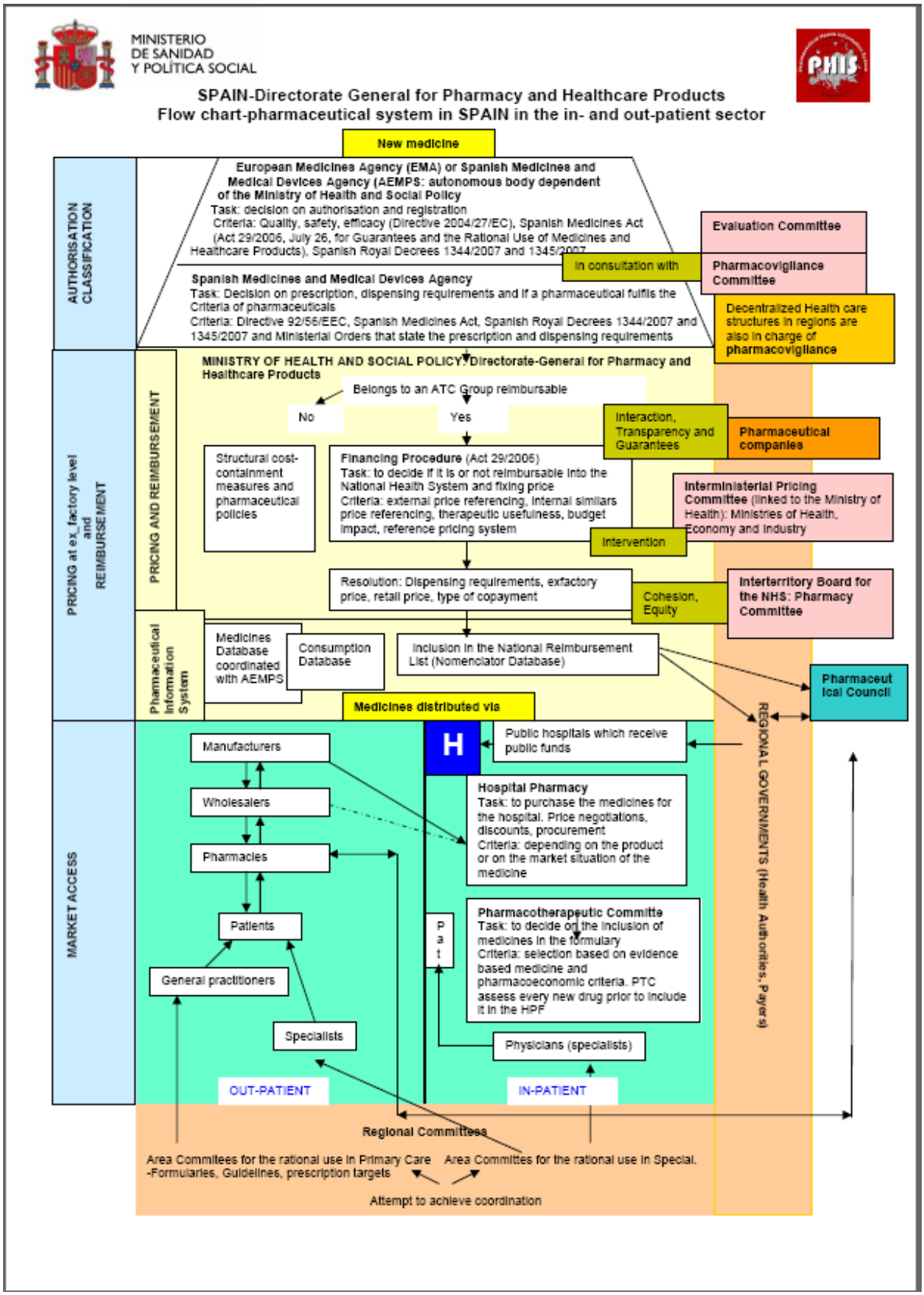
2 Pharmaceutical system

This chapter gives an introduction to the pharmaceutical system, including organisation, key statistic data, market players, and funding.

2.1 Organisation

This section describes the regulatory framework (legal basis, main authorities and their tasks) addressing both the out-patient and the in-patient sector.

Figure 2.1: Spain – Flowchart of the pharmaceutical system



ATC: Anatomic therapeutic chemical classification

PTC: Pharmaceutic and Therapeutic Committee

HPF: Hospital pharmaceutical formulary

Source: Created by Mercedes Martínez Vallejo according to PHIS template

2.2 Regulatory framework

This section includes a description of the legal framework for the out-patient and in-patient pharmaceutical policy, the key authorities and important players and their roles as of 2010.

Table 2.1: Spain – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2010

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Market authorisation	Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products Royal Decree 1345/2007, 11 October, regulating the marketing authorization and prescription conditions of medicinal products for human use.	In- and out-patient sectors	Spanish Medicines and Medical Devices Agency AEMPS	Responsible for marketing authorisation of medicines in Spain and assessment of medicines and medical devices which are already on the market regarding efficacy, adverse reactions, production, shipment and storage.	Pharmaceutical companies Interest associations: Farmaindustria: pharmaceutical industry association, AESEG: generics industry associations
Pricing / Purchasing	Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products. Royal Decree 271/1990 about medicinal products pricing regulation	In- and out-patient sectors	Council of Ministers Ministries of Health, Social Policy and Equality; Economy and Finance; and Industry Tourism and Trade. Interministerial Pricing Committee (IPC) Directorate General for Pharmacy and Health Care Products	Responsible for the price system: Pricing decisions at manufacturer price level, and wholesale and pharmacy margins.	Pharmaceutical companies, Wholesale federation- National Federation of Associations Wholesalers and Distributors of Medicines (FEDIFAR), and General Council of pharmacists

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Reimbursement	Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products	In- and out-patient sectors	Council of Ministers Ministry of Health, Social Policy and Equality Directorate General for Pharmacy and Health Care Products	Responsible for the reimbursement decisions for medicines and healthcare products.	Pharmaceutical companies, The wholesale federation National Federation of Associations Wholesalers and Distributors of Medicines (FEDIFAR), and General Council of pharmacists
Promotion	Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products Royal Decree 1416/1994, 25 June, regulating the publicity of human medicines	In- and out-patient sectors	Ministry of Health, Social Policy and Equality Health Services of the autonomous Regions	Information to health professionals and public	Pharmaceutical companies,
Distribution	Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products Royal Decree 2259/1994, 25 November, regulating Wholesale and distribution of human medicines.	In- and out-patient sectors	Ministry of Health, Social Policy and Equality Health Services of the autonomous Regions	Establishment of the general rules for the distribution system. Authorise the wholesalers which operates in their region.	Pharmaceutical companies, The wholesale federation National Federation of Associations Wholesalers and Distributors of Medicines (FEDIFAR),

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Vigilance	Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products Royal Decree 1344/2007, 11 October, regulating pharmacovigilance of medicinal products for human use	In- and out-patient sectors	Ministry of Health, Social Policy and Equality Health Services of the autonomous Regions	Pharmacovigilance system	Pharmaceutical companies, health professionals, patients.

Source: Mª Jesús Guilló according PHIS template

Regarding medicines, the responsibilities of the Spanish Government are: Legislation on medicines; Evaluation, authorisation and registration of medicines for human and veterinary use and medical products; Decision on public funding and pricing of medicines and health products; Guarantee deposit of narcotic substances in accordance with international treaties; Importation of urgent foreign medicines unauthorized in Spain; To maintain a strategic official deposit of pharmaceuticals and medical products for emergencies and disasters; Acquisition and distribution of pharmaceuticals and medical products for international cooperation programmes.

The principles and criteria for promoting the rational use of medicines are contained in Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products, in order to ensure the quality of coverage throughout the National Health System in a decentralised framework, in such a way as to achieve the key objective of guaranteeing that all citizens continue to have access to the medicines they need at all times and in any location, under effective and safe conditions. This Act regulates human medicines and medical products: clinical research, evaluation, authorisation, registration, manufacture, preparation, quality control, storage, distribution, circulation, traceability, marketing, information and advertising, importation and exportation, prescription and dispensing, monitoring of the benefit-risk ratio, as well as their rational use and the procedure for public funding.

2.3 Statistics

This section gives an overview on the number of medicines as well as on market figures and consumption.

2.3.1 Availability of medicines

2.3.1.1 Market authorisation

This section provides insight in the number of medicines according to different classification.

Table 2.2: Spain – Number of medicines 2000, 2005–2010

Medicines	2000	2005	2006	2007	2008	2009	2010	Method of counting[2]
Authorised	9,475	16,077	17,542	19,363	20,884	22,655	24,877	All authorised medicines, including different pharmaceutical forms, pack sizes and dosages
On the market	---	---	---	---	---	---	---	No data available
POM[1]	8,042	14,196	15,557	17,245	18,701	20,400	22,528	All authorised prescription-only-medicines, including different pharmaceutical forms, pack sizes and dosages
Reimbursable	121,99	16,016	16,818	18,151	18,976	19,820	20,894	All reimbursable medicines, including different pharmaceutical forms, pack sizes and dosages, including larger packs which are intended to cover greater amounts of medicines needed in hospitals (called “envases clínicos”) and hospital-only-medicines
Generics	965	4,072	5,030	6,117	7,023	8,100	9,335	All reimbursable generic medicines, including different pharmaceutical forms, pack sizes and dosages, including larger packs which are intended to cover greater amounts of medicines needed in hospitals (called “envases clínicos”) and hospital-only-medicines
Parallel traded	---	10	12	13	14	19	26	All reimbursable medicines, including different pharmaceutical forms, pack sizes and dosages

Medicines	2000	2005	2006	2007	2008	2009	2010	Method of counting[2]
Hospital-only	914	1,247	1,382	1,563	1,725	2,056	2,211	All reimbursable medicines including different pharmaceutical forms, pack sizes and dosages, including larger packs which are intended to cover greater amounts of medicines needed in hospitals (called "envases clínicos")
Non-prescription medicines with advertising addressed to the public[2]	989	1,339	1,432	1,529	1,567	1,597	1,612	All authorised medicines, including different pharmaceutical forms, pack sizes and dosages
DH[3]: "Diagnóstico Hospitalario"	414	432	458	510	531	552	589	All reimbursable medicines, including different pharmaceutical forms, pack sizes and dosages
CPD[4]: "Cupón precinto diferenciado"	49	249	383	498	517	660	742	All reimbursable medicines, including different pharmaceutical forms, pack sizes and dosages
ECM[5]: "Especial control medico"	8	26	27	26	30	28	24	All reimbursable medicines, including different pharmaceutical forms, pack sizes and dosages
SCP[6]: "Sin cupón precinto"	2	22	23	28	28	28	35	All reimbursable medicines, including different pharmaceutical forms, pack sizes and dosages

POM = prescription-only medicines

Data as of 1 January

1 Prescription-only-medicine was synonymous in Spain of "medicamento ético", but no longer. This term is not used anymore, instead, "medicamento sujeto a prescripción médica" (prescription-only-medicine) is used. This classification is granted by the Spanish Medicines Agency.

