Pharmaceutical Pricing and Reimbursement Information

Portugal

October 2008

PPRI

Pharmaceutical Pricing and Reimbursement Information

PORTUGAL

Pharma Profile

Final version, October 2008

PPRI Representatives
National Authority of Medicines and Health Products, I.P. (INFARMED): Inês Teixeira, Iolanda Agostinho

Authors
National Authority of Medicines and Health Products, I.P. (INFARMED): Inês Teixeira, Isaura Vieira

Editors
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG: Sabine Vogler, Simone Morak

PPRI Secretariat
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG

Acknowledgements

Several people contributed to the conclusion of this document, directly or indirectly: thanks to Iolanda Agostinho for her participation in the PPRI project during these years, thanks to Eunice Trigueirão for her contribution in completing some of the Tables and Figures and thanks to Bruno Costa for his contribution to the Background Chapter.

Executive Summary

BACKGROUND

The Portuguese health care system is a mix of public and private financing, characterised by three co-existing systems: the National Health Service (NHS), the Health Subsystems and voluntary private healthcare insurance. The NHS is predominantly funded through general taxation. Apart from direct transfers from the State Budget, the NHS raises its own revenues (mainly generated by hospitals).

In recent years, co-payments in health care were increasingly applied with the aim, to some extent, of making consumers more cost-aware. The majority of these payments are for pharmaceuticals and therapeutic products.

PHARMACEUTICAL SYSTEM

The pharmaceutical policy emerges as an essential component of the Portuguese Health System, to guarantee access to an efficient, safe and high quality pharmaceutical treatment, guaranteeing rational use and equity to all citizens.

The main authorities in the pharmaceutical system in Portugal are: the Ministry of Health being responsible for the overall strategic framework of pharmaceuticals; the Medicines Agency (INFARMED) in charge of market authorisation (pharmaceuticals) and registration (medical devices), vigilance, monitoring of the market, distribution and reimbursement of pharmaceuticals, as well as the decision of price of reimbursed pharmaceuticals; and the Directorate-General of Economic Activities (DGAE) responsible for the maximum pricing of pharmaceuticals.

There are approximately 153 pharmaceutical companies in Portugal (manufacturers and importers) according to data from the Portuguese Pharmaceutical Industry Association and the Portuguese Generics Association. Pharmaceutical wholesale is operated within a multi-channel system. Currently there are approximately 334 registered wholesale companies. In 2008 there were 2,666 community pharmacies authorised and 598 Over-The-Counter (OTC) pharmaceuticals dispensaries (only authorised since 2005). Internet pharmacies have only been permitted since 2007.

In 2007 the total pharmaceutical sales at consumer price level amounted to € 3,288 mio. The generics consumption in Portugal had an enormous increase after 2002, due to the promotion of these pharmaceuticals. In 2007 the market share of generics was 17.85% in value. The public pharmaceutical expenditure makes up 54.3% of the total pharmaceutical expenditure (TPE) while the private pharmaceutical expenditure makes up 45.7%, subdivided into expenses for self medication (27.3%) and out-of pocket payments (18.4%).

PRICING

The Directorate-General of Economic Activities (DGAE - under the supervision of the Ministry of Economy and Innovation) is the entity responsible for setting the maximum price of pharmaceuticals in Portugal, except for OTC pharmaceuticals and hospital-only-medicines (HOM). The Medicines Agency (INFARMED – under the supervision of the Ministry of Health) regulates the prices of reimbursable and reimbursed pharmaceuticals.

The prices of prescription-only-medicines (POM) for outpatient sector and reimbursed OTC pharmaceuticals are statutory fixed with a maximum manufacturer price. In 2007 a new methodology (Decree-Law No. 65/2007, 14th March) was introduced to calculate this maximum price, based on the average manufacturer price observed in 4 reference countries (Spain, France, Italy and Greece). Annually the Ministry of Economy and Innovation and the Ministry of Health should publish a general revision index of pharmaceuticals.

The pricing process of HOM is totally different. The hospitals purchase the pharmaceuticals through negotiating directly with suppliers or by public procurement process. In the public procurement procedure favourable prices offered are an important criterion in the decision process. In 2007, a major change was the introduction of a maximum price and the budget control for new pharmaceuticals introduced in public hospitals (Decree-Law No. 195/2006, 3rd October).

In Portugal there is always room in the pricing process for negotiating between INFARMED and pharmaceutical industry. This negotiating depends more on the nature of the product (e.g. if it is identified a new innovative product with therapeutic added value). It is also explicitly stated in Portuguese legislation which provides the possibility to establish conditional reimbursement through agreements with companies.

There is a special pricing regime for generics. The pharmacy retail price of the generic has to be lower at a certain percentage than the reference pharmaceutical. The criteria defining the price difference were modified in 2007. The prices of generics should be annually revised and may be subject to price cuts depending on the market share (Decree No. 300-A/2007, 19th March).

Since September 2005 manufacturers of OTC products are free to set the price (Decree-Law No. 134/2005, 16th August, and Decree No. 618-A/2005, 27th July).

Both wholesale and pharmacy remuneration are regulated by a linear percentage mark up. Currently the wholesale and pharmacy mark ups (Decree-Law No. 65/2007, 14th March) are lower for reimbursed POM (6.87% and 18.25% of the net pharmacy retail price) than for non-reimbursed POM (8% and 20%). Since 2005 OTC products have no longer been regulated by a statutory mark up mark up.

For all pharmaceuticals a value added tax (VAT) rate of 5% is applied. In addition a sales tax of 0.4% of the net Pharmacy Retail Price (PRP) is applied, known as INFARMED tax.

In Portugal different pricing related cost-containment measures were taken, in particular the first mark up cut in 2005, some current price cuts and the introduction of annual price reductions for generics depending on its market share in 2007.

REIMBURSEMENT

The reimbursement and the pricing system are very closely linked. After the approval of the maximum price of outpatient POM by DGAE, the companies can apply for reimbursement at INFARMED, which is responsible for reimbursement. The Ministry of Health then decides on the pharmaceutical´s reimbursement based on INFARMED´s proposal.

In Portugal there is a positive list of pharmaceuticals used in the outpatient sector. Pharmaceuticals on the list are reimbursed at a certain rate by the NHS. Currently there are 4 reimbursement categories based on therapeutic classification (Category A - 95% and 100% for pharmaceuticals essential for life maintenance; Category B - 69%; Category C - 37%; Category D - 15%).

The pharmaco-therapeutic groups and subgroups included in each reimbursement category are pre-defined in legislation (Decree No. 1474/2004, 21st December).The co-payment rate depends on the importance of life maintenance, the level of the disease (chronic disease?) or the economic and social situation of patients.

There are special regimes of reimbursement that are defined in legislation: an additional reimbursement level was created for pensioners with low income (Decree-Law No. 129/2005, 11th August); the reimbursement of pharmaceuticals used in defined pathologies or special groups of patients (Decree-Law No. 205/2000, 1st September) is object of a special regime regulated in appropriately legal basis.

The legislation also includes the possibility to reimburse a specific medicine through the conclusion of an agreement between INFARMED and the company, if justified by interest of the public health and of the patients.

Normally OTC products are not reimbursable, unless in exceptional circumstances which have to be justified on grounds of public health.

In Portugal, the Reference Price System (RPS) was introduced in 2002, with the first list published in March 2003. This list is currently reviewed four times a year by INFARMED. The reference prices are approved by the Ministry of Health and the Ministry of Economy and Innovation. Pharmaceuticals are clustered in what is known as homogeneous groups (with the same active substance, pharmaceutical form, strength and route of administration), that include at least one generic on the market. The reimbursement of the NHS is based on the Reference Price (the highest unitary retail price of all marketed generics in each homogeneous group). The basic mechanism is still the same as of the time when the RPS was created. The patient pays the difference between the PRP and the Reference Price. The Reference Price for pensioners whose income is below the national minimum wage has an additional increment of 20%.

Between 2000 and 2005 there was an increased reimbursement rate (10% higher) for generics in place, with the aim of promoting and developing the generics market.

Fixed co-payments, like prescription fees, do not exist in Portugal.

In the inpatient sector the reimbursement process is different. Hospitalised patients are not charged for the pharmaceuticals they consume. The NHS pays for all the expenses of inpatient pharmaceuticals consumed in public hospitals, through the General State Budget.

The major change in reimbursement lists was in 2007 with the introduction of legislation that requires the reimbursement evaluation for new HOM, based on its therapeutic as well as the economic effectiveness (Decree-Law No. 195/2006, 3rd October).

In the last few years there were several changes in the Portuguese reimbursement system related to cost-containment measures. Some examples are the reduction in the NHS reimbursement rates and the abolishing of the additional reimbursement rate of 10% for generics.

Also within a period of 3 years after inclusion into reimbursement, INFARMED should undertake the re-assessment of pharmaceuticals with regard to the reimbursement status. The criteria to delisting pharmaceuticals are diverse, including the excessive cost of pharmaceuticals or lower therapeutic efficacy proven by a pharmaco-epidemiological study.

RATIONAL USE OF PHARMACEUTICALS

In Portugal there are some guidelines but they are not mandatory, they are considered more as a useful tool for appropriate prescribing. Some examples are the National Prescribing Formulary or the National Hospital Pharmaceutical Formulary published by INFARMED.

Advertising of pharmaceuticals is regulated by law (Decree-Law No. 176/2006, 30th of August) in line with the European Commission. INFARMED is the institution responsible for supervising pharmaceutical advertising activities.

Pharmaco-economic evaluations play an important role when companies apply for reimbursement both in the outpatient and inpatient sector. In 1998, INFARMED published the Methodological Guidelines for Economic Evaluation Studies to help companies in performing studies.

In 2000 generic substitution was introduced. Doctors and pharmacists have the responsibility to inform the patient about the existence of generics and their prices. Whether the patient gets a generic alternative, this depends on the doctor authorising or rejecting substitution. Neither physicians nor pharmacists have monetary incentives for generic substitution.

Pharmaceuticals consumption is regularly monitored by INFARMED, which publishes monthly reports about the development of pharmaceutical consumption and expenditure, and occasionally also develops studies concerning the evaluation of a specific pharmaco-therapeutic group, or the prescription habits or the adopted government policies.

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS

In Portugal one of the main challenges which the pharmaceutical system faces is, as in many other countries, the rising pharmaceutical expenditure in outpatient and inpatient sector. The major reasons for the growing costs are an ageing population, the increase of patients with chronic diseases and the uptake of new and more expensive pharmaceuticals.

Consequently measures to promote a rational and sustainable use of pharmaceuticals are desirable, but it is not possible yet to report on future plans. These may cover several policy measures, including the continuation of the generics market promotion, price cuts of reimbursed pharmaceuticals, the promotion of prescription guidelines or reviewing the methods used for determining therapeutic added value.

Table of content

List of tables and figures

List of abbreviations

ACSS	Administração Central do Sistema de Saúde / Central Administration of Health System
AFP	Associação de Farmácias de Portugal / Pharmacy Association
AIM	Autorização de Introdução no Mercado / Authority for Market Authorisation
ANF	Associação Nacional das Farmácias / Pharmacy Association
APIFARMA	Associação Portuguesa da Indústria Farmacêutica / Portuguese Pharmaceutical Industry Association
APOGEN	Associação Portuguesa de Medicamentos Genéricos / Portuguese Generics Association
ATC	Anatomic Therapeutic Chemical classification
ATV	Therapeutic added value
BMGFJ	Austrian Ministry of Health, Family and Youth
CHNM	Código Hospitalar Nacional do Medicamento / National Hospital Code
CNPM	Conselho Nacional de Publicidade de Medicamentos / National Advice of Medicine Advertising
DGAE	Directorate-General of Economic Activities
DGS	Director-Geral da Saúde / General Directorate of Health
DG SANCO	Health and Consumer protection Directorate General
ERS	Entidade Reguladora da Saúde / Health Regulatory Agency
FECOFAR	Federação de Cooperativas de Distribuição Farmacêutica / Federacy of Cooperatives of Pharmaceutical Distribution
FHNM	Formulário Hospitalar Nacional de Medicamentos / National Hospital Pharmaceutical Formulary
GDP	Gross Domestic Product
GGE	General Government Expenditure

GROQUIFAR	Associação de Grossistas de Produtos Químicos e Farmacêuticos / Wholesalers Association of Chemical and Pharmaceutical Products
HE	Health Expenditure
HOM	Hospital-Only Medicine(s)
IDT	Instituto da Droga e da Toxicodependência / National Institute of Drug Addiction
INE	Institute Statistics Portugal
INEM	Instituto Nacional de Emergência Médica, I.P. / National Institute for Medical Emergencies
INFARMED	National Authority of Medicines and Health Products, I.P.
INN	International Non-proprietary Name
INPI	Instituto Nacional da Propriedade Industrial / National Institute of Industrial Property
INSA	Instituto Nacional Saúde Dr. Ricardo Jorge, I.P. / National Institute of Health
I.P.	Instituto Público / Public Institute
IPS	Instituto Português do Sangue, I.P. / Portuguese Blood Institute
NCU	National Currency Unit
NHS	National Health Service
Mio.	Million
MNSRM	Medicamentos Não Sujeitos a Receita Médica / non-prescription pharmaceuticals
NORQUIFAR	Associação do Norte dos Importadores Armazenistas de Produtos Químicos e Farmacêuticos / North Association of Wholesalers Imports of Chemical and Pharmaceutical Products
GÖG/ÖBIG	Gesundheit Österreich GmbH / Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OM	Ordem dos Médicos / Doctor´s Association

OPP	Out-of Pocket Payment
OTC	Over-The-Counter Pharmaceuticals
PE	Pharmaceutical Expenditure
PFM	Postos Farmacêuticos Móveis / Pharmacy Extensions
POM	Prescription-Only Medicine(s)
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
RHAs	Regional Health Authorities
RPS	Reference Price System
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WHO	World Health Organisation

PPRI Pharma Profile Update 2008

Rationale

In the beginning, the Pharmaceutical Pricing and Reimbursement Information (PPRI) project was a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of more than 50 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals (for the list of PPRI members see the PPRI website http://ppri.oebig.at → Network)

Within the course of the PPRI project, country reports on pharmaceutical pricing and reimbursement systems, the "so-called PPRI Pharma Profiles", were produced (see http://ppri.oebig.at → Publications → Country Information). These PPRI Pharma Profiles refer, in general, to the year 2006/2007. The work was mainly done under the responsibility of the WHO Regional Office for Europe assisted by the team of the GÖG/ÖBIG.

Despite of the official end of the research project in 2007, the PPRI network participants agreed to continue the network and up-date the PPRI Pharma Profiles.

Outline

The PPRI Pharma Profile Template consists of six chapters, referring to the situation in 2008:

- Chapter 1 (Background) gives a brief overview of the Portuguese health care system and provides the main indicators of the country's health care system.
- Chapter 2 (Pharmaceutical system) provides a description of the pharmaceutical system; the regulatory framework, the pharmaceutical market, the market players and the funding of pharmaceuticals and the methods of evaluating the system.
- Chapter 3 (Pricing) covers a description of the organisation of the pricing system, the pricing policies, the pricing procedures, exceptions to these procedures, as well as a section on margins and taxes and pricing related cost-containing measures.
- Chapter 4 (Reimbursement) covers a description of the organisation of the reimbursement system, the reimbursement scheme including the eligibility criteria, the reimbursement categories and rates and the reimbursement lists. Also described in this chapter is the reference price system, the private pharmaceutical expenditure, the reimbursement in the hospital sector and the reimbursement related cost-containing measures.
- Chapter 5 (Rational Use of Pharmaceuticals) is a description of the methods used to improve rational use of pharmaceuticals including the impact of pharmaceutical budget, prescription guidelines, patient information, pharmaco-economics, generics and consumption.

- Chapter 6 (Latest changes and future developments) is a concluding chapter on the latest changes, current challenges and future plans for developments in the pharmaceutical sector.

Further deliverables

Besides the PPRI Pharma Profiles and the PPRI network, the PPRI project produced further deliverables, among those:

The **PPRI Glossary**, which is a unique glossary of pharmaceutical terms to establish a common "Pharma" terminology within the EU. See http://ppri.oebig.at → Glossary

The **PPRI Conference**, held in Vienna in June 2007. See http://ppri.oebig.at → Conferences → PPRI Conference

The **Set of Core PPRI Indicators** to compare information of different pharmaceutical system. See http://ppri.oebig.at → Publications → Indicators

A comparative analysis, based on the developed indicators, filled with real data from 27 PPRI countries. The PPRI comparative analysis is included in the **PPRI Report** and summed up in the concise report **"PPRI at a Glance"**. See http://ppri.oebig.at → Publications → PPRI Report and http://ppri.oebig.at → Publications → Concise Information

Contact

The PPRI Secretariat is located at GÖG/ÖBIG which featured as the main partner of the PPRI research project.

Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG)
Stubenring 6, 1010 Vienna, Austria
E-Mail: ppri@goeg.at
Fax.: +43 1 5138472
URL: http://ppri.oebig.at

Sabine Vogler, PPRI Project Manager, E-Mail: vogler@goeg.at, Tel.: + 43-1-51561/147

Claudia Habl, Deputy Project Manager, E-mail: habl@goeg.at, Tel.:+ 43-1-51561/161

Christine Leopold, Communication Officer, E-mail: leopold@goeg.at, Tel. +43-1-51561/149

Simone Morak, Editor-in-Chief, E-mail: morak@goeg.at, Tel. +43-1-51561/241

1 Background

Chapter 1 aims to provide an overview on the country, in particular on the health care system. As the focus on the PPRI Pharma Profiles is on pharmaceutical pricing and reimbursement, the authors of this Profile did not write a full chapter like for the following ones, but opted for the presentation of some key figures on health care systems presented in 2 tables, accompanied by a brief description of the health care system.

The Portuguese health care system is characterized by three co-existing systems: the National Health Service (NHS; Serviço Nacional de Saúde), financed by the General State Budget; the Health Subsystems - special Social Security schemes for certain professions (primarily civil servants and employees of private financial institutions) that cover about a quarter of the population; and voluntary private healthcare insurance, that covers around 10% of the population (Bentes, M., et al, 2004).

The foundation of the NHS in 1979 was based on a principle of universal coverage and equality of care. The revision of the Constitution in 1989 altered the principle of free health care services to “tendentiously free”. Access to hospital and primary care is characterised by being “tendentiously free”, and requires that, in some cases, the user make a payment.

Reforms over the recent years moved the NHS towards a public-contract model, with the private sector playing an increasingly important role in the management of publicly owned institutions.

The central government through the Ministry of Health is responsible for developing health policy and controlling and evaluating its implementation. It is also responsible for the coordination of health-related activities of other Ministries (e.g. Ministry of Education, Ministry of Environment). The core function of the Health Ministry is regulation, planning and management of the NHS.

Regional Health Authorities (RHAs) have overall responsibility for supervising and allocating financial resources to NHS healthcare providers in their regions. There are five RHAs on the mainland – North, Centre, Lisbon and Tagus Valley, Alentejo and Algarve – all accountable to the Ministry of Health. The islands of Azores and Madeira operate as autonomous regions, with their own political-administrative structures.

The High Commissioner for Health (Alto Comissário da Saúde) is responsible for the public policies of preparation and execution of the National Health Plan (Plano Nacional de Saúde 2004-2010) and the specific programs in the priority areas, at national level.

The General Directorate of Health (Director-Geral da Saúde, DGS), plans, regulates, directs, coordinates and supervises all health promotion, disease prevention and health care activities, institutions and services.

The General Inspectorate of Health (Inspecção-Geral das Actividades em Saúde) performs the disciplinary and audit function for the National Health Service in collaboration with the General Directorate of Health and audits NHS institutions and services.

A new Health Regulatory Agency (Entidade Reguladora da Saúde; ERS) was created at the end of 2003, to regulate all healthcare providers (public and private hospitals, primary health-care centres and continuous care institutions). It is responsible for ensuring citizens to have equal access to healthcare, and that suppliers deliver high quality services.

The National Authority for Medicines and Health Products, I.P. (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.; INFARMED) is a Government agency accountable to the Ministry of Health. The objective is to monitor, assess and regulate all activities relating to human medicines and health products for the protection of Public Health.

The Central Administration of Health System (Administração Central do Sistema de Saúde; ACSS) is the Institute responsible for evaluating the effectiveness and progress of the public health system in Portugal. The main role of ACSS is to manage the financial assets necessary to provide better health services, promote new management models and innovation, and the dissemination of the latest technologies throughout the system.

Other National Institutes are the following:

- The National Institute for Medical Emergencies (Instituto Nacional de Emergência Médica, I.P.; INEM)

- The Portuguese Blood Institute (Instituto Português do Sangue, I.P.; IPS)

- The National Institute of Health (Instituto Nacional Saúde Dr. Ricardo Jorge, I.P.; INSA)

- The National Institute of Drug Addiction (Instituto da Droga e da Toxicodependência, I.P.; IDT)

The Portuguese health care system is a mix of public and private financing. The NHS is predominantly funded through general taxation. Apart from direct transfers from the State Budget, the NHS raises its own revenues (mostly generated by hospitals). These include flat-rate admission charges, consultations and diagnostic tests, payments received from patients for special services such as private rooms, payments from beneficiaries of health subsystems and private insurers, payment received for the hiring of premises and equipment, income from investment, donations, fines (Bentes et al., 2004).

In recent years, co-payments in health care were increasingly applied with the aim of making consumers more cost-aware. The majority of these payments are for pharmaceuticals and therapeutic products. User charges are charged on many NHS services. Flat rate charges exist for consultations (primary care and hospital outpatient visits), emergency visits, home visits, diagnostic tests and therapeutic procedures.

Table 1.1: Portugal – Key figures on the healthcare system, 2000–2007

Variable	2000	2001	2002	2003	2004	2005	2006	2007	Source
Total population	10,256,658	10,329,340	10,407,465	10,474,685	10,529,255	10,569,592	10,599,095	10,617,575	INE b)
Life expectancy at birth, total	76.6	76.9	77.2	77.4	77.8	78.2	n.a.	n.a.	OECD c)
Life expectancy at birth, females	80.0	80.3	80.5	80.5	81.0	81.4	n.a.	n.a.	OECD c)
Life expectancy at birth, males	73.2	73.5	73.8	74.2	74.5	79.9	n.a.	n.a.	OECD c)
GDP in Mio. €	122,270	129,308	135,434	138,582	144,274	149,021	155,289	n.a.	OECD c)
GGE in Mio. €	23,623	25,436	27,144	28,129	29,789	31,639	32,217	n.a.	OECD c)
Total Health Expenditure in Mio. €	10,815	11,402	12,181	13,430 a)	14,084 a)	15,127 a)	n.a.	n.a.	OECD c)
Public Health Expenditure in Mio. €	7,846	8,156	8,800	9,851 a)	10,089 a)	10,993 a)	n.a.	n.a.	OECD c)
Private Health Expenditure in Mio. €	2,969	3,247	3,381	3,579	3,995	4,134	n.a.	n.a.	OECD c)
Total number of hospitals	n.a.	n.a.	213	204	209	204	200	n.a.	INE b)
Number of acute care beds	n.a.	n.a.	37,709	38,117	38,239	37,330	36,563	n.a.	INE b)
Total number of doctors [2]	n.a.	n.a.	33,751	34,440	35,213	36,138	36,924	n.a.	INE b)

GDP = Gross Domestic Product, GGE = General government expenditure

n.a. = not available

Data: Portugal and Islands

a) Estimative Data

b) INE, Statistics Portugal

c) OECD, Health Data 2007

Table 1.2 represents the five leading causes of mortality in Portugal in 2005 (last year available), using the ICD-10 coding system on the 3-character level.

Table 1.2: Portugal – Diseases with highest morbidity and the leading causes of mortality, 2008

No.	Top 5 diseases with highest morbidity (1 = most common)	ICD-10 code	No.	Top 5 leading causes of mortality (1 = most common)	ICD-10 code
1	n.a.		1	Diseases of the Circulatory System	I00 – I99
2	n.a.		2	Malignant Neoplasms	C00 – C97
3	n.a.		3	Diabetes Mellitus	E10 – E14
4	n.a.		4	Diseases of the Respiratory System	J00 – J99
5	n.a.		5	Diseases of the Digestive System	K00 – K93
Source:			Source: INE a) - 2005 data		

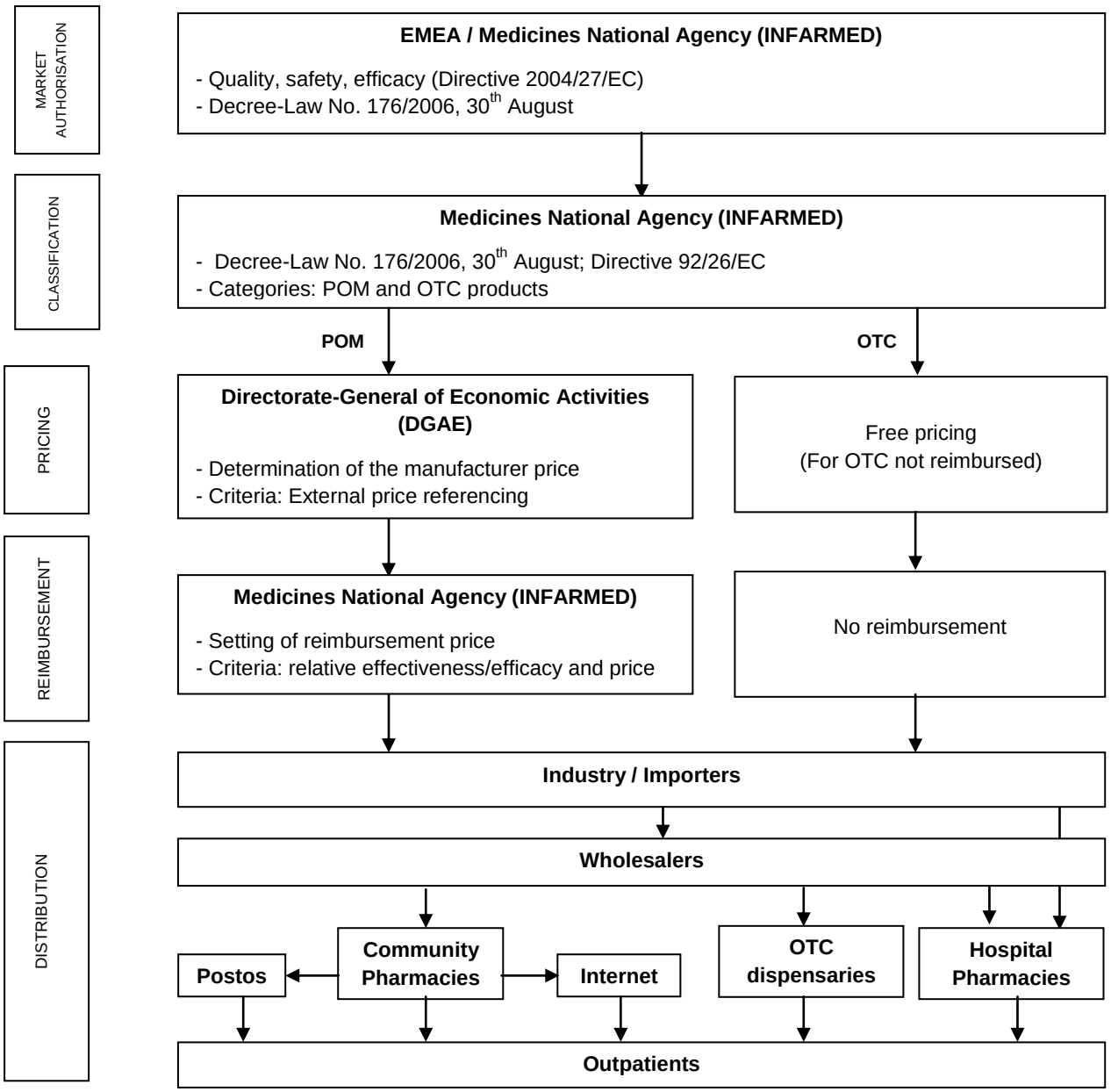
a) INE - Statistics Portugal

2 Pharmaceutical system

2.1 Organisation

This section describes, on one hand, the regulatory framework (legal basis, main authorities and their tasks), and, on the other hand, the pharmaceutical market (data, key players) as of 2008. Figure 2.1 provides a comprehensive overview of the Portuguese pharmaceutical system.