2 These kind of medicines are non-prescription medicines with advertising (publicity) addressed to the public, for merely called "Especialidades Farmacéuticas Publicitarias", but this term was derogated by Royal Decree 109/2010 modifying among others, Royal Decree 1345/2007, regulating the procedure for the marketing authorisation, registration (i.e. listing of authorized medicines into the register) and dispensing conditions for medicinal products for human use industrially manufactured, in order to adapting them to the Act 17/2009 on free access to services activities. Thus, the term EFP is not used anymore, instead "Medicamentos objeto de publicidad destinada al público" is. This advertising has been previously submitted by the company and authorised by the Ministry of Health. Medicines with advertising to the public are not synonymous of OTC, since all OTC medicines might not be advertising medicines. The classification of non-prescription medicine ("Medicamento no

sujeto a prescripción médica) is granted by the Spanish Medicines Agency, however the advertising message is granted by the Directorate-General for Pharmacy and Healthcare Products of the Ministry of Health. These medicines are also regulated by art. 78. of the Medicines Act. The requirements for advertising medicines are the following:

-They are not reimbursed with public funds.
-They are non-prescription medicines.
-They do not contain any psychotropic/narcotic substance.

[3] medicines that must be prescribed by the in- and out-patient sector specialists and administered and followed-up by those specialists in the in-and-out patient sector. This classification is granted by the Spanish Medicines Agency.

[4] medicines which do not need to be prescribed by a specialist but the Ministry of Health imposes a mechanism of inspection ("visado de inspección") in order to guarantee the medicine's proper and rational use. This classification is granted by the Directorate-General for Pharmacy and Healthcare Products.

[5] medicines than can produce severe adverse reactions which require prescription by specialist and special monitoring throughout the treatment. This classification is granted by the Spanish Medicines Agency.

[6] dispensing limits imposed by the Ministry of Health for certain medicines to out-patients through hospital pharmacies. This classification is granted by the Directorate-General for Pharmacy and Healthcare Products.

Source: Pharmaceutical Information System (Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

2.3.1.2 Access to medicines

The average time between marketing authorisation and reimbursement approval is estimated to be 109 days according to the MSPSI. The medicine is then included into the national positive list the first day of the next month, date at which the medicine is ready for being prescribed and dispensed. However, the MAH has a legal period of 3 years for launching the product into the market.

Table 2.3: Spain – Number of new molecular entities, 1999-2009

New molecular entities	1999 – 2009	2004 – 2009
Number of new molecular entities	293	136

Source: Pharmaceutical Information System (Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

2.3.2 Prescriptions

The prescriptions in the out-patient sector both in volume and in value at gross retail price have increased in the last years as follows.

Table 2.4: Spain – Annual prescriptions 200.2005-2009

prescription	2000	2005	2006	2007	2008	2009
No. of prescriptions (in volume)[1]	579,725,140	732,910,317	775,326,826	821,464,602	867,320,256	912,008,473
Prescriptions in value (in Euro)	6,859,675,246	10,365,256,757	11,084,066,001	11,635,817,196	12,465,011,660	13,097,760,538

Prescription in volume = number of items prescribed.

[1]: into the NHS.
Prescription in value = public expenditure of prescribed medicines.

Source: Pharmaceutical Information System (Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

2.3.3 Sales

The sales in the out-patient sector at ex-factory price level have shown the following pattern in the last years. There is no available official information on hospital sales. Sales of parallel traded medicines have been significantly increased in the last two years.

Table 2.5: Spain – Pharmaceutical sales 2000, 2005-2009

Sales	2000	2005	2006	2007	2008	2009
Sales at ex-factory price level*	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– Sales in out-patient sector[1]	4,314,536,781	6,659,534,496	7,217,787,243	7,604,092,889	8,166,173,387	8,590,149,324
– Sales at hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded medicines[2]	n.a.	22,717	32,574	87,158	188,275	382,875
Sales increases		**2000-2005**	**2005-2006**	**2006-2007**	**2007-2008**	**2008-2009**
Pharmaceutical sales at ex-factory price level - % increase		54.35	8.38	5.35	7.39	5.19
Sales of parallel imported medicines - % increase		n.a.	43.39	167.57	116.02	103.36

Data as of 31 December

n.a. = not available

[1] Only through prescriptions, i.e. medicines dispensed in community pharmacies and accounted by medical prescription. No data available neither for hospitals nor nursing, residential care facilities and prisons.

[2] referred to parallel imported medicines.

Source: Pharmaceutical Information System. Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

The development of the pharmaceutical sales at ex-factory price level has been the following in the past years:

The share of the parallel imported medicines compared to total pharmaceutical sales is not relevant, accounting for 0.0045%. The development has been:

2.3.4 Consumption

The consumption in packs in the out-patient sector has increased in the last years as follows. There is no official data available for the in-patient sector. Consumption in DDD is not available.

Table 2.6: Spain – Annual pharmaceutical consumption 2000, 2005-2009

Consumption	2000	2005	2006	2007	2008	2009
Total pharmaceutical consumption						
In packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the in-patient sector						
In packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the out-patient sector[1]						
In packs	592,756,057	738,054,788	779,962,499	826,197,951	872,184,910	917,356,176
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = defined daily doses, n.a = not available

[1] Only data available for pharmaceutical consumption in packs in the out-patient sector through prescriptions, i.e. medicines dispensed in community pharmacies and accounted by medical prescription.

Source: Pharmaceutical Information System (Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

Pharmaceutical consumption in the out-patient sector could be contained in the last years as the following figures show:

Table 2.7: Spain – Increases in annual pharmaceutical consumption in the out-patient sector

Pharmaceutical consumption in the out-patient sector	2005-2006	2006-2007	2007-2008	2008-2009
% Increase	5.68	5.93	5.57	5.18

Source: Pharmaceutical Information System (Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

According to the Medicines Act 29/2006 (art. 95 on prescribing monitoring and art. 97 on prescriptions information management) it is the responsibility of the Health Services of the autonomous regions with regard to their own territory and of the General Government for the whole SNHS to monitoring the development of pharmaceutical consumption via their checking of prescriptions.

A system for statistics management in the out-patient sector is available. It was introduced more than twenty years ago by the Spanish Ministry of Health. The Directorate-General for Pharmacy and Healthcare Products of the Ministry of Health, Social Policy and Equality and the Health Services of the autonomous regions manage and run it. The Pharmaceutical Council is also involved. The Pharmaceutical Council regularly receives the prescriptions from the community pharmacies and sends the corresponding information to the regions, which submit it to the Ministry. Thus, it is incorporated it into the Pharmaceutical Information System. Delivering data is mandatory.

Regarding hospital consumption, there is currently a collaborating project between Ministry of Health and regions in order to collect the information relative to pharmaceutical consumption in hospitals.

2.3.5 Generics

The development of the generic shares in the out-patient sector, corresponding to the reimbursed market has been the following in the past years. There is no official data for the in-patient sector.

Table 2.8: Spain – Development of the generic shares 2000, 2005–2009

Generic share	Volume[1]		Value[2]	
	2005	2009[3]	2005	2009[3]
Shares in % of total market (in-patient/ out-patient)	n.a.	n.a.	n.a.	n.a.
Shares in % of total out-patient market	n.a.	n.a.	n.a.	n.a.
Shares in % of out-patient reimbursement market	14.10%	23.82%	7.35%	9.38%
Shares in % of out-patient off-patent market	n.a.	n.a.	n.a.	n.a.
Shares in % of the in-patient market	n.a.	n.a.	n.a.	n.a.

n.a. = not available

1 Expressed in number of prescriptions
2 Expressed in expenditure Source: Pharmaceutical Information System (Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

The procedure for granting a market authorisation of generics does not differ from other medicines, as established in Royal Decree 1345/2007, in which article 7 sets up the specific requirements for granting a marketing authorisation of a generic medicine.

The procedure for pricing and reimbursement of generics is the same as for other medicines, but with some exception: it corresponds to the Interministerial Pricing Committee (IPC) to establish the general economic criteria for pricing of generics (Royal Decree 4/2010). The IPC is assigned to the Ministry of Health, Social Affairs and Equality with participation of the Ministry of Economy and Finance and the Ministry of Industry, Tourism and Trade and is

responsible for fixing maximum ex-factory prices of pharmaceuticals and health care products to be included in the National Health Service for their reimbursement. Thus, the procedure for generics is simplified and shorter in time for generics as they are neither subject to a comparative pharmacotherapeutic evaluation neither are fixed price in the IPC. The Ministry of Health, Social Policy and Equality is in charge of pricing of generics according to those criteria and communicates the decisions to the IPC.

Generics coming into the market for the first time receive a price 40% below original medicines (IPC), for generics included in a cluster (reference group), the price will be reduced up to a maximum of 30% taking into account the difference between the reference price and the corresponding gross pharmacy retail price according to Royal Decree 4/2010.

In Spain generic substitution (see also section 3.3.2.1) is mandatory in accordance with the reference price system principles, for instance for pharmaceuticals under the reference price when the generic has the lowest price. In such a case the pharmacist must dispense the pharmaceutical having a lower price and, should the price be the same, a generic one, if available. When the prescription is made by active ingredient subject to a reference price, the pharmacist must also dispense the pharmaceutical having a lower price and, should the price be the same, a generic one (art. 93.4 of the Medicines Act 29/2006).

The Medicines Act promotes the prescription by International Non-proprietary Name (INN) as well. In this sense, art. 85 sets up that “The Health Authorities shall encourage the prescription of pharmaceuticals identified by their active pharmaceutical ingredient in the prescription”.

Generic uptake plays a role in the out-patient sector, and the market share of generics has increasing. In 2005 generics represented 14.10% by volume of packages of total prescribed medicines at the expense of the NHS and 7.35% by value. In 2009, they represented 23.82% by volume of packages (69 percent increase) and 9.38% by value.

Regarding authorised generic medicines (see also Table 2.2), the number increase by nearly 100% from 2005 to 2009 and about 15% from 2009 to 2010.

2.3.6 Top 10 medicines

The following table informs about the top active ingredients in Spain. However, information is only available for the out-patient sector.

Table 2.9: Spain – Top 10 active ingredients in value and volume in the out-patient sector, 2009

Position	Top active ingredients used in the out-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the out-patient sector, ranked with regard to expenditure	
1	A02BC01	Omeprazole	1	C10AA05	Atorvastatin
2	N02BE01	Paracetamol (Acetaminophen)	2	R03AK06	Salmeterol
3	M01AE01	Ibuprofen	3	B01AC04	Clopidogrel
4	B01AC06	Acetylsalicylic acid (as anti-platelet)	4	R03AK07	Formoterol
5	C10AA01	Simvastatin	5	A02BC01	Omeprazole
6	A10BA02	Metformin	6	N05AX08	Risperidone
7	C10AA05	Atorvastatin	7	R03BB04	Tiotropium, bromide
8	N05BA06	Lorazepam	8	N05AH03	Olanzapine
9	N02BB02	Metamizol sodium	9	N06AB10	Escitalopram
10	C09AA02	Enalapril	10	N03AX16	Pregabalin

Source: Pharmaceutical Information System (Directorate-General for Pharmacy and Healthcare Products, MoH, Social Policy and Equality of Spain

Table 2.10: Spain – Top 10 active ingredients in value and volume in the in-patient sector, 2009

Position	Top active ingredients used in the in-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the in-patient sector, ranked with regard to expenditure	
1	n.a.	n.a.	1	L01XC07	Bevacizumab
2	n.a.	n.a.	2	L01XC03	Trastuzumab
3	n.a.	n.a.	3	L01XC02	Rituximab
4	n.a.	n.a.	4	L01XC06	Cetuximab
5	n.a.	n.a.	5	L01XX32	Bortezomib
6	n.a.	n.a.	6	L01XE01	Imatinib
7	n.a.	n.a.	7	L01XA03	Oxaliplatin
8	n.a.	n.a.	8	L01XE03	Erlotinib
9	n.a.	n.a.	9	L01XE05	Sorafenib
10	n.a.	n.a.	10	L01XE04	Sunitinib

Source: IMS

2.4 Market players

This section gives an overview of the key players in production, distribution and dispensing of medicines in 2010.