Figure 2.1: Portugal – Flowchart of the pharmaceutical system, 2008



Source: INFARMED

2.1.1 Regulatory framework

This section includes a description of the legal framework for the pharmaceutical policy, the principal authorities and important players in this framework and their roles as of 2008.

Over the years the Portuguese Health System has been subjected to several modifications that reflected the influence of a series of factors related with the economic, social and political changes. The pharmaceutical policy emerges as an essential component of the Health System, to assure access to an efficient, safe and high quality pharmaceutical treatment, guaranteeing rational use and equity to all citizens.

2.1.1.1 Policy and legislation

Since 1990 several legislative changes have resulted from the implementation of European Union directives, such as that to guarantee the quality and safety of pharmaceuticals. In addition, programs of public information and education on the rational use of pharmaceuticals were developed, namely to promote the use of generics, and cost-containment policies were adopted.

The major changes and developments on pricing and reimbursing policies over the period 2000-2007 were the following ones: in 2000 conditional reimbursement was introduced based on agreements for products where there were doubts due to lack of information (Decree-Law No. 205/2000, 1st September); in 2002 the reference price system (Decree-Law No. 270/2002, 2nd December) and the obligation to prescribe by International Non-proprietary Names (INN) for pharmaceuticals that have generics approved (Decree-Law No. 271/2002, 2nd December) was introduced; in 2005 the 100% reimbursement rate was reduced to 95% (Decree-Law No. 129/2005, 11th August); in 2006 further reimbursement rates were reduced (from 70% to 69%, from 40% to 37% and from 20% to 15%) (Decree-Law No. 53-A/2006, 29th December); in 2007 a major change was the introduction of the reimbursement evaluation for new pharmaceuticals for intramural/hospital use (Decree-Law No. 195/2006, 3rd October). Finally in 2007 a new methodology to calculate the maximum price was introduced, based on the average price observed in 4 reference countries (Spain, France, Italy and Greece) while before it was based on the lowest price observed in 3 reference countries (Spain, France and Italy) (Decree-Law No. 65/2007, 14th March). The prices approved before the new legislation entered in force were also revised, but in the first application the revision was only applied on the cases that the Portuguese prices decreased (Decree No. 300-A/2007, 14th March).

2.1.1.2 Authorities

Table 2.1 contains the relevant authorities in the regulatory framework in the Portuguese pharmaceutical system.

Table 2.1: Portugal – Authorities in the regulatory framework in the pharmaceutical system, 2008

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Ministério da Saúde	Ministry of Health	Ministry of Health	Overall strategic framework of pharmaceuticals. In charge of the reimbursement decision
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED)	National Authority of Medicines and Health Products, I.P.	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation, vigilance, monitoring, regulatory activities and reimbursement of pharmaceuticals
Direcção Geral das Actividades Económicas (DGAE)	Directorate-General Economic Activities	(subordinate to the Ministry of Economy and Innovation)	Responsible for the maximum price of pharmaceuticals

Source: INFARMED (http://www.min-saude.pt ; http://www.infarmed.pt ; http://www.dgae.min-economia.pt/)

The main authorities in the regulatory framework of the pharmaceutical system are as follows:

- The Ministry of Health (Ministério da Saúde), whose core function is the regulation, planning and management of the NHS. The Ministry of Health is in charge of the overall strategic framework of pharmaceuticals and of the reimbursement regarding pharmaceutical decisions and it is the supervising authority of the Medicines Agency (INFARMED);
- The Medicines Agency (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P., INFARMED) was established in 1993, being the key authority regarding pharmaceuticals in Portugal, covering all relevant tasks except pricing of pharmaceuticals. INFARMED is in charge of market authorisation (pharmaceuticals) and registration (medical devices), vigilance, monitoring of the market, distribution and reimbursement of pharmaceuticals, as well as the decision of price of reimbursed pharmaceuticals;
- The Directorate-General of Economic Activities (Direcção Geral das Actividades Económicas, DGAE) was created in 2003 substituting the former Directorate-General of Commerce and Competition (Direcção-Geral do Comércio e da Concorrência, DGCC). DGAE is subordinated to the Ministry of Economy and Innovation and is responsible for the promotion and the development of a more favourable environment to the enterprise competitiveness and innovation. In the regulatory pharmaceutical framework it is responsible for the maximum price of pharmaceuticals.

The prices of Prescription-Only Medicines (POM) are regulated through a process with two phases: after being granted the pharmaceutical Market Authorization (approved by INFARMED), the company should apply for the price of the pharmaceutical to the Directorate-General of Economic Activities (DGAE). DGAE approves (in 90 days) the maximum price of all new pharmaceuticals (except for the ones only used at hospitals).

After the approval of maximum price (by DGAE – under the supervision of the Ministry of Economy and Innovation) the companies should apply for reimbursement to INFARMED (under the supervision of the Ministry of Health). To submit a reimbursement application companies have to complete a form, send evidence based information that proves the therapeutic added value related to the alternatives already reimbursed (pharmaco-therapeutic and pharmaco-economic information) and propose a price for reimbursement (equal or below the approved price).

With the information of the two reports (pharmaco-therapeutic and economic) INFARMED prepares a document with the proposal if reimbursement should be granted or not. The final decision is taken by the Ministry of Health.

2.1.2 Pharmaceutical market

This section gives an overview on the availability of pharmaceuticals as well as market figures.

2.1.2.1 Availability of pharmaceuticals

In Portugal, there was a total of 41,659 pharmaceuticals authorised in 2008 (counting different pharmaceuticals forms, strength and pack sizes). Of these, 39,858 were Prescription-Only Medicines (POM), which means that a doctor's prescription is required for dispensing these pharmaceuticals to patients. Jointly with EMEA, the Medicines National Agency (INFARMED) is the authority responsible for the classification of pharmaceuticals into prescription-only and non-prescription pharmaceuticals. The number of authorised pharmaceuticals and POM has increased substantially since 2002 (Table 2.2).

Table 2.2: Portugal – Number of pharmaceuticals, 2000–2008[1]

Pharmaceuticals[2]	2000	2001	2002	2003	2004	2005	2006	2007	2008
Authorised	17,791	21,849	22,398	28,430	31,528	33,998	36,432	38,481	41,659
On the market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
POM	n.a.	19,971	20,751	26,707	29,844	32,300	34,717	36,737	39,858
Reimbursed [3]	6,022	6,020	6,171	7,508	7,886	8,497	8,777	7,117	6,642
Generics	711	1,512	2,658	4,071	5,815	8,231	11,534	13,913	17,783
Parallel traded	0	0	0	0	0	0	0	0	0
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	1,381	1,624	1,820	1,995

n.a. = not available, POM = Prescription-Only Medicines

[1] as of 1 January

[2] Counted including different pharmaceutical forms, strength and pack sizes

[3] Number of reimbursed pharmaceuticals (the number of reimbursable pharmaceuticals is not available)

Source: INFARMED, Medicines Statistic Yearbook 2007

The number of generic pharmaceuticals had an enormous increase over the years, due to the implementation of several information campaigns to promote generics (to physicians and to the general public) and to regulatory policies implemented such as: in 2000 there was a 10% increase in the reimbursement rates for generics (Decree-Law No. 205/2000, 1st September); in

2002 changes concerned the introduction of a reference price system (Decree-Law No. 270/2002, 2nd December), the obligation to prescribe by INN for pharmaceuticals that have generics approved, the obligation for physicians and pharmacists to inform the patient about the existence of generics and their prices, the obligation for pharmacists to sell the less expensive generic when authorised by physician (Decree-Law No. 271/2002, 2nd December); incentives for products known as "copies" to switch for generics by promoting tax exemption for alterations for market authorisation and by being granted a higher price (although lowest than the original) while maintaining reimbursement; in 2006 the simplification of the reimbursement process and use of electronic communication for reimbursement applications; and for new generics where the originators have the maximum ex-factory price per package of 10 Euros the minimum interval between the price of the generic and the original product changed from 35% to 20% (Decree-Law No. 65/2007, 14th March).

Since 2007, some pharmaceuticals have received the non-prescription status (Decree-Law No. 238/2007, 19th June), to allow the growth of the Over-The-Counter (OTC) market, expressed in a growing number of OTC dispensaries (that were authorised in 2005). On the other hand reimbursed OTC pharmaceuticals were also allowed to be dispensed by the OTC drugstores, however without NHS reimbursement.

2.1.2.2 Consumption

Table 2.3 presents an overview for Portugal, between 2000 and 2007, on the annual pharmaceutical prescription and consumption. In 2007 the annual number of prescriptions was 56,222,601 and in value € 2,167 mio. In the same year the number of packs consumed was of 129,193,201. The highest increase during the represented period was verified in value of prescriptions.

Table 2.3: Portugal – Annual prescriptions and consumption, 2000–2007

Consumption	2000	2001	2002	2003	2004	2005	2006	2007
No. of prescriptions per year (in volume, in thousands)	43,345	44,584	45,405	49,744	51,399	52,706	53,945	56,223
No. of annual prescriptions in value (in NCU = in Mio. €)	1,521	1,662	1,762	1,833	2,023	2,120	2,136	2,167
No. of annual consumption in packs (in thousands)	117,740	121,815	123,135	120,079	124,408	127,704	127,610	129,193
No. of annual consumption in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = Defined Daily Doses, n.a. = not available, NCU = National Currency Unit, No. = Number

Source: INFARMED, Medicines Statistic Yearbook 2007

Portugal has a legal limitation on how many items (packs) a prescription may include. A maximum of 4 different pharmaceuticals per prescription is allowed, with a limit of 4 packs or 2 packs of the same pharmaceutical (Decree No. 1501/2002, 12th December).

2.1.2.3 Market data

Table 2.4 presents pharmaceutical market data for Portugal. In 2007 the total pharmaceutical sales at consumer price level amounted to € 3,288 mio. between 2006 and 2007 total pharmaceutical sales rose by 4.0%, whereas between 2003 and 2004 total pharmaceutical sales increased by 9.0%. Pharmaceuticals sales at ex-factory price level amounted to a value of € 2,155 mio. in 2006.

Table 2.4: Portugal – Market data, 2000–2007

In million €	2000	2001	2002	2003	2004	2005	2006	2007
Pharmaceutical sales								
Sales at ex-factory price level [1]	1,593 [2]	1,739 [2]	1,865 [2]	1,863	2,031	2,116	2,155	n.a.
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at pharmacy retail price level [3]	2,337 [2]	2,552 [2]	2,735 [2]	2,734	2,979	3,105	3,162	3,288
Sales at hospitals [4, 5]	432.2	522.9	565.6	660.1	742.3	829.0	859.2	n.a.
Sales of generics [3]	2.9 [2]	8.8 [2]	48.3 [2]	154.4	235.2	392.7	479.1	586.7
Sales of parallel traded pharmaceuticals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exports and imports								
Total pharmaceutical exports	316 [6]	361 [6]	346 [4]	308 [4]	308 [4]	297 [4]	346 [4]	n.a.
Total pharmaceutical imports	1,067 [6]	1,272 [6]	1,383 [4]	1,459 [4]	1,597 [4]	1,646 [4]	1,836 [4]	n.a.

n.a. = not available

[1] Estimate Data

[2] Portugal and Islands (Madeira and Azores)

[3] Source: INFARMED, Medicines Statistic Yearbook 2007

[4] Source: ACSS data 2007

[5] Hospitals of National Health Service

[6] Source: OECD (Manufacturing)

The share of generics in Portugal had an enormous increase after 2002, as a result of the promotion of these pharmaceuticals, due to diverse information campaigns and regulatory changes. In terms of value, generics sales amounted to € 586.7 Mio. in 2007. This value represents a market share of 17.85% of the total outpatient sales.

In 2006 the total pharmaceutical Portuguese export amounted to € 346 mio., while the total pharmaceutical import made up to € 1,836 Mio.

Table 2.5 lists the top 10 best-selling reimbursed pharmaceuticals by active ingredient, based on their total expenditure for the National Health Service and consumer in 2007. Simvastatin and Omeprazole were also the two active ingredients in 2007 with the highest expenditure in the generics market.

Table 2.5: Portugal – Top 10 best selling pharmaceuticals, by active ingredient, 2007

Position [1]	Pharmaceutical, by active ingredient
1	Simvastatin
2	Omeprazole
3	Clopidogrel
4	Lansoprazole
5	Amoxicilin + Clavulanic acid
6	Atorvastatin
7	Valsartan + Hydrochlorothiazide
8	Pantoprazole
9	Losartan + Hydrochlorothiazide
10	Rosuvastatin

[1] Reimbursement Market

Source: INFARMED, Medicines Statistic Yearbook 2007

2.1.2.4 Patents and data protection

In Portugal pharmaceuticals receive a protection for 20 years through the National Institute of Industrial Property (Instituto Nacional da Propriedade Industrial, INPI). During these 20 years only the manufacturer that has the patent is allowed to produce the pharmaceutical in question. After the 20 years have passed, manufacturers can apply for an additional period (5 years maximum) of market protection (called the Complementary Protection Certificate).

Under the recently adopted legislation (Decree-Law No. 176/2006, 30th August) there is a period of 8 + 2 +1 year for data protection. Only 8 years after the Market Authorisation the Medicines Agency can accept an application for generics, which can then be authorised when the 10 year data protection period ends. There is an additional year of data protection for additional innovative indications.

2.1.3 Market players

This section describes the key players in the pharmaceutical system except from the authorities which have been introduced in section 2.1.1.2. It gives an overview of the key players in production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy making as of 2008.

2.1.3.1 Industry

According to data provided by the Portuguese Pharmaceutical Industry Association (Associação Portuguesa da Indústria Farmacêutica, APIFARMA) there were 137 pharmaceutical companies (manufacturers including generic companies and importers) in 2006, which were represented as members in that association. The number of staff in the pharmaceutical industry in Portugal, by the same data source was 10,953 in 2005 (Table 2.6).

The Portuguese Generics Association (Associação portuguesa de medicamentos Genéricos, APOGEN) includes national pharmaceutical industries that produce and commercialize generics. Currently 16 companies are members of this association.

Pharmaceutical production in Portugal (manufacturing raw materials and pharmaceutical products) amounted to € 1,829 mio. in 2006, with an increase of 4.8% compared to the year 2005 (APIFARMA, 2006).

Table 2.6: Portugal – Key data on the pharmaceutical industry, 2000–2007[1]

Pharmaceutical industry	2000	2001	2002	2003	2004	2005	2006	2007
Total no. of companies [2]	126	129	130	137	141	139	137	n.a.
– research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– generic producers [3]	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	16
– biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of persons employed [4]	n.a.	10,484	10,897	10,691	10,717	10,953	n.a.	n.a.

[1] annual data

[2] members of APIFARMA

[3] members of the generic's association APOGEN

[4] counted per head

Source: APIFARMA, Pharmaceutical Industry in Figures 2007

Manufacturers have to apply to EMEA or to Medicines National Agency (INFARMED) for the market authorisation (Autorização de Introdução no Mercado, AIM) which is in line with Community law (Decree-Law No. 176/2006, 30th August - Estatuto do Medicamento). An expert committee at INFARMED then evaluates, authorises and decides on the prescription status of the authorised pharmaceutical. There are prescription-only-medicines (POM) and non-prescription pharmaceuticals (Medicamentos Não Sujeitos a Receita Médica, MNSRM). The prescription status has consequences on the pricing of the pharmaceuticals. Normally, OTC products are not reimbursable, unless in exceptional circumstances which have to be justified on grounds of public health (ÖBIG, 2006).

For imports of pharmaceuticals from non-EU Member States, a prior authorisation from the INFARMED is needed, while pharmaceuticals from EU Member State can be imported without restrictions.

Since 1997, the Pharmaceutical Industry (through APIFARMA) has regularly signed framework agreements with the Ministry of Health, committing both parties to reforms: the Industry was targeted by cost-containment measures like price freezes, price cuts and paybacks, while the government promises to shorten procedure time and to pay the hospital debts.

The latest protocol was signed in 2006 (Protocol No. 7/2006, 10th February) and is valid from 2006 to 2009.The aim of this protocol was to contain the NHS pharmaceutical expenditure, not only in the outpatient but also (for the first time) in the hospital sector, creating conditions to develop politics of sustainability between the Ministry of Health and the pharmaceutical industry.

2.1.3.2 Wholesalers

Pharmaceutical wholesale is operated within a multi-channel system in Portugal. Like the pharmaceutical industry and retailers, wholesalers have to licence with INFARMED (Decree-Law No. 176/2006, 30th August, and Decree No. 348/98, 15th June). Pharmaceutical wholesalers usually deliver to pharmacies three times a day. In case of emergencies, immediate delivery is also possible.

Table 2.7 represents key data on pharmaceutical wholesale, between 2000 and 2008. Currently there are approximately 334 registered wholesale companies.

The market leaders Alliance Unichem, Codifar and OCP-Portugal have a common market share of nearly 50%. The possibilities for wholesalers to own pharmacies are limited (ÖBIG, 2006).

Table 2.7: Portugal – Key data on pharmaceutical wholesale, 2000–2008[1]

Wholesalers	2000	2001	2002	2003	2004	2005	2006	2007	2008
Total number of wholesale companies[1]	355	355	419	433	334	232	267	305	334
Total number of importers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total number of outlets	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

n.a. = not available, n.app. = not applicable

[1] as of 1 January

Source: INFARMED, Medicines Statistic Yearbook 2007

The wholesale margin is fixed for POM. Non-reimbursed medicines have a mark up of 8% of the retail price excluding VAT. The reimbursed pharmaceuticals have a mark up of 6.87% of the retail price excluding VAT (Decree-Law No. 65/2007, 14th March). Until September 2005 the wholesale margin was equal to reimbursed or non-reimbursed pharmaceuticals.

There are three major associations of wholesalers: GROQUIFAR - Wholesalers Association of Chemical and Pharmaceutical Products (Associação de Grossistas de Produtos Químicos e Farmacêuticos), NORQUIFAR – North Association of Wholesalers Imports of Chemical and Pharmaceutical Products (Associação do Norte dos Importadores Armazenistas de Produtos

Químicos e Farmacêuticos) and FECOFAR – Federation of Cooperatives of Pharmaceutical Distribution (Federação de Cooperativas de Distribuição Farmacêutica).

These Associations represent the associate's enterprises, defending their interest (in dialogue with the Government and office entities) and, in general, proceeding with all the activities and measures which contribute to the progress of these companies.

2.1.3.3 Pharmaceutical outlets / retailers

During several years pharmaceuticals in Portugal were dispensed only through the community pharmacies and hospital pharmacies.

In 2005 (cf. section 2.1.3.3.2) there was a new legislation (Decree-Law No. 134/2005, 16th August). Since then, OTC dispensaries (drugstores) have been authorised to operate. They are only allowed to sell the OTC pharmaceuticals.

In 2007, the new approved legislation of pharmacies (Decree-Law No. 307/2007, 31st August) also allowed the community pharmacies (and the OTC dispensaries in case of OTC pharmaceuticals) to dispense pharmaceuticals through the internet and to the domicile (home deliveries).

2.1.3.3.1 Pharmacies

In Portugal, the establishment of a new pharmacy requires the authorisation by INFARMED (supervised by the Ministry of Health) and it involves also health authorities and local entities.

The pharmacy establishment results from criteria regarding the population´s access to pharmaceuticals, and has as priority the quality of the service. Due to this matter, there are several requirements concerning establishment and functioning that pharmacies must follow.

One of the requirements is the space available that must be of a minimum size of 95 m^2, and which must cover different rooms (public attendance room, stock material room, laboratory, toilette installations and a personalized attendance room to special pharmaceuticals services).

Before 2007 there was a very restricted regulation, with the following major criteria: the pharmacy must be owned by a pharmacist, there were geographic and demographic restrictions for the establishment of a new pharmacy and pharmacy chains were not allowed.

In 2007 there was a huge reform of the legal framework of pharmacies (Decree-Law No. 307/2007, 31st August): the property of pharmacy is now allowed to a single person or commercial society (not only to pharmacists); currently the technical director does not need to be the owner of the pharmacy, but must be a pharmacist in exclusivity; pharmacies are also allowed to dispense pharmaceuticals through the internet and home deliveries; pharmacies may now acquire pharmaceuticals through tendering; pharmacies may as well provide pharmaceutical services (defined by the Government); and pharmacies have the obligation to provide a book of claims to the clients, when asked.

In 2008 there were 2,666 community pharmacies authorised in Portugal, while in 2000 the number was 2,460 (Table 2.8). In 2007 one community pharmacy corresponded to 3,983 inhabitants (Figure 2.2) or there was 0.25 community pharmacy per 1,000 inhabitants.

Table 2.8: Portugal – Retailers of pharmaceuticals, 2000–2008[1]

Retailers	2000	2001	2002	2003	2004	2005	2006	2007	2008
Number of community pharmacies	2,460	2,474	2,470	2,478	2,605	2,663	2,670	2,666	2,666
No. of private pharmacies	2,460	2,474	2,470	2,478	2,605	2,663	2,670	2,666	2,666
No. of public pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Number of hospital pharmacies for outpatients	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of other POM dispensaries: Pharmacies Extensions [2]	321	321	302	301	262	247	239	240	241
Total number of POM-dispensaries	2,781	2,795	2,672	2,779	2,867	2,910	2,909	2,906	2,907
No. of internet pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	90 [3]
No. of OTC dispensaries, like drugstores	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	55	346	598

OTC = Over-The-Counter Pharmaceuticals, POM = Prescription-Only Medicines; n.a. = not available, n.app. = not applicable, No. = number

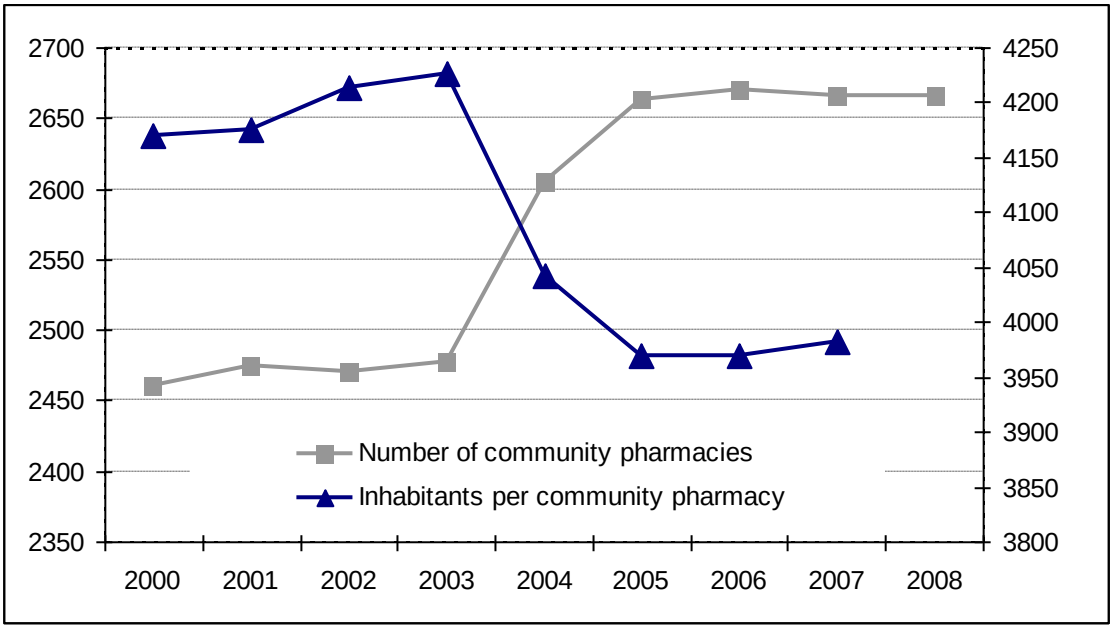
[1] as of 1 January

[2] Postos Farmacêuticos Móveis (PFM) / Pharmacies Extensions

[1] as of 1 July

Source: INFARMED, Medicines Statistic Yearbook 2007/ INE, Statistics Portugal

Figure 2.2: Portugal – Number of community pharmacies and number of inhabitants per community pharmacies, 2000–2008



Source: INFARMED, Medicines Statistic Yearbook 2007

Presently in Portugal there are the following pharmacies associations: the most representative and with great influence is ANF (Associação Nacional das Farmácias) and the other one is AFP (Associação de Farmácias de Portugal). There are only a few pharmacies that are not members of any of these associations.

The pharmacy margin is fixed for POM. The non-reimbursed POM have a mark up of 20% of the pharmacy retail price excluding VAT. The reimbursed pharmaceuticals have a mark up of 18.25% of the pharmacy retail price excluding VAT (Decree-Law No. 65/2007, 14th March). Until September 2005 the pharmacy margin was equal to reimbursed or non-reimbursed pharmaceuticals.