The common delivery chain for the out-patient sector is via wholesale, and for the in-patient sector it is direct distribution.

Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products, regulates the distribution of authorized medicines that can be done via wholesale or directly by the marketing authorization holder. The distribution activity must guarantee a service of quality, being its priority and essential function supplying to legally authorized community pharmacies and hospital pharmacy services. The use of third parties on the part of a marketing authorization holder or a wholesaler should be included in their corresponding authorization.

In case a hospital does not have an authorized pharmacy service, it may only be served by other pharmacies.

2.4.1 Industry

The pharmaceutical industry is a leader sector regarding investment on Research and Development as well as on productivity.

Table 2.11: Spain – Key data on the pharmaceutical industry 2000, 2005–2010

Pharmaceutical industry	2000	2005	2006	2007	2008	2009	2010
Total number of companies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	86[1]
– generic producers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	30[2]
– biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of persons employed[1]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

Data as for 2011

Source: [1] http://www.farmaindustria.es/Farma_Public/Farmaindustria/Asociados/index.htm

[2] http://www.aeseg.es/es/asociados-aeseg

2.4.2 Wholesalers

Wholesalers are either private companies or co-operatives owned by pharmacies which they also serve. Additionally, the wholesale system is multichannel and full liners (i.e. the vast majority of wholesalers is full-liners).

The wholesale federation National Federation of Associations Wholesalers and Distributors of Medicines (FEDIFAR) represents approximately 95% of the companies in the sector, and is one of the institutions that must be consulted by the National Government when preparing legislation that affects the pharmaceutical policy. It thus undertakes a negotiating role on behalf of wholesalers in all aspects of their activity.

The wholesale plays a key role in the pharmaceutical chain on guaranteeing a quick supply of medicines. The distribution channel represents about the 77% of the market, being the remaining 23% directly supplied from the manufacturer to hospitals and community pharmacies.

Table 2.12: Spain – Key data on pharmaceutical wholesale 2000, 2005–2010

Wholesalers	2000	2005	2006	2007	2008	2009	2010
Total number of wholesale companies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	54 (with 192 stores or wholesale
Total number of importers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total number of outlets	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

Data as for 2011

Source:
http://www.fedifar.net/index.php?option=com_content&view=article&id=10&Itemid=11&lang=es, Rafael BorràsMadrid–03/2011, Antares Consulting Bioindustrias y Farmacia, © 2011

2.4.3 Retailers

Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products establishes that only community pharmacies for the out-patient sector, or authorised pharmacy services of health care centres and hospitals for the in-patient sector and the out-patient sector in case of medicines restricted to hospital use, may dispense medicines to patients. Act 29/2006 does not allow Community pharmacies or Pharmacy services to dispense POM via internet. As long as the regulation (i.e. EU regulation) to dispense via internet is not approved, to dispense medicines via internet in Spain is not allowed.

2.4.3.1 Community pharmacies

Act 16/1997 of 25th April 1997 relating to the regulation of Community Pharmacy services establishes that community pharmacies are private health establishments in the public's interest, subject to the health planning rules laid down by the autonomous territories, in which the licensed-owner pharmacist, assisted where appropriate by assistants or auxiliaries, that should provide basic services to the community.

In Spain, the licensed pharmacist must be a qualified pharmacist, either alone or working with other pharmacists, each of whom may only be the owner of one pharmacy.

Pharmacy chains are not allowed, each pharmacist may only be the owner of one pharmacy.

The establishment of pharmacies is provided for in Article 2.2 of the Act 16/1997, of 25th April, relating to the Regulation of Services in Pharmacies, which states that they are opened in accordance with demographic and geographical criteria. These criteria relate to a regula-

tion for community pharmacies for the benefit of the general public. The competent Autonomous Regional Administrations, on the basis of the planning criteria set forth in the State Act 16/97, lay down the population modules required to open pharmacies. For instance, concentrations of pharmacies should be avoided in densely populated areas, when the health services available in less popular areas would be neglected for which sufficient pharmaceutical care should be provided.

In establishing a planning policy for pharmacies, account shall be taken of population density, geographical characteristics and the distribution of inhabitants, with a view to ensuring accessibility and quality of service, as well as the satisfactory supply of medicines, in accordance with the public health needs in each territory.

The territorial distribution of pharmacies shall be established by unit of population and distance between pharmacies, as determined by the Autonomous Regions in accordance with the general criteria. In any event, the rules for territorial distribution must ensure adequate pharmaceutical services for all citizens.

The minimum unit of population required for the opening of a pharmacy shall be, as a general rule, 2,800 inhabitants per establishment. Depending on the concentration of the population, the Autonomous Regions may establish higher minimum units of population up to a maximum of 4,000 inhabitants per pharmacy. In any event, once those thresholds have been exceeded, a new pharmacy may be opened per fraction above 2,000 inhabitants.

Notwithstanding this provision, the Autonomous Regions may establish smaller units of population for rural, mountainous or tourist areas, or for areas where, by reason of their geographical, demographic or public health characteristics, pharmaceutical services would not be possible if the general criteria were applied.

As a general rule, the minimum distance between pharmacies, account being taken of geographical criteria and the distribution of inhabitants, shall be 250 metres. Depending on the concentration of the population, the Autonomous Regions may authorise shorter distances between pharmacies. In addition, the Autonomous Regions may set limits on the establishment of pharmacies in the proximity of public health centres.

Regarding recent and ongoing court cases we may mention the joint cases C-570/07 and C-571/07. The references were submitted in the course of proceedings brought by Mr Blanco Pérez and Ms Chao Gómez against, on the one hand, the Consejería de Salud y Servicios Sanitarios (Ministry of Health and Public Health Services) (C-570/07) and, on the other, the Principado de Asturias (C-571/07), concerning a call for applications in connection with the issue of licences to open new pharmacies in the Autonomous Community of Asturias. In both cases, Mr Blanco Pérez and Ms Chao Gómez disputed the legality of the decisions and of Decree 72/2001 of Asturias on the ground that they had the effect of preventing pharmacists from gaining access to new pharmacies in the Autonomous Region of Asturias.

On those grounds, the Court (Grand Chamber) ruled:

"1.Article 49 Treaty on the Functioning of the European Union (TFEU) must be interpreted as not precluding, in principle, national legislation, such as that at issue in the cases before the referring court, which imposes restrictions on the issue of licences for the opening of new pharmacies, by providing that:

- in each pharmaceutical area, a single pharmacy may be opened, as a general rule, per unit of 2,800 inhabitants;
- a supplementary pharmacy may not be opened until that threshold has been exceeded, that pharmacy being established for the fraction above 2,000 inhabitants; and
- each pharmacy must be a minimum distance away from existing pharmacies, that distance being, as a general rule, 250 metres.

Nevertheless, Article 49 TFEU precludes such national legislation in so far as the basic '2,800 inhabitants' and '250 metres' rules prevent, in any geographical area which has special demographic features, the establishment of a sufficient number of pharmacies to ensure adequate pharmaceutical services, that being a matter for the national court to ascertain.

2. Article 49 TFEU, read in conjunction with Article 1(1) and (2) of Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of certain activities in the field of pharmacy, and Article 45(2)(e) and (g) of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications must be interpreted as precluding criteria, such as those set out in points 6 and 7(c) of the Annex to Decree 72/2001 of 19 July 2001, regulating pharmacies and dispensaries in the Principality of Asturias (Decreto 72/2001 regulador de las oficinas de farmacia y botiquines en el Principado de Asturias), under which licensees for new pharmacies are to be selected."

Associations of pharmacies and pharmacists are organized as follows: The General Council is the representation, coordination and cooperation body of the pharmacy profession**.** In the professional sphere, the General Council conducts various activities aimed at the Associations and over 50,000 association members, such as the Health Information Data Base, scientific publications, technical, professional and legal advice, continuous training activities, and the application of communication technologies for its own purposes.

At the moment, there is no potential vertical integration of wholesalers and pharmacies, since the licensed pharmacist must obligatorily be a qualified pharmacist, either alone or working with other pharmacists, each of whom may only be the owner of one pharmacy.

The General Council is one of the institutions that must be consulted by the National Government when preparing legislation that affects the pharmaceutical profession and thus undertakes a negotiating role on behalf of pharmacists in all aspects of their activity.

The latest change regulation of pharmacy margins was issued by Royal Decree Law 4/2010 (cf. chapter 3.1.5.2 for more detailed information).

Pharmacy outlets depending on a community pharmacy are allowed in Spain.

Table 2.13: Spain – Retailers of medicines 2000, 2005–2010

Retailers	2000	2005	2006	2007	2008	2009	2010
No. of community pharmacies[1]	n.a.	n.a.	n.a.	n.a.	n.a.	21,166	21,364
– *Thereof: No. of private pharmacies*[2]	n.a.	n.a.	n.a.	n.a.	n.a.	21,166[3]	21,364[3]
– *Thereof: No. of public pharmacies*	0	0	0	0	0	0	0
No. of hospital pharmacies for out-patients	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of dispensing doctors	0	0	0	0	0	0	0
No. of other POM disp., *please specify*	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total no. of POM dispensaries	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of internet pharmacies	0	0	0	0	0	0	0
No. of OTC disp., like drug-stores	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Disp. = dispensaries, n.a. = not available, No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients (PHIS Glossary).

1 Hospital pharmacies dispensing to out-patients are not included in this figure (according to PHIS Glossary).

2 Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

3 Pharmacies in Spain are defined as private establishments devoted to give a public service

Data as of 1 January

Source: General Council of Pharmaceutical Official Colleges in Spain

2.4.3.2 Dispensing doctors

Doctors are not allowed to dispense medicines.

2.4.3.3 Hospital pharmacies

Not all the hospitals have a pharmacy. They should comply with prerequisites and must be authorised by the competent Autonomous Regional Administrations.

Authorised pharmacy services of health care centres and hospitals may dispense medicines (hospital-only medicines, for some medicines dispensing limits for hospital pharmacies) to patients.

When a hospital does not have an authorized pharmacy, a deposit of medicines can be authorized in the premises of the hospital. This medicines deposit only can be served by a community pharmacy.

The tasks of hospital pharmacy staff are: to guarantee and to assume the technical responsibility of the acquisition, quality, correct conservation, cover of the needs, preparation of medicines for the special needs of patients, dispensation of medicines to in-patients and out-patients for extra-hospital treatments, that require a particular monitoring, supervision and control; to establish an effective and safe system of distribution of medicines, to guarantee its correct management, to guard and to give products in phase of clinical investigation; to guard according to legislation psychoactive substances or of any other medicines that it requires a special control; to participate in the hospital committees in their knowledge for the selection and scientific evaluation of medicines; to establish an information service of medicines for all the personnel of the hospital, a system of hospital pharmacovigilance, and carry out systematic studies of medicine use and activities of clinical pharmacokinetics; to carry out educative activities directed to the sanitary personnel of the hospital and to the patients; to carry out investigation or in collaboration with other units or services and to participate in the clinical trials with medicines; to collaborate with primary care centres; To participate and coordinate the management of the acquisition of medicines and clinical products in order to assure the efficiency of the system.

2.4.3.4 Other POM dispensaries

Medicine deposits (“depósitos”) are allowed in Spain, depend of a community pharmacy and must be authorised. They are regulated by the competent Autonomous Regional Administrations.