Pharmacies may run Pharmacies Extensions (what is called Postos Farmacêuticos Móveis, PFM) to guarantee the provision of pharmaceuticals to the population in rural areas. These establishments are dependent of a pharmacy and in charge of a pharmacist, and they may be installed in places where a pharmacy or another PFM does not exist. In 2008 there were 241 Pharmacies Extensions authorised in Portugal.

The current process of PFM establishment involves the local and health authorities, the Commission of evaluation and INFARMED, allowing meeting the real needs of the population.

2.1.3.3.2 Other pharmacy outlets

In 2005 there was a new legislation (Decree-Law No. 134/2005, 16th August). Since then the sale of over-the-counter pharmaceuticals outside pharmacies, in so-called OTC dispensaries was regulated and authorised.

The establishment of OTC dispensaries requires authorisation by INFARMED. According to the legislation, these outlets may be established under the following conditions:

- the outlet has to possess adequate facilities (e.g. storage space);
- it has to be technically supervised by a pharmacist or a pharmacy technician (who could be technically responsible for up to 5 OTC dispensaries within an area of 50 kilometres, but is not allowed to act as technical director of a community pharmacy simultaneously);
- the outlet has to comply with the pharmacovigilance rules established by law.

In 2008 598 OTC dispensaries were registered in Portugal (only after two years of the authorisation regulation of OTC dispensaries).

2.1.3.3.3 Internet pharmacies

In 2007, the new legal framework of pharmacies (Decree-Law No. 307/2007, 31st August) also allowed the community pharmacies (and the OTC dispensaries in case of OTC pharmaceuticals) to dispense pharmaceuticals through the internet and home deliveries, after official communication to INFARMED.

INFARMED presents the list of these internet sites in adequate place of its electronic page (www.infarmed.pt). In July 2008 90 internet pharmacies were registered in Portugal.

Home deliveries must be made under the supervision of a pharmacist in case it is a pharmacy, or by the pharmacy technician in case of OTC dispensaries. This person (pharmacist or pharmacy technician) is also responsible for giving the necessary information for patients to guarantee the appropriate use of the pharmaceuticals.

The remuneration of this new service (set by the community pharmacies and the OTC dispensaries) was neither restricted nor regulated.

Due to this new process, in July 2008 INFARMED launched an information campaign which intended to alert the citizens to the risks of the pharmaceuticals purchased from non authorised internet sites.

2.1.3.3.4 Dispensing doctors

In Portugal there are no self-dispensing doctors.

2.1.3.4 Hospitals

In Portugal all public hospitals had their own pharmacy, but due to a recent consolidation of some units, some of them have a central pharmacy now. Hospital Pharmaceutical Services have to be obligatorily led by a pharmacist. This is the service that assures the pharmaceutical dispensation to the patients, the quality, effectiveness and security of pharmaceuticals, integrates the health care teams and promotes scientific investigation and education activities.

Hospitals pharmacies are not allowed to deliver pharmaceuticals to the public unless there are exceptional circumstances with social implications or for clinical reasons (Decree-Law No. 206/2000, 1st September).

In 2006 legislation (Decree-Law No. 235/2006, 6th December) was approved that establishes the framework (establishment, functioning) for pharmacies in NHS hospitals which are allowed to dispense pharmaceuticals to the public. The hospital has the initiative for the application for the concession to run the hospital pharmacy, but Health Ministry authorises public procurement for the concession of these pharmacies. Hospital pharmacies may sell pharmaceuticals in unit dose to outpatients. In July 2008 no such pharmacy has been approved yet.

There is a National Hospital Pharmaceutical Formulary (Formulário Hospitalar Nacional de Medicamentos, FHNM). The use of the FHNM is required for NHS Hospitals. In rule, they only must use the pharmaceuticals included in that list, but if justified it is possible to make exceptions. The FHNM is an orientation document that supports wide range of pharmaceuticals with very different prices, but it is not obligatory prescription guidance.

The INFARMED website offers information on authorised pharmaceuticals in Portugal and indicates if they are dispensed exclusively in hospital pharmacy.

In 2007 a legal requirement was introduced for the first time asking for a reimbursement evaluation for new pharmaceuticals for intramural/hospital use (Decree-Law No. 195/2006, 3rd October). Reimbursement evaluations should be based on the therapeutic added value as well as the economic effectiveness of the pharmaceutical.

In 2007 a national unique code (Código Hospitalar Nacional do Medicamento, CHNM) was also created to standardize the relevant information of pharmaceuticals used in the hospitals and other services of the National Health Service (Decree No. 155/2007, 31st January). This was an important measure not only from the point of view of the management of the pharmaceuticals circuit distribution but also from the point of view of the rational use of pharmaceuticals.

2.1.3.5 Doctors

Doctors are represented by their professional organization (Ordem dos Médicos, OM). The Portuguese State delegates to OM to monitor the quality of the medicine, the strictness and requirements of the training of the doctors and, consequently, for the defence of the citizens´ rights to quality health care.

There are some doctors´ societies of different specialities (e.g. Portuguese Society of Diabetology, Portuguese Society of Rheumatology). These societies, without lucrative propose, aim to promote the development of the speciality, to serve the Portuguese population through the promotion of education and the scientific knowledge, and the endorsement of better medical care and assistance to the citizens with a specific illness.

Reimbursed pharmaceuticals may be prescribed by doctors, from public or private services. Before 1995 the prescriptions from the private medical consultation were not reimbursed by the NHS (Order No. 14/95, 22nd May).

Doctors have neither financial incentives nor pharmaceutical budgets and there is few monitoring of their prescription practice. There are some guidelines, but they are not mandatory, they are considered more as a useful tool to facilitate appropriate prescribing. There are several available information publications and databases (e.g. INFARMED publishes quarterly the

"Pharmaceuticals Generics Guide" and the "Reference Price System Guide"; INFARMED also developed a national prescribing formulary that describes the benefits and side-effects of prescription-only-medicines, as well as the price and reimbursement status).

Doctors have the obligation to prescribe by INN for pharmaceuticals that have generics approved (Decree-Law No. 271/2002, 2nd December). They have the responsibility to inform the patient about the existence of generics and their prices, but they may not allow the patient to choose a specific pharmaceutical, like a generic one (they may reject generic substitution by determine it on the prescription).

In 2003 for the first time in Portugal the electronic prescription model was approved (Order No. 7330/2003, 18th March). The use of electronic prescription turns the prescription process more rigorous and speediness, and brings important advantages in comfort for patient and efficiency for doctors. It also helps to reduce the incorrect reading of the doctors´ hand writing. The prescription doctor has a broad range panel of information that includes the price of the pharmaceutical and allows him/her to choose the alternative that seems most adequate, also from an economic point of view, among the alternatives.

2.1.3.6 Patients

The influence of the patient over the choice of prescription-only-medicines (POM) is quite limited, due to the doctor's behaviour, the pharmacist`s behaviour, the information available and his/her capacity to pay.

The "preferences" of patients may be incorporated in the decision of the doctor, as a result of the doctor's interest in establishing a good relationship with his/her clients.

Patients have access to information on authorised and reimbursed pharmaceuticals: the prices and reimbursement of pharmaceuticals (as well as other related pharmaceutical information) are available to the general public through internet data base at the INFARMED webpage (http://www.infarmed.pt/infomed/inicio.php); INFARMED also publishes quarterly the "Pharmaceuticals Generics Guide" and the "Reference Price System Guide" (paper version and electronic version).

Patients are required to pay a co-payment towards the price of POM (0%, 5%, 31%, 63% and 85%), depending on the reimbursement level, that is pre-defined according to therapeutic classification (Decree No. 1474/2007, 21st December). In addition for POM included in the Reference Price System if the patient buys a pharmaceutical that costs more than the reference price (the price that the NHS reimburses), he/she will have to pay the difference between the reference price and the pharmacy retail price.

A pensioner whose income is below the national minimum wage has an extra 15% reimbursement (cf. section 4.2.2). The reference price for these pensioners is also at a 20% higher level (cf. section 4.3).

With regard to OTC pharmaceuticals, patients can purchase these pharmaceuticals since 2005 outside the pharmacies (in OTC dispensaries). Information on where to find these pharmaceuticals is provided on the website of INFARMED.

There is a protocol between the industry association (APIFARMA) and several patient organisations on mutual co-operation on the exchange of information and experience.

2.2 Funding

This section provides an overview of the funding of pharmaceuticals. This includes pharmaceutical expenditure and the allocation of funds for pharmaceuticals.

2.2.1 Pharmaceutical expenditure

The Portuguese pharmaceutical sector has been characterised by a substantial increase in expenditure since the beginning of the 1990s. The total pharmaceutical expenditure (POM and OTC pharmaceuticals) amounted to € 3,311 mio. in 2005 (that corresponds to € 313 per inhabitant). The pharmaceutical expenditure per capita rose by 29.5% between 2000 and 2005. This increase could be explained, among others, by demographic factors (e.g. the ageing population, development of chronical diseases) and medical progress factors (e.g. introduction of new biological pharmaceuticals).

The proportion of public pharmaceutical expenditure as a share of total health care expenditure was 15.9% in 2005, while the private pharmaceutical expenditure was 6.0%.

Table 2.9: Portugal – Total pharmaceutical expenditure, 2000–2007

Pharmaceutical expenditure	2000	2001	2002	2003 [1]	2004 [1]	2005 [1]	2006	2007
TPE in million €	2,418	2,625	2,838	2,876	3,141	3,311	n.a.	n.a.
TPE in % of Total Health Expenditure	22.4	23.0	23.3	21.4	22.3	21.9	n.a.	n.a.
TPE per capita in € [2]	242	254	273	275	298	313	n.a.	n.a.
Public PE in % of THE	16.2	16.4	16.8	15.7	16.0	15.9	n.a.	n.a.
Private PE in % of THE	6.2	6.6	6.5	5.7	6.3	6.0	n.a.	n.a.

GDP = Gross Domestic Product, NCU = National Currency Unit, PE = Pharmaceutical Expenditure, TPE = Total Pharmaceutical Expenditure,

Data refers only to sales of pharmaceuticals in pharmacies and not in hospitals.

1 Estimative data from 2003 to 2005

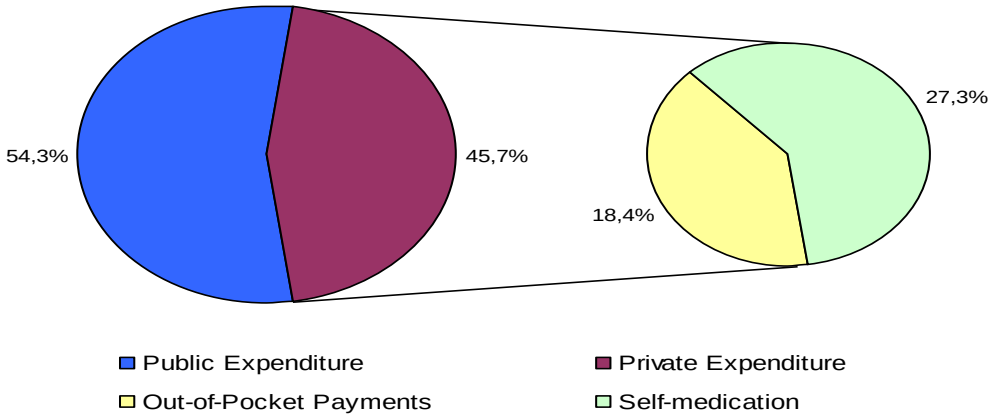
2 Population data from Table 1.1 were used as basis for calculation

Source: OECD Health Data 2007

2.2.2 Sources of funds

Public pharmaceutical expenditure makes up 54.3% of the total pharmaceutical expenditure (TPE year 2007). This expenditure includes the reimbursement by the NHS of POM outpatient expenditure and public hospitals´ expenses on pharmaceuticals.

Figure 2.3: Portugal – Share of private and public pharmaceutical expenditure, 2007



Data refer to pharmaceuticals dispensed in pharmacies, OTC dispensaries and public hospitals in 2007.

Source: INFARMED

Private pharmaceutical expenditure makes up 45.7% of TPE, subdivided into expenses for self medication (27.3%), which include the non-reimbursed, and OTC pharmaceuticals, and out-of pocket payments (18.4%) which include the percentage co-payment of reimbursed pharmaceuticals.

2.3 Evaluation

INFARMED, through the Medicine and Health Products Observatory, monitors the pharmaceutical market, concerning the pharmaceutical expense and consumption, and the major policies implemented in Portugal:

- For the whole reimbursed market the periodicity of monitoring is monthly. Every month a report is produced displaying the general evolution until the month immediately before. This report includes total pharmaceutical expenditure in the outpatient reimbursement segment, the growth rates by month and year, for the whole country and by region. It also comprises an estimation for the future based on SARIMA models (seasonal models for forecasting a time series);

- On a monthly basis another report especially for generics is produced. This report contains information on the relation between the generic and non-generic market in value and volume, the generics market share and its evolution and the top INN with highest generic market share;

- In addition a monthly report is produced on the sales of OTC pharmaceuticals outside pharmacies (in the OTC dispensaries), with information in value and volume per dispensary and the index price compared before and after the liberalisation;

- Since 2007 it has also been possible to monitor the public hospitals` pharmaceutical consumption. Every month INFARMED publishes the hospital value consumption;

- Every 3 months is an analysis on all reimbursed pharmaceuticals in order to identify the ones that most contribute to the sales evolution. This report helps to identify which products are more responsible for growth;

- Every year a study is also performed to identify which INN will go off-patent soon and which have already gone off-patent. The report makes an analysis of the INN market share to identify the relevant ones and also identifies the ones that have already generics and the ones that do not have generics. The report also provides information on companies, in particular the ones that have a higher market share among the top INN generic market and the ones that have a higher market share in the rest of generic market.