2.4.4 Promotion

The relevant legislation is Act 29/2006, 26 July 2006, on guarantees and rational use of pharmaceuticals and medical products and Royal Decree 1416/1994, 25 June, regulating the publicity of human medicines.

Direct advertising of OTC medicines is allowed according to Directive 2001/83/EC. However, Act 29/2006 does not allow Community pharmacies or Pharmacy services to dispense POM via internet. As long as the regulation (i.e. EU regulation) to dispense via internet is not approved, to dispense medicines via internet in Spain is not allowed.

There are measures implemented in order to restrict or control promotional spending of manufacturers. For instance there is one contained in Chapter V (on post-authorisation studies) of the RD 1344/2007on Farmacovigilance: the planning, conducting of financing of post-authorisation studies, with the purpose to promote the prescription of medicinal products is forbidden. Chapter V also highlights the role of Ethics Committees on Clinical Investigation and the Autonomous Regions.

Spain also has regulations on the activities of representatives of pharmaceutical companies who visit doctors. The Royal Decree 1416/1994, 25 June, regulating the publicity of human medicines, establishes the prerequisites at national level, and the competent Autonomous Regional Administrations are responsible for their specific regulations and management.

Concerning the sending of medicines samples, these must be authorised by the Spanish Medicines Agency AEMPS. They are not allowed for psychoactive substances. The medicines samples have to comply with the same prerequisites as the corresponding authorised medicine but with the statement that is free for the patient and not on sale.

Actions are also taken to inform patients on the rational use of medicines. The competent authorities of Autonomous Regions established a system in order to carry out this task.

Regarding the in-patient sector, Hospital Pharmacies carry out educative activities directed to the sanitary personnel of the hospital and to the patients.

2.5 Funding

This section provides an overview of the funding of medicines.

2.5.1 Pharmaceutical expenditure

Table 2.14: Spain – Total pharmaceutical expenditure 2000, 2005–2009

Pharmaceutical expenditure in mio. Euro	2000	2005	2006	2007	2008	2009
TPE	n.a.	18,830	20,041	21,096	n.a.	n.a.
– thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
PE in the out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
PE in the in-patient sector	n.a.	1,997	2,258	2,443	n.a.	n.a.
– thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure

Note: Data of out-patient and in-patient health expenditure does add up to the total health expenditure due to the methodology applied.

Source: EUROSTAT-OECD-WHO Joint SHA collection

2.5.2 Sources of funds

This section gives an overview of the funding of medicines in the out-patient and in the in-patient sector.

The main funding sources of public pharmaceutical expenditure are national and regional taxes. Co-payments constitute the main funding sources of private pharmaceutical expenditure. However, there are no out-of-pocket payments applied for in-patient pharmaceutical care.

3 Pricing, reimbursement and volume control in the out-patient sector

This chapter gives an overview of the pricing and reimbursement system as well as some volume control mechanisms in the out-patient sector.

3.1 Pricing in the out-patient sector

3.1.1 Organisation of pricing

The legal framework with regard to pricing of medicines in the out-patient sector is provided by the Medicines Act 29/2006 art 90. Thus; the current pricing system was implemented following the provisions of the Medicines Act 29/2006.

The authorities in charge of pricing decisions are the Ministry of Health, Social Affairs and Equality (MSPSI), the Ministry of Economy and Finance and the Ministry of Industry Tourism and Trade. There is an Interministerial Pricing Committee (IPC) assigned to the Ministry of Health, Social Affairs and Equality with participation of the aforementioned ministries responsible for fixing maximum ex-factory prices of pharmaceuticals and health care products to be included in the National Health Service for their reimbursement. The Committee takes into account the reports on relative effectiveness and comparative costs issued by the Ministry of Health, Social Affairs and Equality. The Committee meets every month.

The Ministry of Health is also in charge of reimbursement decisions and modalities, modifications or exclusions taking into account the views of the NHS Interterritorial Board under the provisions of the Medicines Act (art 89).

The process of pricing may take up to six months, with the exception of generics, whose pricing/reimbursement procedure is faster. There is a different approach in pricing policies, in particular with regard to the evaluation, for innovative products and generics. Generics should comply with established pricing criteria and do not need to be submitted to the IPC.

Pricing decisions are made at manufacturer price level. The public price, i.e. the pharmacy retail price (PRP), is obtained by taking into account wholesale and pharmacy margins in accordance with applicable rules. Price changes are possible under the provisions of the Medicines Act (art 91). Time limits of one year for applications for price changes have been eliminated in Royal Decree Law 4/2010. The competent body for pricing and reimbursement decisions is the Directorate General for Pharmacy and Health Care Products. Decisions about pricing and decisions about reimbursement of new products are communicated to Companies by the same administrative action.

The Medicines Act 29/2006 lays down pricing and reimbursement criteria in article 89 (the severity of the disease, needs of selected groups of patients, therapeutic usefulness, rationality of expenditure and degree of innovation should be taken into consideration).

Pricing criteria for medicines are checked by the IPC taking into account proposals submitted by the Directorate General for Pharmacy and Health Care Products of the Ministry of Health.

Price information is publicly available for medicines funded by the National Health Service, information is updated on a monthly basis

http://www.mspsi.es/profesionales/farmacia/frmNomenclator.jsp

Provisional IPC decisions are also published

http://www.mspsi.es/profesionales/farmacia/financiacion/home.htm

3.1.2 Pricing policies

The key pricing policy for reimbursable medicines is price negotiations between the marketing authorization holder and the Ministry of Health, Social Affairs and Equality (MSPI) (cf. section 3.1.2.2). This is especially applied for innovative medicines. The prices of medicines in other European countries are one criterion in the price negotiations. The manufacturer may freely set the prices of medicines for which no reimbursement has been applied.

In case of generics and copy-products which are included in a cluster of the reference price system, statutory pricing is applied (cf. section 3.1.2.1).

OTC products to be included in the NHS follow price negotiations, if they are not going to be reimbursed, price is free.

Parallel traded medicines to be reimbursed may have the same price as the original products following criteria established by the IPC, if not, pricing is free.

No matter if prices are negotiated or determined via statutory prices, the relevant price type which is fixed is also the ex-factory price level.

Table 3.1: Spain – Ways of pricing of medicines at manufacturer level, 2010

Pricing policies	(Non) prescription market		(Non) reimbursement market		Specific groups of medicine		
	POM	OTC	Reimbursa-ble	Non-reimbursable	Generics	Parallel traded	
Free pricing	Yes, but only if not reimburs-able	Yes, but only if not reimburs-able	No	Yes	No, unless not-reimburs-able	No, unless not-reimburs-able	
Statutory pricing	Reim-bursable POM in a reference price cluster	Reim-bursable OTC (only few) in a reference price custer	If included in a reference price cluster	No	Yes	Yes	
Price negotia-tions	Yes	Yes	Yes	No	No	No	
Tendering	Only for a few medicines						

POM = prescription-only medicine, OTC = over-the-counter medicines

3.1.2.1 Statutory pricing

While price negotiations is the key pricing policy for new (innovative) medicines (see below, section 3.1.2.1), there is statutory pricing for generics and copy-products.

Generics coming into the market for the first time receive a price 40% below original medicines (IPC),. For generics included in a cluster of the reference price system (cf. section 3.2.3), prices have been reduced up to a maximum of 30% taking into account the difference between the reference price and the corresponding gross retail price according to Royal Decree 4/2010.

Prices are fixed at ex-factory price level.

The statutory pricing system that settled the reference pricing system was implemented in art. 93 of Medicines Act 29/2006. It has been modified in some of its provisions by Royal Decree Law 4/2010, mainly concerning the way how the reference price is calculated, minimum prices, time limits for companies to reach the reference price or price reductions for pharmaceuticals with generics available abroad. The last Ministerial Order establishing clusters and their reference price has been published in November 2010.

The authorities involved are Directorate General for Pharmacy and Health Care Products, and the Interministerial Pricing Committee.

3.1.2.2 Negotiations

The key pricing policy for new (innovative) medicines for which the manufacturer seeks reimbursement is negotiations about the price between the Ministry of Health, Social Policy

and Equality (MSPI) and the marketing authorisation holder. The final decisions are taken by the Interministerial Pricing Committee allocated to the MSPI.

The criteria for the pricing decision are laid down in article 89 of the Medicines Act 29/2006 and comprise the severity of the disease, needs of selected groups of patients, therapeutic usefulness, rationality of expenditure and degree of innovation.

When submitting a price application for a medicine seeking reimbursement, the marketing authorization holder must provide information, about the production cost., estimated sales, comparative costs with similar products in Spain, price in other countries and whatever information supporting their pricing proposal

3.1.2.3 Free pricing

Free pricing only plays a role in the case of non-reimbursable products. Many OTC medicines are not reimbursed, but there are still a few reimbursable OTC medicines.

3.1.2.4 Tendering

In general, tendering has not played till now an important role, apart from vaccines.

However, there are consideration of regions to stronger apply this pricing policy in future and do joint regional tendering. Tendering procedures are linked to the regions. Regional authorities initiate the tendering process in the out-patient sector.

The legal framework for the current system allowing regions to get involved in tendered was implemented by Law 30/2007 October 30 on Public Sector Contracts. Royal Decree Law 8/2010 introduced an additional point to Law 30/2007 dealing with the centralised procurement of medicines and health care products.

If a tender ulfils the technical specifications, then the price offered will be a key criterion.

3.1.2.5 Others

There are no further pricing policies for medicines in place in Spain.

3.1.3 Pricing procedures

In Spain, both external and internal price referencing play a role.

External price referencing is applied for medicines where no similar medicines are on the Spanish market, i.e. new medicines. The prices of other European countries are, among others, one important criterion in the price negotiations (for further information on the methodology see below section 3.1.3.1.)

Internal price referencing is mainly applied for generics and further similar medicines which are included in the reference price system. Also, in the context of new products cost comparisons with similar medicines or alternatives in Spain, play a key role

Table 3.2: Spain – Pricing procedures, 2010

Pricing procedure	In use: yes / no	Price type[1]	Scope[2]
External price referencing	Yes	manufacturer	For medicines with no similar market available in Spain
Internal price referencing	Yes	manufacturer	Whenever possible before price negotiations In the context of reference price groups
Cost-plus pricing	No	-	-
Indirect profit control	No	-	-
Risk/cost sharing	No	-	-
Price/volume agreements	No	-	-
Annual review			High impact medicines

1 Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

2 Scope = a pricing procedure does not always refer to all medicines: e.g. a pricing procedure could only refer to reimbursable medicines, whereas for Over-The-Counter medicines there is free pricing.

Source: Directorate General for Pharmacy and Health Care Products

3.1.3.1 External price referencing

In general, external reference pricing is applied for medicines where there are no similar medicines available on the market in Spain.

Regarding the regulation of external reference pricing, the Royal Decree Law 4/2010 which modifies Medicines Act 29/2006 just states that in the pricing and reimbursement procedure the prices of medicines in Member States of the European Union also will be taken into account. However, there is not a specific country basket defined. In general, the lowest price available is taken. Even if the prices in the other countries are one among different criteria, they often impacted the negotiated price in the end. In any case, yearly reviews of European prices for selected products are performed.

Manufacturer information is considered for price data. In some cases, data bases from countries as provided by the Network of competent authorities on pricing and reimbursement are consulted.

3.1.3.2 Internal price referencing

Internal price referencing is a very relevant procedure for all medicines whenever possible.

Internal price referencing is regulated for active ingredients included or to be included in a reference price group. In other cases, the selection of comparators and methodology follows criteria defined by the Directorate-General for Pharmacy and approved by the Interministerial pricing committee.

In the context of reference pricing groups prices are compared at ATC 5 level. In other cases, comparisons might be with identical, similar or alternative products in view of the results of therapeutic assessments.

3.1.3.3 Cost-plus pricing

Currently, cost-plus pricing (i.e. setting the price on the basis of the production costs plus granting a profit margin) is not applied as a pricing procedure in Spain. However, the production costs should be provided by the Company in the pricing application form.

Cost-plus pricing techniques are regulated in RD 271/1990 on medicines pricing regulation.

3.1.3.4 (Indirect) profit control

3.1.3.5 Others

There are no other pricing policies.

3.1.4 Discounts / rebates

Discounts per early payment or sales volume from distributors to pharmacies are allowed until a maximum of 5% for reimbursed products and up to a 10% for generic medicines.

Mandatory discounts have been introduced by RD Law 8/2010 for original products. It is a discount of 7.5 percent on the pharmacy retail price, which is borne and shared among pharmacies, wholesale and industry. The discount for, orphan medicines is of 4 percent. All these discounts should be granted to the NHS.

3.1.5 Mark-ups and taxes

This section contains a description of the wholesale and pharmacy margins, dispensing fees and sales taxes applied to medicines, as of 2010. As shown in the following table, medicines remuneration is regulated in Spain for all medicines via regressive margin schemes.

Table 3.3: Spain – Regulation of wholesale and pharmacy mark-ups, 2010

Wholesale mark-up/margin			Pharmacy mark-up/margin		
Regulation	**Content**	**Scope**	**Regulation**	**Content**	**Scope**
Yes	Regressive margin scheme	All medicines	Yes	Regressive margin scheme	All medicines

3.1.5.1 Wholesale remuneration

Wholesale margins are regulated for all medicines in Spain and the last regulation of wholesale margins was issued by RD 823/2008. It is a regressive, two-scale margin scheme.

Table 3.4: Spain – Wholesale margin scheme, 2010

Ex-factory price in €	Wholesale margin in % of wholesale price
Equal or lower to 91.63	7.6%
Higher than 91.63	€ 7.54 per pack

Source: Royal Decree 823/

3.1.5.2 Pharmacy remuneration

In Spain pharmacy margins are regulated for all medicines and the last regulation of pharmacy margins was issued by RD Law 4/2010. It is a regressive, four scale margin scheme, providing for a percentage margin of the pharmacy retail price and a fixed fees.

Table 3.5: Spain – Pharmacy margin scheme, 2010

Ex factory price in €	Pharmacy Margin in % of pharmacy retail price
Equal or lower to 91.63	27.9 %
Higher than 91.63 and equal or inferior to 200	€ 38.37 per pack
Higher than 200 and equal or inferior to 500	€ 43.37 per pack
Higher than 500	€ 48.37 per pack

Source: Royal Decree Law 4/2010

3.1.5.3 Remuneration of other dispensaries

3.1.5.4 Taxes

3.1.5.4.1 Value-added tax

As from July 2010, standard VAT has increased in two points to 18%.

However, VAT on medicines remains as before, 4%. The VAT for diagnostic aids increases a point to 8%.

3.1.5.4.2 Other taxes

There are no other taxes or fees on medicines.

3.2 Reimbursement in the out-patient sector

This section describes the scope of the reimbursement system, the regulatory framework and the main authorities in the out-patient sector as of 2010.

3.2.1 Organisation

Once a pharmaceutical is authorized and registered, the Ministry of Health decides upon grounded resolution, before it is launched on the market, on the inclusion into the pharmaceutical coverage of the NHS under the provisions of Art. 89 of the Medicines Act 29/2006 about public financing procedure.

The vast majority of pharmaceuticals are covered by the NHS. Certain predefined therapeutic groups might not be included. OTC medicines that may be advertised have free pricing and are not covered by the system. However, in addition to general reimbursement, there is a possibility to apply for individual reimbursement for very specific cases.

The policy, under the provisions of Royal Decree 1030/2006 establishing a common services portfolio, covers the whole country regions may increase their services complying with the Law of cohesion and quality of the Spanish NHS 2003.

The Ministry of Health, Social Affairs and Equality has the decision making power about medicines financing. Regions may apply to the Ministry of Health for specific conditions.

Reimbursement conditions and prices are established together under the same administrative action issued by the Directorate General for Pharmacy and Health Care Products. The only prerequisite which a company needs to comply with before applying for reimbursement is the market authorization of a product.

In any case, a reimbursed medicine may be totally or partially excluded or it may be subject to special reimbursement conditions

3.2.2 Reimbursement schemes

The legal framework for reimbursement decisions is considered in Art. 89 of the Medicines Act 2006. Reimbursed pharmaceuticals, negative lists and reduced co-payments for chronic illness are items regulated in Royal Decree 83/1993, with further modifications in RD 1663/1998 and RD 1348/2003

The population coverage is nearly 100%. The aim is to reach universality.

3.2.2.1 Eligibility schemes

Spain has, in principle, product-specific reimbursement eligibility, i.e. it is decided at the product level if a medicine is reimbursed or not.

3.2.2.2 Reimbursement lists

Several therapeutic groups are excluded from public financing in accordance with Royal Decree 83/1993 and Royal Decree 1663/1998. The Ministry of Health, Social Affairs and Equality decides on the inclusion of medicines into reimbursement. The Autonomous Communities may apply for specific reimbursement conditions.

The list of reimbursable products (Nomenclator) contains active ingredients and trade names. They are published on http://www.mspsi.es/profesionales/farmacia/frmNomenclator.jsp and are updated monthly on the website.

The rational selection of medicines for reimbursement takes into account criteria specified in art. 89 in the Medicines Act 29/2006. Moreover, a pharmacotherapeutic evaluation is undertaken followed by a pharmacoeconomic evaluation with cost-comparative information.

3.2.2.3 Reimbursement categories and reimbursement rates

Most of the reimbursable medicines are reimbursed at 60%. However, there is also reimbursement at 100% and 90% (see Table 3.6

Table 3.6: Spain – Reimbursement categories of medicines, 2010

Reimbursement category	Reimbursement rate	Description
Hospital medicines Pensioners	100%	-
Chronic illnesses	90%	Patient pays up to a maximum of € 2,64 / pack
Most reimbursable pharmaceuticals	60%	-
Excluded pharmaceuticals	0%	-

Source: Royal Decree 1030/2006

3.2.3 Reference price system

There is a reference price system in Spain. The current system was implemented in the Medicines Act 26/2006 art 93. It was recently modified by RD Law 4/2010, this regarded mainly the procedure to calculate the reference price and “graduality” (adoption time) for companies to comply with the provisions (i.e. after passing of the act in 2010, companies had two years to reach the reference price, before this period had been longer).

The reference price system covers products for which a generic alternative exists; Medicines are grouped by the same active ingredient and same route of administration. The system includes 179 active ingredients.

The reference price for a particular group is calculated selecting the preparation with the lowest cost/treatment/day (as modified by RD Law 4/2010). Defined daily doses DDD are used for these calculations.

199 groups and 179 active ingredients are included in the last Ministerial Order (3052/2010 from 26 November) updating the groups. The system covers a total of 7,297 pharmaceutical presentations. Groups are reviewed/updated at least once a year and made public by ministerial order.

If a doctor prescribes a medicine above the reference price, the pharmacist must substitute with the lowest priced preparation. There is no option for the patient to pay the difference.

There are additional groups of identical products for substitution.

3.2.4 Private pharmaceutical expenses

3.2.4.1 Direct payments

Direct payments are possible for medicines privately prescribed and for non reimbursed products e.g. OTC medicines in self-medication.

3.2.4.2 Out-of-pocket payments

In Spain, the system for medicines operates by out-of-pocket percentage payment. That means that the patient pays 40 percent or 10 percent for medicines in the retail pharmacy and the system borne the remaining cost. There is no reimbursement.

Table 3.7: Spain – Out-of-pocket payments for medicines, 2010

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	no	n.appl.
Percentage payments	40%, 10%	n.appl
Deductibles	no	n.appl.
Reference price system	no	n.appl.

Source: Royal Decree 1030/2006

3.2.4.2.1 Fixed co-payments

There are no fixed co-payments applicable in Spain.

3.2.4.2.2 Percentage co-payments

The most common percentage co-payment is 40% of the retail price to be paid by patients in the dispensing act.

A reduced co-payment of 10% of the retail price with a ceiling of € 2.64 per pack is applied to medicines for severe chronic illness, certain medical devices, medicines for AIDS patients

Exemptions from co-payment do exist for pensioners, handicapped, labor disease treatments and medicines in hospital settings

Could you pls. inform us about the percentage co-payments – e.g. the most common percentage co-payment of 40%, and the reduced one of 10% (refer to section 3.2.4.3.)

3.2.4.2.3 Deductibles

There are no deductibles in place in Spain

3.2.4.3 Mechanism for vulnerable groups

For information on mechanisms for vulnerable group please refer to section 3.2.4.2.2.

3.3 Volume control in the out-patient sector

3.3.1 Pharmaceutical budgets

No information available.

3.3.2 Generic policies

3.3.2.1 Generic substitution

Generic substitution is allowed in Spain.

Generic substitution is mandatory for pharmaceuticals under the reference price system when the generic has the lowest price. In such a case, the pharmacist must dispense the pharmaceutical having a lower price and, should the price be the same, a generic one (art. 93.4 of the Medicines Act 29/2006)

Generics market share in Spain has been low for a long time, but it is rising. Moreover, public campaigns have contributed to an improved public perception.

Pharmacists may substitute a branded medicine with a generic under the provisions of the Medicines Act 29/2006. However, analogous substitution is not regulated and thus not allowed.

Under the reference price system if the parallel imported medicine is included in a reference price group.

3.3.2.2 INN prescribing

Doctors are allowed as stated in art. 85 of the Medicines Act 29/2006 to prescribe per active pharmaceutical ingredient and health administrators would encourage such prescription. However, this is not mandatory and is regulated at the regional level.

3.3.2.3 Other generic promotion policies

The use of generic is promoted. The latest campaign to promote generics use by the NHS has been issued on November 2010 with the aim to improve patient information and education, involve pharmacists, improve doctors information and speed up authorization and reimbursement procedure.

http://www.medicamentosgenericosefg.es/

3.3.3 Claw-backs / Pay back

The last regulation in relation with claw-backs/pay backs is the one of RD Law 4/2010.

Figure 3.1: Spain - Claw-backs / Pay back

Total sales deduction rest up to percentage

Ventas totales a PVP IVA hasta – Euros	Deducción – Euros	Resto hasta – Euros	Porcentaje aplicable
0,00	0,00	37.500,00	0,00
37.500,01	0,00	45.000,00	7,80
45.000,01	585,00	58.345,61	9,10
58.345,62	1.799,45	120.206,01	11,40
120.206,02	8.851,53	208.075,90	13,60
208.075,91	20.801,83	295.242,83	15,70
295.242,83	34.487,04	382.409,76	17,20
382.409,77	49.479,75	600.000,00	18,20
600.000,01	89.081,17	En adelante	20,00

Source: Royal Decree Law 4/2010

These rebates are targeted at retail pharmacies to National Health Service and other public purchasing entities

Also, as fixed in the Medicines Act 29/2006, additional disposition 6, manufacturers, may be required to pay back to the NHS a percentage in accordance to volume sales. These pay backs are reinvest for independent investigation, continuous education to health professionals, patient education (generics, antibiotics) and health cohesion policies.