3 Pricing

3.1 Organisation

In Portugal the price setting procedures differ depending on the type of pharmaceutical.

The reimbursement system and the pricing system are very closely linked. The pricing and reimbursement of outpatient pharmaceuticals is a two step process:

- Directorate-General of Economic Activities (DGAE - under the supervision of the Ministry of Economy and Innovation) is the entity responsible for the pricing of pharmaceuticals. DGAE approves (in 90 days) the maximum price of all the new pharmaceuticals (except OTC pharmaceuticals and hospital-only medicines);

- INFARMED (Medicines Agency – under the supervision of the Ministry of Health) regulates the prices of reimbursable and reimbursed pharmaceuticals. Applications for reimbursement are submitted to INFARMED, which can propose the applicant to lower the price in order to obtain reimbursement status.

The maximum manufacture price of prescription-only-medicines (POM) for the outpatient sector and reimbursed OTC pharmaceuticals are statutorily fixed. The wholesale and pharmacy mark ups are regulated via a percentage of the net pharmacy retail price (Decree-Law No. 65/2007, 14th March).

Recently, there have been major reforms in the pricing system in Portugal, with the liberalisation of OTC prices at wholesale and pharmacy level. Since September 2005 for OTC products, there are no longer regulated margins at wholesale and pharmacy level (Decree-Law No. 134/2005, 16th August, and Decree No. 618-A/2005, 27th July).

The pricing process of hospital-only-medicines (HOM) is totally different. Neither the DGAE nor INFARMED are involved. The prices of HOM are variable (there is no maximum price set) and are established by the companies. The hospitals purchase the pharmaceuticals through negotiating directly with the suppliers or by public procurement process (centrally purchased by ACSS). In 2007 a reimbursement evaluation for new pharmaceuticals for intramural/hospital use was introduced (Decree-Law No. 195/2006, 3rd October). Since January 2007 there has been a maximum price and budget control for new pharmaceuticals introduced in public hospitals.

3.2 Pricing policies

Table 3.1 gives an overview of the methods of pharmaceutical pricing in Portugal.

Table 3.1: Portugal – Ways of pricing of pharmaceuticals, 2008

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	OTC pharmaceuticals	OTC pharmaceuticals	OTC pharmaceuticals
Statutory Pricing	Maximum prices are set for POM and reimbursed OTC	Regulated maximum mark up for POM and reimbursed OTC; via a percentage of the PRP (6.87% for reimbursed and 8% for non-reimbursed)	Regulated maximum mark up for POM and reimbursed OTC; via a percentage of the PRP (18.25% for reimbursed and 20% for non-reimbursed)
Price Negotiations	Yes (the maximum price for reimbursement between the company and INFARMED for reimbursable pharmaceutical; and between the hospital and the companies for HOM)	No	No
Discounts / rebates	Yes, cost discounts only for POM and reimbursed OTC	Yes, cost discounts only for POM and reimbursed OTC	Yes, cost discounts only for POM (and applied only in the co-payment patient part)
Public Procurement	➢ Mainly relevant for pharmaceuticals used in hospitals ➢ Not relevant in outpatient sector (e.g. except for vaccinations included in National Plan and contraceptives dispensed in Health Care Centres)		
Institution in charge of pricing	➢ Directorate-General of Economic Activities (DGAE, under the supervision of the Ministry of Economy and Innovation) ➢ INFARMED (under the supervision of the Ministry of Health) for reimbursed pharmaceuticals		
Legal Basis	➢ Decree-Law No. 65/2007, 14th March ➢ Decree No. 300-A/2007, 19th March ➢ Decree-Law No. 134/2005, 16th August		

HOM = Hospital-only Medicines, OTC = Over-The-Counter pharmaceutical, POM =Prescription-Only Medicines, PRP = Pharmacy Retail Price

Source: INFARMED

The price setting procedures differ depending on the type of pharmaceutical. The key distinction is the prescription status (POM, OTC pharmaceutical) and if it is a hospital-only-medicine or (also) used in the outpatient sector.

The pharmacy retail price (PRP) is obtained by adding the wholesale and pharmacy mark ups, the sales tax (collected by INFARMED) and the value added tax (VAT) to the ex-factory price (cf. section 3.5).

In 2007 a new methodology to calculate the maximum price of POM and reimbursed OTC pharmaceuticals was introduced (Decree-Law nr. 65/2007, 14th March). This new methodology is based on the average manufacturer price observed in 4 reference countries (Spain, France, Italy and Greece). Annually the Ministry of Economy and Innovation and the Ministry of Health should publish a general revision index of pharmaceuticals (cf. section 3.3.1).

There is a special pricing regime for generics applied at retail price level. Basically, generic prices have to be lower at a certain percentage than the price of the original product. The criteria were also modified in 2007. The prices of generics should be annually revised and may be subject to price cuts depending on the market share (cf. section 3.4.2).

3.2.1 Statutory pricing

The prices of prescription-only-medicines (POM) for outpatient sector are statutorily fixed by DGAE. There is a maximum manufacturer price and the wholesale and pharmacy mark ups are regulated via a percentage of the net pharmacy retail price. The reimbursed OTC pharmaceuticals have also the same statutory fixed price (Decree-Law No. 65/2007, 14th March).

Currently the wholesale and pharmacy mark ups are lower for reimbursed POM (6.87% and 18.25% of the net PRP) than for non reimbursed medicines (8% and 20%).

3.2.2 Negotiations

In Portugal there is always room for negotiation in the pricing process between INFARMED (Ministry of Health) and pharmaceutical industry. This negotiation depends more on the nature of the product. There is more room for negotiation in case of a new innovative product with therapeutic added value, an orphan product, or a new product for an unserved patient need. This room for negotiation is also reflected in Portuguese legislation by the possibility to establish conditional reimbursement through agreements with companies.

Public hospitals may also negotiate directly with the pharmaceutical industry to purchase hospital-only medicines. In 2007 legislation introducing reimbursement evaluation in hospitals brought a major change regarding new pharmaceuticals in public hospitals (cf. section 3.4.1).

3.2.3 Free pricing

Since September 2005 the prices of OTC pharmaceuticals are freely set at all price levels (Decree-Law No. 134/2005, 16th August, and Decree No. 618-A/2005, 27th July). Before that, manufacturers of OTC products were free to set the price, but the wholesale and pharmacy mark ups are also regulated for PTC products.

3.2.4 Public procurement / tendering

The hospitals may purchase the pharmaceuticals through public procurement. In the public procurement procedure favorable prices offered are important criteria in the decision process.

3.3 Pricing procedures

Table 3.2 gives an overview of the different pricing procedures in Portugal and in the following subsections the procedures are explained in more detail.

Table 3.2: Portugal – Pricing procedures, 2008

Pricing procedure	In use: Yes / no	Level of pricing[1]	Scope[2]
Internal price referencing	Yes	At the pharmacy retail price level	Only reimbursed pharmaceuticals (Reference Price System)
External price referencing	Yes	At the manufacturer price level	Only POM (except the hospital restricted prescription medicines) and reimbursed OTC pharmaceuticals (4 reference countries: Spain, France, Italy and Greece)
Cost-plus pricing	n. app.	n. app.	n. app.
Other, e. g. indirect profit control	n. app.	n. app.	n. app.

[1] Level of pricing = at what stage of the pricing process does the pricing take places (e. g. at the retail price level)

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

n.app. = not applicable

Source: INFARMED

3.3.1 External price referencing

External price referencing is applied to all POM (except the hospital restricted prescription medicines) and reimbursed OTC pharmaceuticals, at the manufacturer price level. The maximum manufacturer price is authorized by DGAE (under the supervision of the Ministry of Economy and Innovation).

In 2007 a new methodology to calculate the maximum price of these pharmaceuticals was introduced (Decree-Law nr. 65/2007, 14th March). This new methodology is based on the average manufacturer price observed in 4 reference countries (Spain, France, Italy and Greece), while before 2007 it was based on the lowest manufacturer price, found in the 3 reference countries (Spain, France and Italy).

There are precise rules on how to carry out the price comparisons, in particular how to proceed if identical or similar pharmaceuticals are not on the market in the reference countries:

1) in case of that pharmaceutical does not exist in the 4 reference countries, it is used the average of at least 2 reference countries;

2) in case that the pharmaceutical exists only in 1 of the 4 reference countries, it is used the manufacturer price of that country;

3) in case that the pharmaceutical does not exist in any reference countries, it is used the average of the lowest manufacturer prices of the identical or similar pharmaceuticals in the reference countries (excluding generics);

4) in case that neither identical or similar pharmaceuticals exist in any reference country but exist in Portugal, it is used the manufacturer price of the identical or similar pharmaceuticals that are commercialised in the national market;

5) in case that neither identical or similar pharmaceuticals exist in any reference country nor in Portugal, it is used the manufacturer price of the original country.

In these cases the prices are temporary and will be subject to annual revision.

The price comparisons between pharmaceuticals are also made via the following methodology: with the same pharmaceutical form, strength and package, or with the same pharmaceutical form, and the closest strength and package (Decree-Law No. 65/2007, 14th March).

The applying manufacturer has to deliver the prices of pharmaceuticals in the reference countries. However DGAE may check the information provided via published sources. DGAE has 90 days to decide, and if there is no response within that period, the manufacturer may use the price that was asked for. The applications to obtain a manufacturer price are the same for an innovative new chemical entity, for a “me too” drug and for a line extension. This methodology is not applied to generics.

3.3.2 Internal price referencing

In Portugal the Reference Price System (RPS) was introduced in 2002 (Decree-Law No. 270/2002, 2nd December) with the first list published in 13 March 2003. To set this practice up experience from literature, experts and of other countries were used.

The aim was to eliminate price gaps between similar reimbursed pharmaceuticals (and to contain pharmaceutical expenditure by defining a fixed amount to be paid by the NHS), assuring that the patient has access to an alternative of quality and proven therapeutic equivalence.

The reference groups (homogenous groups) and reference prices are reviewed by INFARMED at each quarter (4 times a year), but the basic mechanism is still the same as of the time when the reference price system was created.

The RPS is based on the Reference Price that is the price established by the NHS for a group of pharmaceuticals – what is called homogeneous group (with the same active substance, pharmaceutical form, strength and route of administration), that includes at least one generic on the market. The same homogeneous group could enclose several sizes of packages, which is denominated as the range size package. The Reference Price corresponds to the highest unitary retail price of all marketed generics in each homogeneous group (so it has in consideration the number of units of each package).

The reimbursement of NHS is based on the Reference Price. The patient pays the difference between Pharmacy Retail Price and Reference Price.

The Reference Price for pensioners whose income is below the national minimum wage has an additional increment of 20% (since the 3rd quarter of 2006). Initially this increment was 25%.

3.3.3 Cost-plus pricing

Cost-plus is not applied in Portugal.

3.3.4 (Indirect) Profit control

In Portugal there is no direct profit control concerning pharmaceutical industry. The profits are indirectly influenced by the payback agreement in the outpatient and hospital sectors, through the protocols (framework agreement) signed between the Ministry of Health and the pharmaceutical industry. The latest protocol was signed in 2006 (Protocol No. 7/2006, 10th February).

3.4 Exceptions

3.4.1 Hospitals-only

As mentioned earlier, prices for hospital-only medicines (HOM) are set in a different way. Neither the DGAE nor INFARMED are involved. The prices of HOM are variable (there is no maximum price set) and are established by the companies. The hospitals purchase the pharmaceuticals through negotiating directly with the suppliers or by public procurement process. In the public procurement procedure favourable prices offered are considered as an important criterion in the decision process.

A major change occurred in 2007 with the introduction of reimbursement evaluation for new pharmaceuticals for intramural/hospital use (Decree-Law No. 195/2006, 3rd October): the companies have to demonstrate the therapeutic added value and the economic advantage for these pharmaceuticals. Since January 2007 there has been a maximum price and budget control for new pharmaceuticals introduced in public hospitals.

In 2007 a national unique code to standardize relevant information regarding pharmaceuticals used in the hospitals was also created (Decree No. 155/2007, 31st January). This allowed INFARMED to start monitoring the public hospitals´ pharmaceutical consumption and expenditure which is done monthly.

3.4.2 Generics

In Portugal there is a special pricing regime for generics applied at pharmacy retail level. The wholesale and pharmacy mark ups for generics follow the same rules as for branded original products.

The pharmacy retail price (PRP) of a generic brought on the Portuguese market will have to be at least 35% lower than the PRP of a reference pharmaceutical, with the same strength and equal pharmaceutical form. In 2007 other criterion was introduced: if the PRP of all packages of

the reference pharmaceutical are below € 10.00, the price difference applied is 20% (Decree-Law No. 65/2007, 14th March).

The pharmacy retail price of a new generic that enters a homogeneous group (of the Reference Price System, cf. section 3.3.2) must be 3% lower than the lowest price of generic, that has at least 10% generics market share in that homogeneous group (Decree-Law No. 65/2007, 14th March).