3.3.4 Monitoring

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policy and system, and its impact on health, access to medicines, and cost-containment. It mainly focuses on monitoring of prescriptions, price, expenditure and consumption.

3.3.4.1 Prescription monitoring

Prescription monitoring is performed at a regional level. In general terms, specific indicators have been defined, there are incentives and economic compensations for practitioners complying with good practices

3.3.4.2 Price monitoring

Price changes are possible under the provisions of the Medicines Act (Art 91).

Prices should comply with the regulations in the reference price system.

For new products with health or budget impact, annual reviews may be done taking into account sales and European prices.

3.3.4.3 Pharmaceutical expenditure monitoring

Pharmaceutical expenditure monitoring is performed monthly at a national level with data provided by the Regions. Figures about expenditure per prescription, number of prescriptions, total expenditure for the reimbursed market, are compiled in the databases of the Directorate General for Pharmacy and Health Care Products.

The link for this information is as follows:

http://www.mspsi.gob.es/profesionales/farmacia/datos/marzo2011.htm

In Spain, pharmaceutical expenditure accounts for a very significant part of total health expenditure.

3.3.4.4 Consumption monitoring

Pharmaceutical consumption is monitored in Spain. The first monitoring was developed in 1974. The data on pharmaceutical consumption for out-patient care is obtained from the information contained in NHS prescriptions in each Region. The information is provided by the Regions through a computer application (Alcántara) as required by the national statistical programme.

The National Health System Annual Report is published in the website of the Ministry of Health, Social Affairs and Equality (including an English version) with a section regarding the analysis of pharmaceutical consumption based on NHS prescriptions

http://www.msc.es/organizacion/sns/planCalidadSNS/isns2008Ingles.htm

3.3.5 Assessment and evaluation

3.3.5.1 Decision-making tools

Pharmaco-therapeutic and pharmaco-economic analyses are performed within the pricing and reimbursement process for decision making in the Directorate General for Pharmacy and Health Care Products. Applied criteria may be approved by the IPC.

3.3.5.2 Evaluation of measures

No information available

3.3.5.3 Reports and results

Concerning Health Technology Assessments (HTA), rapid (single) technology assessments are performed as a basis for decision-making.

Reports for selected products are fulfilled by external contribution.

3.4 Overview on policy measures in the out-patient sector

Table 3.8: Spain – Policy measures in the out-patient sector, 2005–2010

Measures	Description	Year
Changes in the pricing policies (e.g. new policies or methodology and changes, external price referencing; price freezes / cuts, (obligatory) discounts	Price cuts for generics and health care products Price discounts for original products and orphan medicines	2010
Changes in the regulation of the mark-ups	-	-
Changes concerning the VAT rates on medicines	-	-
Changes regarding the reimbursement lists and schemes (e.g. de-listings, new reimbursement scheme)	-	-
Changes regarding a reference price system (e.g. introduction, methodology changes conc. clustering and/or the reference price)	Annual updating of reference price groups Methodology to calculate reference price	/year 2010

Measures	Description	Year
Changes concerning OPP in the out-patient sector (e.g. introduction of a prescription fee, increase of percentage co-payments)	-	-
Changes in the generics policies (e.g. introduction of INN prescribing, generics substitution)	-	-
Changes concerning monitoring of medicines (e.g. new monitoring tools)	-	-
Changes concerning evaluations and assess-ments (e.g. price review, reimbursement reviews)	Annual price review for selected products	2010

conc. = concerning, OPP = out-of pocket payment, VAT = value added tax

Description = please list the major measures in the field of policy measures mentioned

Year = please list the year in which the measures were taken

Source: Royal Decree Law 4/2010, Royal Decree Law 8/2010

Updated information for 2011

In 2011, further measures are being applied to guarantee sustainability. Royal Decree Law 9/2011 introduces some relevant modifications affecting sections in the Profile:

3.1.1. Art 89 in the Medicines Act 29/2006 adds the incremental benefit considering cost-effectiveness, budget impact and alternatives availability as items to be considered in the pricing and reimbursement process

3.1.4 Discounts from distributors to pharmacies are allowed until a maximum of 10% for original or generic medicines. (before 5% for original and 10% for generics)

An additional discount has been introduced accounting for 15% for original medicines more than 10 years in the market without a generic.

3.1.5.2 A pharmacy margin correction is introduced for small pharmacies taking into account total sales, they should take part in pharmaceutical care programs

3.2.3 Groups may be created when a generic or biosimilar becomes available and not by Ministerial Order

3.3.2.1 The mandatory substitution with a generic if this has the lowest price has been eliminated. Substitution under the reference price system will be done dispensing the lower priced product, generic or original

3.3.2.2 Generalised prescription by active ingredient has been introduced

4 Pricing, reimbursement and volume control in the in-patient sector

4.1. Pricing and procurement in the in-patient sector

4.1.1 Pricing

4.1.1.1 Framework

The pricing framework as of 2010 is the general pricing framework (as referred to in section 3.1.1.): the Law 29/2006 on Guarantees and Rational Use of Medicines and Healthcare Products (Medicines Law), Title VII Public Financing of Medicines, especially Art. 89 and 90. Royal Decree 271/1990 on Intervention of Medicines Prices is also applicable. Official prices are fixed as maximum ex-factory prices (Law 29/2006, RD 271/1990).

As a specific rule, prices of medicines in hospitals are also under the scope of the Law 30/2007 on Contracts of Public Sector which incorporates Directive 2004/80/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts into the national legislation. Regarding the differences between prices, actual prices in hospitals can be lower than official prices, however only in case of voluntary discounts or price reductions offered by manufacturers to hospital pharmacy services due to either quick settlement of the bill or to great volume of purchase (Law 29/2006 art. 3º.6.) These discounts must be reflected in the invoice and should not stimulate the product's purchase. Otherwise, discounts are not allowed and official prices must be respected. Discounts can play a key role also in a tender as long as fixed and equal discounts, due to either quick settlement of the bill or to great volume of purchase, for all tenders are laid down as a condition for the tender during the framework agreement (Informe 17/08).

The Ministry of Health, Social Policy and Equality is the competent authority for pricing and reimbursing medicines. Therefore it has the power and responsibility to decide on official prices (maximum) of medicines that will be reimbursed to the National Health Service. This competence also applied to medicines used in hospitals or medicines classified as HOM (hospital only medicines) (Law 29/2006). In a next step, hospitals themselves or their owners, e.g. regions, negotiate on lower actual prices. They can only do so when negotiating on contract. Sometimes, regions establish a maximum price lower than the official one, and hospitals further negotiate prices locally.

At hospital level there are specific bodies as purchasing committees which are in charge of deciding at which price medicines are purchased. Hospital pharmacy services within hospitals are also in charge of the purchase decision, in case that the hospital directors delegated this task to them.

If hospital pharmacists play a decision-taking of advisory role in the purchasing process depends on the procedure. For open procedures, hospital pharmacists shall set out the

technical specifications as required. The hospital pharmacist's role in the purchasing committees may either be a decision-taking or advisory one. Direct purchases are sometimes also made by hospital pharmacists, who assume a full decision-taking capacity in such a case. Hospital pharmacists also have a role in defining which medicines are considered as therapeutically equivalent. This is a way of increasing competition even for medicines that are still under patent.

4.1.1.2 Hospital prices

In Spain, the "hospital price" corresponds to the ex-factory price. The VAT applicable is 4%, the same that applies to all medicines. Therefore, the hospital price is the ex-factory price plus VAT.

There is an official price calculation scheme for all medicines, including those used in hospitals, as follows:

Maximum ex-factory price (PVL)

Maximum ex-factory price + wholesaler margin + community pharmacy margin = net retail price

Net retail price + VAT = Gross retail price

These margins are regulated.

Margins are not relevant for medicines used in hospitals. Medicines are usually sold to hospitals directly by manufacturers and do not include a wholesale margin. A wholesale margin is regulated as a maximum and would be applicable for wholesalers for those specific cases when the wholesaler acts as an intermediate for distributing a medicine to hospital (optional but rare).

There exists a large package size of medicines in order to cover great amounts of medicines needed in hospitals. This large pack size is called "envase clínico". It is an economic package. For these large packages, the MAH has to grant the Administration (Directorate-General for Pharmacy and Healthcare Products of the Ministry of Health, responsible on pricing), a mandatory discount between 10% and 17% over the normal package unit price.

There are voluntary discounts or price reductions granted to hospitals, due to either quick settlement of the bill or to great volume of purchase (Law 29/2006 art. 3º.6.). These discounts must be indicated in the invoice and should not promote the product's purchase. Otherwise, discounts are not allowed and official prices must be respected. It is difficult to estimate how high discount are and what the actual prices are. Cost-free products can also be provided and hospitals can buy products not included into the positive list for the outpatient sector.

In general, prices of medicines used in hospitals are considered either equal or lower than pharmacy retail prices, because of the existence of discounts or reductions.

Concerning the transparency about hospital prices, there is no legal obligation for hospitals to publish the medicine prices. Regarding notification, hospitals must notify the price to a competent authority as required (e.g. correspondent health service in regions, Ministry of Health). Regional authorities require this information regularly.

Public information on official prices for new medicines in hospitals is available after every Spanish Interministerial Pricing Committee:

http://www.mspsi.es/profesionales/farmacia/financiacion/home.htm

Prices for all medicines in hospitals are available on the Pharmaceutical Council web, although this web page gives prices as pharmacy retail prices:

https://botplusweb.portalfarma.com/botplus.asp?anteriores.x=1&lastPrimero=201&Accion=BUSCAR&tipoBusqueda=AVANZGEN&hmed=on&hpa=&hsin=&haf=&hcjt=&hext=&pmed=&ppa=&psin=on&paf=&vmed=&vpa=&vsin=&vaf=&pfpro=&pfing=&pfaf=&dpro=&ding=&daf=&dfpro=&dfing=&dfaf=&pspro=&psing=&psaf=&homed=&hopa=&BuscarEn=&BuscarTxt=

Just hospitals of the same region share information on prices through the regional authorities.

4.1.2 Purchasing policies

The major purchasing policies used in the in-patient sector as of 2010 are tendering (either open or restricted procedure), negotiated procedure and direct purchase.

Many regions start the purchasing process with a joint tendering for their region.

4.1.2.1 Tendering

The legal provisions which need to be complied when purchasing medicines via tendering are the Law 30/2007 on Contracts of Public Sector and the European Directive 2004/80.

However, tendering is neither the sole nor the most common purchasing policy. It is likely to be very common for products with a wide supply, where there is no market exclusivity. Tendering is mandatory when the estimated supply value exclusive of value-added tax (VAT) is equal or greater than 100,000 euro (Law 30/2007). Hospitals carry out open or limited (restricted) tenders, depending on the circumstances and according to the law (Law 30/2007, Directive 2004/18/EC).

Tendering contracts usually have one year of duration. Nevertheless, for certain medicines like not interchangeable ones, it would be possible to make a framework agreement with several economic operators (suppliers) for a longer period, in order to establish and schedule the acquisitions conditions for those medicines for four years (Moliner X).

Tender is mandatory to be published in the Official Bulletin of Spain (Boletín Oficial del Estado, BOE) and/or in the Official Bulletin of the autonomous regions, when its value exclusive of value-added tax (VAT) is estimated to € 100,000 and more. Tenders which have a value of € 137,000 and beyond exclusive of value-added tax (VAT), are mandatory to be additionally published in the Official Journal of the European Union. In the later case, the contracts are binding to the European harmonized regulation and the procedure must also comply with the European Law (Law 30/2007).