After March 2007, generics were subject to price reductions depending on the market share:

- 50% ≤ market share of the active ingredient < 60% → generic price reductions of 5%;
- 60% ≤ market share of the active ingredient < 70% → generic price reductions of 4% (9%);
- market share of the active ingredient ≥ 70% → generic price reductions of 3% (12%);

This percentage cuts are only applied once (when the active ingredient reaches for the first time the market share) and are cumulative (Decree No. 300-A/2007, 19th March).

3.4.3 Over-The-Counter pharmaceuticals

Over-the Counter (OTC) pharmaceuticals are freely priced. The wholesale and pharmacy mark ups are also free since September 2005. But for the reimbursed products the pricing process is different, with the same procedures applied for the POM (maximum manufacturer price set by DGAE and then by INFARMED, the wholesale mark up of 6.87% and the pharmacy mark up of 18.25%).

3.4.4 Parallel traded pharmaceuticals

The legal basis for pricing parallel traded pharmaceuticals is regulated by Decree-Law No. 176/2006, 30th of August. The parallel importer communicates to INFARMED the price of the pharmaceutical, which is always lower to the price of the considered pharmaceutical and of the identical or essential similar pharmaceuticals with a market authorisation in Portugal.

3.4.5 Other exceptions

There are no other exceptions in Portugal.

3.5 Margins and taxes

This section contains a description of the wholesale and pharmacy margin and mark up regulations applied to pharmaceuticals.

Table 3.3 gives an overview of the methods for regulating wholesale and pharmacy mark ups.

Table 3.3: Portugal – Regulation of wholesale and pharmacy mark ups, 2008

Wholesale mark up			Pharmacy mark up		
Regulation (yes/no)	**Content**	**Scope**	**Regulation (yes / no)**	**Content**	**Scope**
Yes	Percentage mark ups	POM (except hospital POM) and reimbursed OTC products[1]	Yes	Percentage mark ups	POM (except hospital POM) and reimbursed OTC products[1]

[1] Applied to all outpatient pharmaceuticals before September 2005. Since that date mark ups have been free for OTC pharmaceuticals

Source: INFARMED

3.5.1 Wholesale remuneration

Since 1990 (Decree No. 29/90, 13th January) wholesale remuneration has been a fixed mark up for all pharmaceuticals (POM and OTC). This mark up was of 8% of the net pharmacy retail price.

In 2005 a new legislation (Decree No. 618-A/2005, 27th July) reduced the mark up to 7.45% of the net pharmacy retail price for reimbursed POM. In this year there was a major reform with the liberalisation of OTC prices, at wholesale and pharmacy level (Decree-Law No. 134/2005, 16th August).

In 2007 there was another reduction of mark ups. Currently the prescription-only-medicines (except the hospital restricted prescription medicines) and the reimbursed OTC pharmaceuticals have a mark up of 6.87% of the net pharmacy retail price (Decree-Law No. 65/2007, 14th March). The non-reimbursed pharmaceuticals in outpatient sector have a mark up of 8% of the retail price excluding VAT. The mark up is free for OTC pharmaceuticals.

3.5.2 Pharmacy remuneration

Since 1990 (Decree No. 29/90, 13th January) the pharmacies remuneration has been a fixed mark up for all pharmaceuticals (POM and OTC). This mark up was of 20% of the net pharmacy retail price.

In 2005 a new legislation (Decree No. 618-A/2005, 27th July) reduced the mark up to 19.15% of the net pharmacy retail price for reimbursed POM. In this year there was a major reform with the liberalisation of OTC prices, at wholesale and pharmacy level (Decree-Law No. 134/2005, 16th August).

In 2007 there was another reduction of mark ups. Currently the prescription-only-medicines (except the hospital restricted prescription medicines) and the reimbursed OTC pharmaceuticals have a mark up of 18.25% of the net pharmacy retail price (Decree-Law No. 65/2007, 14th March). The non-reimbursed pharmaceuticals in outpatient sector have a mark up of 20% of the pharmacy retail price excluding VAT. The mark up is free for OTC pharmaceuticals.

3.5.3 Remuneration of other dispensaries

Presently, OTC pharmaceuticals have a free price. So OTC dispensaries remuneration is not regulated by any price limit.

3.5.4 Value added tax

For all pharmaceuticals a value added tax (VAT) rate is applied of 5%. This is a reduced rate for pharmaceuticals, while the standard rate is 20%.

3.5.5 Other taxes

In addition, there is the so-called INFARMED tax, which is a sales tax of 0.4% of the net pharmacy retail price (Decree-Law No. 282/95, 26th October).

3.6 Pricing related cost-containment measures

This section contains a description of the price control mechanisms currently used in Portugal in the last few years.

3.6.1 Discounts / Rebates

Since 1997, and over the years, there have been 4 agreements between the Ministry of Health and the pharmaceutical industry association (APIFARMA), which established limits of public pharmaceutical expenditure in the NHS and industry paybacks in case of excess. The latest agreement, signed in 10 February 2006, limits the growth of reimbursed pharmaceuticals in the outpatient sector and (for the first time) in the hospital sector, from 2006 to 2009.

The public hospitals may negotiate directly with the pharmaceutical companies to purchase hospital-only medicines, so they can receive discounts in general.

In 2007 the new legislation allowed price/costs discounts for POM and reimbursed OTC pharmaceuticals at all price types (manufacturer, wholesale and pharmacy). In pharmacies the price discounts may only be applied in the co-payment patient part (Decree-Law No. 65/2007, 14th March).

3.6.2 Margin cuts

In Portugal between 1990 and 2005 the wholesale and pharmacy mark ups for outpatient pharmaceuticals were maintained at 8% and 20% of the net pharmacy retail price respectively (Decree No. 29/90, 13th January).

In 2005 there was the first cut of the mark ups to 7.45% (wholesale) and 19.15% (pharmacy) for all reimbursed pharmaceuticals (Decree No. 618-A/2005, 27th July). In 2007 there was another cut of the mark ups to 6.87% (wholesale) and to 18.25% (pharmacy) also for all reimbursed pharmaceuticals (POM and reimbursed OTC) (Decree-Law No. 65/2007, 14th March).

3.6.3 Price freezes / Price cuts

Since 1997, the Pharmaceutical Industry (through APIFARMA) has regularly signed framework agreements with the Ministry of Health. In this position industry has been targeted by cost-containment measures like price freeze and price cuts.

On 15 September 2005, the pharmacy retail prices of all reimbursed pharmaceuticals were cut by 6%. This price cut was divided between the manufacturer price (3%), the wholesale mark up and the pharmacy mark up. The aim of this measure was to reduce and contain public pharmaceutical expenditure. In 2007 there was another cut of the wholesale and pharmacy mark ups for reimbursed pharmaceuticals (cf. section 3.6.2).

The Ministry of Health can authorise an exceptional price increase for pharmaceuticals in specific situations, justified from the necessity of maintaining these (cheaper) products on the market and consequently to avoid the shift from cheaper to expensive pharmaceuticals. This exceptional price increase is asked for by companies and is analysed by DGAE and INFARMED.

3.6.4 Price reviews

After March 2007 the annual price revision is based on the average of the prices in the reference countries at the date of the annual communication of prices. The companies have to present the prices to DGAE and INFARMED with the rules explained in the section of the external price referring (cf. section 3.3.1). If the changes in the pharmacy retail price (PRP) are of 2.5% reduction or 2.5% increase, the PRP should not be altered. In case that identical or similar pharmaceuticals do not exist in reference countries the RPR is not changed. The reduction in pharmaceutical prices is made through a gradual 10% steps annual decrease (Decree No. 300-A/2007, 19th March).

Pharmaceuticals with pharmacy retail price of less than € 15.00 shall be excluded from the revision. In 2007 pharmaceuticals integrated in homogeneous groups (Price Reference System) were also excluded from the revision.

Under the same legislation, generics are also subject to annual price reductions depending on their market share (cf. section 3.4.2).

4 Reimbursement

4.1 Organisation

The current Portuguese reimbursement system of pharmaceuticals is the result of a long process in which principles of accessibility, therapeutic value, essentiality, equity, universality and effectiveness were introduced. Reimbursement rules have come to be used as an instrument of price negotiation, because the per capita income is low, and the companies do not risk placing most of the pharmaceuticals on the market without getting reimbursement. The general policy for reimbursement covers the whole country.

The reimbursement system and the pricing system are very closely linked. After the approval of maximum price by DGAE (under the supervision of the Ministry of Economy and Innovation) of outpatient POM, the companies should apply for reimbursement to INFARMED (Medicines Agency, under the supervision of the Ministry of Health), which is responsible for the reimbursement process.

To submit a reimbursement application companies have to fill a formulary, send evidence based information that proves the therapeutic added value (ATV) related with the alternatives already reimbursed (pharmaco-therapeutic and pharmaco-economic information) and propose a price for reimbursement (equal or below the approved price).

The application is received and validated by INFARMED, and in case of missing data, the companies have a defined period to submit this information. After all documents are validated they are analysed by pharmacologists (external experts) in order to establish the grade of innovation and the therapeutic added value when compared to alternatives (for the same indications) already reimbursed. The result of this evaluation consists of a pharmacotherapeutic report with information on: size of the package and strength needed; therapeutic alternatives; grade of ATV; measure units of the product and alternatives (for example: daily defined dose approved by WHO). When needed companies are asked to provide extra information in order to respond to possible doubts.

After the pharmacotherapeutic evaluation the application is analysed by economists in order to demonstrate economic advantage. If the product does not demonstrate an ATV compared to the alternative the economic evaluation is only based on the comparison of prices (considering the differences in daily posologies). The product under evaluation should present a lower daily price than the alternative. When the price is higher the companies are asked to decrease the price.

If the product demonstrates an ATV or if it is a totally new product without alternative, the economic advantage should be demonstrated by presenting an economic evaluation study. The result of economic evaluation is an economic report. When needed companies are asked to provide clarifications on doubts related to the economic evaluation study. INFARMED published the guidelines for economic evaluation studies in 1998. These guidelines help the companies to perform these studies (cf. section 5.4).

With the information of the two reports (pharmacotherapeutic and economic) INFARMED prepares a document with the proposal to grant, or not, reimbursement. The final decision is taken by the Ministry of Health.

If the decision is negative, before the final resolution the companies are notified and could present extra information that could change the final proposal. This information is always evaluated. After the decision the company is notified by mail. If the decision is negative the company can appeal to the supreme administrative court.

Normally OTC products are not reimbursable, unless in exceptional circumstances which have to be justified on grounds of public health.

4.2 Reimbursement schemes

The National Health Service (NHS, Serviço Nacional de Saúde) was created with the principle of universal coverage and is the basis of the general reimbursement system. It covers almost the whole population.

The NHS reimbursement criteria are also applied by the health subsystem for civil servants. The other health subsystems adopt the NHS reimbursement criteria as reference but may have different lists and levels of reimbursement.

Since 1995 the prescriptions from private medical consultation have been also reimbursed by the NHS (Order No. 14/95, 22nd May).

There are special regimes of reimbursement that are defined on legal basis: an additional reimbursement level was created for pensioners with low incomes (cf. section 4.2.2); the reimbursement of pharmaceuticals used in defined pathologies or special groups of patients is subject to a special regime regulated in appropriately legal basis.

According to the legal basis the reimbursement procedure can take a maximum of 90 days, but this can be postponed if more information is required by INFARMED (the entity responsible for the reimbursement process).

4.2.1 Eligibility criteria

The Ministry of Health decides on the pharmaceutical`s reimbursement based on the proposal done by INFARMED.

In order to be eligible for reimbursement, pharmaceuticals must fulfil one of the following conditions (Decree-Law No. 129/2005, 11th August):

a) Innovative pharmaceuticals with no direct equivalent, demonstrating a higher level of efficacy or safety than alternatives;

b) New pharmaceuticals that demonstrate an economic advantage over existing pharmaceuticals of the same composition and pharmaceutical form, i.e. priced 5% less than the cheapest non-generic pharmaceutical;

c) Pharmaceuticals with a new pharmaceutical form, strength or pack size demonstrating a higher cost-benefit ratio with regard to existing similar pharmaceuticals;

d) New pharmaceuticals that do neither constitute significant therapeutic innovation nor possess identical qualitative composition with regard to the reimbursed pharmaceuticals if they present economic advantages with that used pharmaceuticals with same therapeutic purposes;

e) Fixed combination products made up of active ingredients already reimbursed as separate products with demonstrated therapeutic benefit and an equal or lower price compared to the ingredients administered separately;

f) Fixed combination products made up of active ingredients that do not exist as separate products on the market and that demonstrate a therapeutic benefit.

Thus, reimbursement eligibility in Portugal is a product-specific one.

4.2.2 Reimbursement categories and reimbursement rates

The legal basis of the reimbursement categories is the Decree No. 1474/2004, issued on 21st December (Ministry of Health). The pharmacotherapeutic groups and subgroups included in each reimbursement category are pre-defined in this legislation. This classification is not linked to the price, even though the final decision depends on the result of the evaluation of the application.

The reimbursement categories and the reimbursement rates in Portugal are listed in Table 4.1.