Discounts can play a key role in a tender and are allowed as long as fixed and equal discounts, due to either quick settlement of the bill or to great volume of purchase, for all tenders are laid down as a condition for the tender during the framework agreement (Informe 17/08).

4.1.2.2 Negotiations

Some medicines used in hospitals are purchased via competitive negotiations, or negotiated procedure, for example when the medicine is very exclusive (Law 30/2007). The hospital manager launches them.

Direct purchases from suppliers by hospitals have relevance. For amounts lower than 18,000 euro, there can be direct purchases through minor contracts (Law 30/2007). In these cases a purchase authorization by the hospital manager and a bill are sufficient

The negotiated procedure/competitive negotiation is launched by the hospital manager on behalf of the contracting authority, the hospital itself or the regional health service. In the process a purchasing committee (or contract body) is involved, in which the hospital pharmacists and the Pharmacy and Therapeutic Committee have a role in defining therapeutically equivalent medicines which are subject of the competitive negotiation. The juridical and economic services are also involved.

Contracts are valid for one year with the option of extending the contract one further year (Law 30/2007). Nevertheless, for certain medicines like not interchangeable ones or others exclusive, it would be possible to make a framework agreement with the unique economic operator (supplier) for a longer period, in order to establish and schedule the acquisitions conditions for those medicines for four years.

The negotiated procedure may be public or not. The negotiated procedure can be published depending on the value estimated. A negotiated procedure with an estimated value exclusive of value-added tax (VAT) equal to or lower than € 60,000, does not have to be published, however if the value is from € 60,001 to 100,000, it is mandatory to be published in the Official Bulletin of Spain and/or in the Official Bulletin of the autonomous regions (Law 30/2007).

4.1.2.3 Other purchasing policies

There are no other purchasing policies.

4.1.3 Organisation of procurement

Joint procurement is applied at a regional level in some regions, whenever it is considered relevant for medicines with high economic impact. In these cases there are regional procurement committees, and all hospitals of the joint purchasing group have to use the awarded medicine.

There is no centralized procurement agency/body at national level but there is the provision in Royal Decree Law 8/2010 introduced as additional point to Law 30/2007 on Contracts of Public Sector, which sets the basis for allowing the centralized procurement of medicinal and healthcare products.

There can be regional procurement committees and joint procurement for a group of hospitals. Additionally, hospitals can carry out their own procurement as well.

The procurement process is launched by the contracting authority, either the hospital itself or the regional health service. A purchasing committee or contract body is involved in the procurement process, and the hospital pharmacy, the main and responsible physician in the respective field and the hospital manager participate in the purchasing committee or contract body. The juridical and economic services are also involved. For joint procurement at a regional/joint hospital level (i.e. hospitals of the same owner), regional authorities for pharmacy and juridical and economical services would be involved as well. The contracting body may be composed by a President, a Vice-president and several “vocals”, members with the right to vote (Law 30/2007, Law 29/2006). The role of all actors differs among the different cases.

Contracts should be awarded on the basis of objective criteria which ensure compliance with the principles of transparency, non-discrimination and equal treatment and which guarantee that tenders are assessed in conditions of effective competition (Directive 2004/18/EC). On the one hand, the most relevant criteria for awarding could be the lowest price and the most economically advantageous tender; on the other hand the relevant criteria could be certain characteristics referred in the technical specifications set out in the contract documentation, depending on the product, as follows: quality, a certain therapeutic indication approved, proper characteristics of packaging and labeling, full capacity of supplying for suppliers, etc (Directive 2004/18/EC, Law 30/2007).

4.2 Reimbursement in the in-patient sector

4.2.1 National framework

Medicines in the in-patient sector are funded out of the pharmacy budgets as part of the hospital budgets. The main payer of medicines in hospitals is the Spanish National Health System. But funding of medicines is covered by hospital budgets.

There is a hospital formulary and selected medicines are fully covered by hospitals budgets for in-patient care. If a medicine that is not included in the formulary is considered necessary

for a specific patient, it is fully covered as well. Depending on the cost of the medicine, it is or not mandatory to be approved into the PTC.

Positive and negative lists applied in the out-patient sector are not relevant for the in-patient sector, but the hospital formulary is in itself a positive list defined locally in the hospital.

The criteria for funding of medicines in the hospital sector are different from the general sector.

4.2.2 Hospital pharmaceutical formularies

There are separate hospital pharmaceutical formularies for each hospital. There are no country-national hospital formularies but there may be joint hospital pharmaceutical formularies at regional level.

Active pharmaceutical ingredients are listed in the HPF, and they are organized by therapeutic subgroups as well. They approximately account for 1,200 medicines and 700 active substances. As mentioned before, medicines are included in the hospital budget and are paid by the NHS through regions.

The Pharmaceutical and Therapeutic Committees (PTC) are responsible for setting, developing and updating HPF. A PTC is a multidisciplinary team of pharmacists, physicians and nurses. The multidisciplinary team of the PTC is in charge of deciding which new medicines, according to the medical needs in the hospital, should be included in the PTC. Afterwards, in most cases, all doctors can apply for a new medicine. They do so in a standardized form in which items that need to be fulfilled include data on efficacy, security and cost. The hospital pharmacy, which is organisational part of the hospital and is composed by pharmacists, reviews the level of evidence and the place in therapy of the medicine and elaborates a review of the efficacy, safety and cost. Hospital pharmacists created a working group, GENESIS inside the Spanish Society of Hospital Pharmacy, for standardization of these reports (http://genesis.sefh.es/).The reports are discussed locally in the pharmacy and therapeutic committee meetings and a final decision on whether to include or not include the medicine is taken as well as a definition of authorized conditions of use.

In most hospitals, no clinical pharmacologist work. Instead, a hospital pharmacist is in charge of discussing medicines therapy with the physicians. Most hospitals (71%) work with therapeutic interchange programs and guidelines, which are developed to help doctors to select the most appropriate medication, especially in the reconciliation of treatments. In Spain there is a large tradition of unit dose distribution systems, in which the Pharmacy Department is responsible for supplying (and therefore replacing if necessary) all the medication for in-patients. In some hospitals, the change in the medicines therapy is suggested by a hospital pharmacist but requires the physician’s authorization before it can be administered, whiles in others, the therapeutically equivalent medicine can be administered as long as it adheres to the therapeutic interchange guideline approved by the hospital director of the Pharmacy and Therapeutic Committee. Then, in the next day round, the physician prescribes the new medicine or justifies the necessity of the original one.

Formularies are constantly being updated. The mean number of medicines evaluated per year is 10.3 (SD: 7.4). Also, formularies are published internally in the hospital and in some cases they are also accessible via internet. The following link is an example of this:

http://www.elcomprimido.com/FARHSD/ENLACESVADEMECUMS.htm

4.2.3 Pharmaceutical and Therapeutic Committees

PTC are in place in all hospitals, There might be regional PTC in place additionally.

A PTC is composed by the hospital management, hospital pharmacists, a clinical pharmacologist, the main physician in the respective field and a nurse. They are responsible for promoting safe, effective and efficient use of medicines, of the evaluation and selection of medicines (including off-label use) and of education on cost aware prescribing. In most cases it is the hospital pharmacy service, the ones that monitors expenditure and consumption but the hospital pharmacy shares this information with the Pharmacy and Therapeutic Committee in order to decide on adequate actions. Theoretically, the role of PTC is advisory, while the medicines selection is the responsibility of hospital directors, but in practice it is so extended that up to 99.5% have hospital pharmaceutical formularies approved by the PTC (Puigventol et al. Pham World Sci 2010).

The mean number of meetings per year is 5.1 (SD: 2.9). The numbers differ depending on the hospital size:

<100 beds: 3.6 (SD: 1.7)

100-199: 3.5 (SD: 1.9)

200-499: 5 (SD: 2.6)

≥ 500: 7 (SD: 3)

Usually, hospital pharmacists promote the use of HPF. In most hospitals they act as the president or the secretary of the PTC. Also, they elaborate the medicines reports that are discussed in the PTC meeting and they inform the committee of pharmaceutical expenditures and consumption.

4.3 Volume control in the in-patient sector

4.3.1 Monitoring

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policies and system in the in-patient sector, and its impact on health, access to medicines, and cost-containment. It mainly focuses on monitoring of prices, pharmaceutical expenditure and consumption.

4.3.1.1 Price monitoring

Prices of medicines are monitored by regional authorities that compare prices from different hospitals under their responsibility. This measure was implemented around the year 2000.

Both hospital directors and regional authorities monitor prices although the results are not published. Regional authorities meet once or twice a year with hospital directors and the chief hospital pharmacist to discuss the development of pharmaceutical expenditures. Additionally, prices are sent monthly to some regional authorities but there are no specific indicators to use and the regional authorities return the average price to the local hospital so that it can be compared locally.

4.3.1.2 Pharmaceutical expenditure

Pharmaceutical expenditure has been monitored routinely per patient and, in some hospitals per diagnosis for the last twenty years.

This is done by regional authorities and locally by hospital directors but reports are not available for public consultation. The national government through the Directorate-General for Pharmacy and Healthcare Products is collaborating with the regional authorities in a project in order to obtain the pharmaceutical expenditure data in the Spanish hospitals. As mentioned earlier (cf. section 4.3.1.1.), data are sent monthly. Regional authorities return to hospital medium data so that they can compare their local data with the average.

In this case we find specific indicators being used. Examples are pharmaceutical expenditure per pharmacological group (for example oncology medicines, anti TNF, etc). These are used to compare hospitals of similar size and characteristics.

There are meetings of regional authorities with hospital directors and hospital pharmacists. Regional authorities inform about the development of medicines consumption and elaborate a document that is discussed in the meeting.

In this sense, there is a promotion of generic prescription when the patient is discharged but in hospitals generics might not play such a role since, due to discounts, a brand can be less expensive than a generic.

4.3.1.3 Consumption monitoring

Pharmaceutical consumption has also been monitored routinely per patient and, in some hospitals per diagnosis for the last twenty years.

This is done by regional authorities and locally by hospital directors but reports are not available for public consultation. In most cases the pharmacy department provides data to the hospitals directors. They also inform the directors of medical departments. This way of cost aware prescribing policies is promoted with the involvement of professionals. Additionally, the national government through the Directorate-General for Pharmacy and Healthcare

Products, is collaborating with the regional authorities in a project in order to obtain the pharmaceutical consumption data in the Spanish hospitals.

Specific indicators are defined each year. Some examples are: % raltegravir/per HIV patient dispensed, DDD antifungics medicines/100 hospital stays.

Most hospitals have computerized inventory control, purchase and units care supplies. Furthermore, in most hospitals unit dose distribution system is implemented, and e-prescription is implemented in more than 50% of the hospitals. There are not individual sizes of prescribed packages monitored, but monitoring is done through the unit doses systems.. Normally, in hospitals large size packages are used (called “envases clínicos”), intended to respond to the need of greater amounts of medicines, for example, packages composed by 100 or 500 dose units. These are economic packages. There are some medicines that are dispensed to out-patients in the hospital pharmacy (HIV treatment, multiple sclerosis treatment, hepatitis C treatment...) Patients go monthly or every two months for refills and their adherence is calculated routinely.

The information on hospital sale (in price and volume) is available and regional authorities ask for information routinely in order to monitor their policies.

The hospital pharmacy has an important role inside the hospital. The activities they develop are the following:

- Medicines acquisition. Includes activities related to negotiation of prices and establishment of criteria for public tender.
- Medicines distribution through unit dose distribution system and, in the last years, through automated dispensing.
- Monitoring of pharmaceutical expenditures and consumption. The information is generated in the hospital pharmacy and hospital directors and medical service directors are informed.
- Elaboration of sterile products, although CIVAS are implemented, mostly, for oncology drugs.
- Medicines prescription monitoring: the pharmacist validates daily the medical orders and discusses with doctors any potential medical errors and actions directed to implementation of local pharmaceutical policies (for example adherence to formulary or local guidelines).
- Medicines information service. They answer drug queries from doctors or nurses and they elaborate drug reports for the Pharmacy and Therapeutic Committee.
- Medicines information to patients. These activities are widely implemented in the out-patient hospital pharmacy and, in some hospitals, at discharge.
- Maintenance of electronic assisted prescription system.
- Pharmacokinetic activities (20% hospitals).

- Pharmacovigilance activities.

4.3.2 Assessment and evaluation

4.3.2.1 Decision-making tools

The medicines report model standardised by the GENESIS working group (cf. section 4.2.2) includes a brief pharmacoeconomic evaluation however only considering prices and cost (see table below). These reports are done by hospital pharmacists.

Table 4.1: Pharmacoeconomic evaluation

Cost comparison with other alternatives			
	Medicine		
	Medicine A	**Medicine B**	**Medicine C**
Price (PVL+VTA) *			
Dose			
Cost per day			
Cost per treatment or cost per year			
Additional cost **			
Global cost *** or global treatment cost per year			
Incremental cost (difference) *** with standard therapy			

*Consider actual price for hospital drugs

**Additional cost: It refers to other cost associated to the drug evaluated, for example, other medicines required or non pharmacologic cost. They will be study if considered relevant

***Cost per treatment + associated costs.

****Global difference between the evaluated medicines

Incremental cost-efficacy (ICE) **Binary outcomes**						
Reference	Type of result	**OUTCOME EXPERIMENTAL GROUP**	**Outcome in the control group**	**NNT (IC 95%) ***	**Incremental cost (A-B)**	**ICE (IC95%)**
Referencia 1	Main outcome	xxxx	xxxx	N (Ninf-Nsup)	(A-B) €uros	(A-B) x N (A-B) x N inf (A-B) x N sup

Source: International guidelines

4.3.2.2 Evaluation of measures

Economic evaluation is always done when a medicine is evaluated for inclusion in the hospital pharmaceutical formulary. Regional authorities establish pharmacoeconomic guidelines and annually define targets that are monitored by hospital pharmacists. Moreover, the Pharmacy and Therapeutic Committee monitors the utilization of high cost medicines.

4.3.2.3 Reports and results

No information available.

4.3. Overview of policy measures in the in-patient sector

There have not been specific policy measures for the in-patient sector as a result of the international financial crisis. Instead, most of the financial policy measures applied to medicines in the out-patient sector, do also to the medicines in the in-patient sector.

Table 4.2: Spain – Policy measures in the in-patient sector, 2005–2010

Measures	Description	Year
Changes in the pricing framework (e.g. change pricing regulation with relevance for the in-patient sector, change in hospital specific mark-up / VAT which is relevant for the in-patient sector)	- Based on Art. 8 Royal Decree-Law 8/2010 of May 20 a 7.5% discount (deduction) shall be applied over the retail price invoice to the NHS or over the purchase price in such a case, and of 4% for products with an orphan designation. The deduction applied to all actors in the pharmaceutical chain and is applicable to pharmaceutical products in a position of exclusivity, that is, it is neither applicable to generics nor to those included in the reference price system. - Price cut for generics ranging up to 30% for the most expensive: Royal Decree Law 4/2010 of March 26 - Increases from 20% to 30% price reduction of a product when a generic still not available in Spain is available in a EU country: Royal Decree Law 4/2010 of March 26. - 30% price reduction of original biological medicines when a biosimilar is available in a EU country: Royal Decree Law 4/2010 of March 26. - Dispensing limits to certain medicines to out-patients through hospital pharmacies: Royal Decree Law 4/2010 of March 26.	2010 2010 2010 2010 2010
Changes in procurement (e.g. establishment of new procurement agency, change in relevance of tendering vs. negotiations etc.)	- New Law 30/2007 on Contracts of the Public Sector, which incorporates to the national legislation the European Directive 2004/80. – There have been changes in relevance of tendering vs. negotiations.	-
Changes regarding the reimbursement lists (e.g. concerning a national hospital list, the HPF, ...)	-	-
Changes in funding (e.g. specific budgets for specific medicines, concerning OPP in the in-patient sector)	-	-
Changes concerning evaluations and assessments	-	-

HPF = hospital pharmaceutical formulary, OPP = out-of pocket payment, VAT = value added tax

Description = please list the major measures in the field of policy measures mentioned

Year = please list the year in which the measures were taken

Source: Act 30/2007 on Contracts of the Public Sector. BOE nº 261, 2007 October 31. Royal Decree Law 4/2010 of March 26, to rationalize NHS pharmaceutical expenditure. BOE nº 75, 2010 March 27.

Royal Decree Law 8/2010 of May 20, adopting extraordinary measures to reduce public deficit. BOE nº 126, 2010 May 24.

5 Interface management and developments

This concluding chapter covers information about the interface management and the most important pharmaceutical developments for the health care system.

5.1 Interface management

Hospitals developed lists of therapeutically equivalent medicines in order to manage chronic treatment of patients that are admitted to hospitals.

At discharge, patients are given medicines to cover 24 hours and sometimes medicines information is provided, although there are considerable differences in the way different hospitals work.

There are committees that meet regularly in which there is a representation of primary and secondary care. They discuss medicines consumption and they share certain indicators, for example percentage of generics prescribed.

Most regions are working on reconciliation guidelines that guarantee adequate medicines availability when the patient is admitted and discharged from the hospital.

5.2 Developments in the out-patient and the in-patient sectors

Table 5.1: Spain – Measures in the pharmaceutical system, 2010

Measures	Under discussion	Under implementation
General health reforms (e.g. changes in responsibilities and institutions)	-	-
Pricing policies in general	-	The first national centralized procurement of medicines is being prepared in agreement with several regions for purchasing the flu vaccines 2011-2012.
Mark-ups	-	-
Taxes	-	-
Reimbursement policies	-	A medicine unit dose system will be established in the out-patient sector for certain products in order to adapt to the duration of treatment (RDL 8/2010).
Out-of pocket payments	-	-
Generic policies	-	-

Measures	Under discussion	Under implementation
Reforms targeted at the in-patient sector	-	The first risk-sharing agreement affecting a medicine, between an Andalusian hospital and a pharmaceutical company was signed at the end of 2010.
Evaluation & assessment	-	New IT systems as the electronic prescription and the traceability system applicable to every package of medicine from the manufacturer to the patient.

Source: RDL 8/2010

6 Bibliography

Literature

Studies/Books:

National Health System, Spain 2010. Ministry of Health, social policy and equality of Spain. http://www.msps.es/organizacion/sns/docs/sns2010/Main.pdf

Sistemas de Adquisición: Entorno y protagonistas del Mercado farmacéutico 2004. Gamundi C, Alonso JM.

Journal articles:

Moliner X. Contratos públicos en el sector farmacéutico: contratación de medicamentos no sustituíbles. Cuadernos de Derecho Farmacéutico, pág. 17-20.

Moliner X. Medicamentos no sustituibles y contratación pública. La Vanguardia 27.09.2007.

Puigventós F, Santos-Ramos B, Ortega A, Durán-García E Structure and procedures of the pharmacy and therapeutic committees in Spanish hospitals. Pharm World Sci 2010; 32:767-75.

Vogler S, Espín J, Habl C. Pharmaceutical Pricing and Reimbursement Information- New PPRI analysis including Spain. Pharm Policy & Law 2009;11:213-230

Presentations

Rafael BorràsMadrid–03/2011.Antares Consulting.Bioindustrias y Farmacia.© 2011.

Legislation

Act 14/1986, April 25th, on General Health BOE nº 102, 1986 April 29.

Act 16/1997, April 25th, on the regulation of Community Pharmacy services BOE nº 100, 1997 April 26.

Act 16/2003, May 28th, on the Cohesion and Quality of the National Health System BOE nº 128, 2003 May 29.

Act 29/2006 on Guarantees and Rational Use of Medicines and Healthcare Products. BOE nº 178, 2006 July 27.

Act 30/2007 on Contracts of the Public Sector. BOE nº 261, 2007 October 31.

Act 17/2009, on Free access to services activities. BOE nº 283, 2009 November 24.

Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts.

Royal Decree 271/1990 of February 23, about pharmaceutical pricing intervention. BOE nº 53, 1991 March 2.

Royal Decree 1416/1994, 25 June, on the regulation of the publicity of human medicines. BOE nº 180, 1994 July 29.

Royal Decree 2259/1994, 25 November, regulating Wholesale and distribution of human medicines. BOE nº 12, 1994 January 14.

Royal Decree 1277/2003, October 10th, on regulation the general bases for authorization of healthcare centres and services. BOE nº 254, 2003 October 23.

Royal Decree 1348/2003, October 31 st adapting medicines classification to ATC system. BOE nº 264, 2003 Nov 4.

Royal Decree 1030/2006, September 15 th, regulating a common NHS portfolio. BOE nº 222, 2006 Sept 16.

Royal Decree 1345/2007, October 11th, regulating the marketing authorization of medicinal products for human use and their prescription conditions. BOE nº 267, 2007 November 7.

Royal Decree 1344/2007, October 11th, regulating pharmacovigilance of medicinal products for human use. BOE nº 267, 2007 November.

Royal Decree 823/2008, May 16 th regulating pharmaceutical margins and discounts for distributors and dispensing points. BOE nº 131, 2008 May 30.

Royal Decree 109/2010, which modifies several Royal Decrees to adapting them to free access to services activities. BOE nº 44, 2010 February 19.

Royal Decree Law 4/2010 of March 26, to rationalize NHS pharmaceutical expenditure. BOE nº 75, 2010 March 27.

Royal Decree Law 8/2010 of May 20, adopting extraordinary measures to reduce public deficit. BOE nº 126, 2010 May 24.

Informe 17/08 de 28 Julio 2008, de la Junta Consultiva de Contratación Administrativa.

Web links

http://www.aeseg.es/es/asociados-aeseg

http://www.farmaindustria.es/Farma_Public/Farmaindustria/Asociados/index.htm

ttp://www.fedifar.net/index.php?option=com_content&view=article&id=10&Itemid=11&lang=es

http://www.msps.es/organizacion/sns/docs/sns2010/Main.pdf

http://www.mspsi.es/profesionales/farmacia/legislacion/economia/home.htm

http://www.mspsi.es/profesionales/farmacia/financiacion/home.htm

https://botplusweb.portalfarma.com/botplus.asp?anteriores.x=1&lastPrimero=201&Accion=BUSCAR&tipoBusqueda=AVANZGEN&hmed=on&hpa=&hsin=&haf=&hcjt=&hext=&pmed=&ppa=&psin=on&paf=&vmed=&vpa=&vsin=&vaf=&pfpro=&pfing=&pfaf=&dpro=&ding=&daf=&dfpro=&dfing=&dfaf=&pspro=&psing=&psaf=&homed=&hopa=&BuscarEn=&BuscarTxt=

http://www.mspsi.es/profesionales/farmacia/frmNomenclator.jsp

www.sefh.es