Table 4.1: Portugal – Reimbursement of pharmaceuticals, 2008

Reimbursement category	Reimbursement rate	Characteristic of category
Category A	95%	Essential pharmaceuticals to treat chronic diseases or life-saving pharmaceuticals (100%), such as cancer and diabetes
Category B	69%	Essential pharmaceuticals of therapeutic value for the treatment of serious illnesses (such as anti-asthmatic, cardiovascular pharmaceuticals)
Category C	37%	Not priority pharmaceuticals, with proven therapeutic value (such as anti-infectives, vaccines not included in the National Vaccination Plan, immunoglobins, anti-parasitics)
Category D	15%	New pharmaceuticals whose therapeutic value is not yet proven. It is a transitional category (created in 2000).

Source: INFARMED

The co-payment level depends on the level of essentiality to life maintenance, level of disease (chronic and/or serious disease) and economic and social situation of consumers.

Currently there are 4 reimbursement categories (A, B, C, D) based on therapeutic classification. Category D (15% - initially it was 20%) was created in 2000 (Decree-Law No. 205/2000, 1st

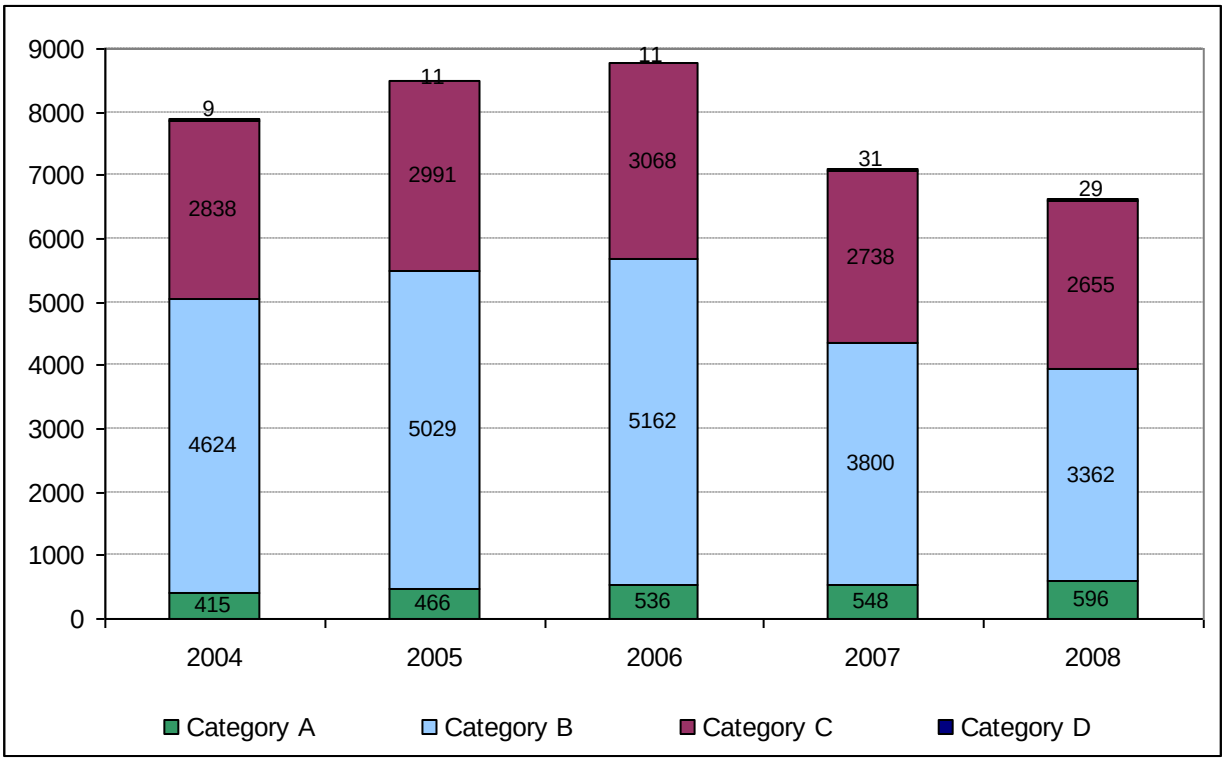
September) with a transitory character (no more than 2 years), for pharmaceuticals whose therapeutic value is not yet proven, and to facilitate the entry of new pharmaceuticals on the market.

The pharmaceuticals included in Category A that are considered essential to life maintenance (insulins and immunomodulators) have a reimbursement rate of 100% (Order No. 19650-A/2005, 1st September). INFARMED is responsible for publishing the updated list of these pharmaceuticals on its webpage. The other pharmaceuticals included in Category A have a reimbursement rate of 95%.

A pensioner whose income is below the national minimum wage (the so called special regime) has an extra 5% reimbursement to the rate of category A and an extra 15% reimbursement to the rates of categories B, C and D (Decree-Law No. 129/2005, 11th August).

In 2000 there was an additional reimbursement of 10% for generics (Decree-Law No. 205/2000, 1st September), with the aim of promoting the generics market, but this additional reimbursement was withdrawn in September 2005 (Decree-Law No. 129/2005, 11th August).

Figure 4.1: Portugal – Development of pharmaceuticals in reimbursement, 2004–2008[1]



[1] as of 1 January, and counted including different pharmaceutical forms, strength and pack sizes

Source: INFARMED

The reimbursement of pharmaceuticals used in defined pathologies or special groups of patients (Decree-Law No. 205/2000, 1st September) is subject to a special regime regulated in a legislation of its own. Examples: reimbursed pharmaceuticals for haemophilia or for Alzheimer disease.

4.2.3 Reimbursement lists

In Portugal there is a positive list of pharmaceuticals used in the outpatient sector. Listed pharmaceuticals are reimbursed at a certain rate by the National Health Service. The list is updated on a monthly basis by INFARMED. The monthly list of reimbursed pharmaceuticals is public available on the website of INFARMED (www.infarmed.pt) and is also published by the Ministry of Health in the official journal (Diário da República). The medicines´ database which is accessible for the general public is also monthly updated. It is made available in database format for related entities (e.g. associations of pharmacies, insurance companies, subsystems, etc).

Economic evaluation is required for reimbursement decisions (cf. section 5.4).

INFARMED, within a period of 3 years after inclusion into reimbursement, should undertake the re-assessment of pharmaceuticals with regard to the reimbursement status (Decree-Law No. 129/2005, 11th August).

Criteria to delist pharmaceuticals include, among others, the following ones: excessive prices; lower therapeutic efficacy proven by a pharmaco-epidemiologic study; the reclassification for OTC status without reasons of public health that justify its reimbursement.

For hospital-only medicines the reimbursement system in place is different (cf. section 4.5).

4.3 Reference price system

The Reference Price System (RPS) was introduced in 2002 (Decree-Law No. 270/2002, 2nd December) with the first list published in 13 March 2003.

In the first year the reference groups (homogenous groups) and the reference prices were reviewed after a year but later they were revised more frequently. The list is currently reviewed 4 times a year (1st January, 1st April, 1st July and 1st October) by INFARMED and published on its website. The reference prices are approved by the Ministry of Health and the Ministry of Economy and Innovation, and are published on the official journal.

The RPS is only applied to pharmaceuticals with generic alternatives included in reimbursement. Pharmaceuticals are clustered in what is called a homogeneous group (covering pharmaceuticals with the same active substance, pharmaceutical form, strength and route of administration), that includes at least one generic on the market. The basic mechanism is still the same as of the time the reference price system entered into force.

The reimbursement of NHS is based on the Reference Price (the highest unitary retail price of all marketed generics in each homogeneous group). The patient pays the difference between Pharmacy Retail Price and Reference Price.

The Reference Price for pensioners whose income is below the national minimum wage has an additional increment of 20% (since the 3rd quarter of 2006). Initially this increment was 25%.

Since 2002 doctors have been obliged to prescribe by INN (International Non-proprietary Names) for pharmaceuticals that have generics approved (Decree-Law No. 271/2002, 2nd December). Generic substitution is allowed but doctors can exclude it on the prescription (cf. section 5.5.1).

In July 2008, 4,239 pharmaceuticals (counted including different pharmaceutical forms, strength and pack sizes) were included in the Portuguese RPS, clustered in 543 homogeneous groups which comprise 135 active substances.

The aim of the Reference Prices was to eliminate price gaps between similar reimbursed pharmaceuticals and to control pharmaceutical expenditure by defining a fixed amount to be paid by the NHS.

In Portugal the implementation of the RPS helped to promote the generics market and to reduce the NHS pharmaceutical expenditures. The RPS should be further investigated - regarding the cost-containment impact (possibility for savings, sustainability and drug innovation) but also regarding the clinical outcomes impact (the health status of patients) and equity issues.

There are several limitations related to this system:

- the savings to patients are limited to the generics market share and to the generic substitution (depending on doctors prescribing or generics authorising substitution on the prescription form);
- the savings could be only generated for a short term because pharmaceutical companies adapt their strategy (pricing around the reference price or by marketing new active substances with no generics approved);
- the reference price corresponds to the highest generic price on the market;
- generics that are not really available on the market although they contributed to the creation of clusters (this affects the functioning of the system and results in an additional expense for patients). In these cases, when the company notifies INFARMED about the initiate commercialization date, but does not accomplish it, INFARMED may apply fines.

4.4 Private pharmaceutical expenses

In Portugal private pharmaceutical expenditure is subdivided into out-of pocket payments which include percentage co-payment of reimbursed pharmaceuticals and expenses for self-medication, which include the non-reimbursed and OTC pharmaceuticals.

Over the years, there were some changes in the pharmaceutical reimbursement system and in co-payment policies, trying to promote a more rational consumption of pharmaceuticals and encouraging the responsibility of the consumers. One of these measures was the introduction of the Reference Price System: if the patient opts to buy the most expensive medicine (instead the generic) he/she has to pay the difference between the prices.

4.4.1 Direct payments

Patients are faced with direct payments in case of self-medication and non-reimbursed pharmaceuticals, e.g. nicotine replacement pharmaceuticals or pharmaceuticals used to increase the sexual drive.

4.4.2 Out-of pocket payments

For all reimbursed pharmaceuticals used in the outpatients sector the patient has to co-pay. The co-payment rate corresponds to the difference between the rate of reimbursement and 100%.

In addition, for pharmaceuticals included in the Reference Price System, patients have to pay the difference between the reference price and the pharmacy retail price (if higher than the reference price).

Table 4.2: Portugal – Reimbursement rates and patient co-payment rates, 2008

Reimbursement Categories	Co-payment rate in %	Reimbursement rate in %
General Regime:		
Category A	5%	95%
Category A [1]	0%	100%
Category B	31%	69%
Category C	63%	37%
Category D	85%	15%
Special Regime: pensioners with income below the national minimum wage		
Category A	0%	95% + 5%
Category A[1]	0%	100%
Category B	16%	69% + 15%
Category C	48%	37% + 15%
Category D	70%	15% + 15%

[1] Essential life-maintaining pharmaceuticals: insulins and immunomodulators

Source: INFARMED

4.4.2.1 Fixed co-payments

Fixed co-payments, like prescriptions fees, do not exist in Portugal.

4.4.2.2 Percentage co-payments

In Portugal patients have to pay a percentage co-payment in the outpatient sector for reimbursed pharmaceuticals (cf. Table 4.2).

4.4.2.3 Deductibles

Deductibles are not applicable.

4.5 Reimbursement in the hospital sector

In the outpatient sector the patients pay a percentage co-payment for pharmaceuticals. In the inpatient sector the reimbursement process is different. Inpatients are not charged for the pharmaceuticals they consume. The NHS pays for all expenditure of inpatient pharmaceuticals consumed in public hospitals, through the General State Budget.

In 2007, legislation introduced the requirement for the reimbursement evaluation for new pharmaceuticals for intramural/hospital use for the first time (Decree-Law No. 195/2006, 3rd October), based on its therapeutic as well as the economic effectiveness.

4.6 Reimbursement related cost-containment measures

In recent years there have been some changes in the reimbursement system related to cost-containment measures (e.g. reductions in the NHS reimbursement rates, cf. section 4.6.3).

4.6.1 Major changes in reimbursement lists

The major change was in 2007 with a legislation introduced the requirement for reimbursement evaluation for new hospital-only medicines.

4.6.2 Introduction / review of reference price system

The basic mechanism is still the same as of the time when the reference price system entered into force. Currently INFARMED is evaluating this process, with the aim of reviewing the method of grouping pharmaceuticals into clusters (homogeneous groups).

4.6.3 Introduction of new / other out-of pocket payments

In 2005 the increased reimbursement rates of 10% for generics (introduced in 2000) was abolished. So patient co-payment increased. In 2005, for outpatient pharmaceuticals, the Category A reimbursement rate decreased from 100% to 95%.

In 2007, the other categories of reimbursement rates had also decreased: Category B from 70% to 69%, Category C from 40% to 37% and Category D from 20% to 15%.

4.6.4 Claw-backs

Since 1997 the pharmaceutical industry (through the Portuguese Pharmaceutical Industry Association, APIFARMA) has regularly signed framework agreements with the Ministry of

Health, committing both parties to reforms, establishing limits of public pharmaceutical expenditure and industry re-payments in case of excess.

The latest agreement was signed in 2006 (Protocol No. 7/2006, 10th February) and is valid from 2006 to 2009. This Protocol limited the growth rates of pharmaceuticals in the outpatient sector to 0% in 2006 and the foreseen nominal growth rate in the GDP in 2007; and it also limited for the first time (plus a special arrangement) the growth rates of pharmaceuticals in the hospital sector to 4% in 2006. According to the Protocol, the goals of the limits for 2008 and 2009 will be set in mutual agreement.

The legislation (Decree-Law No. 205/2000, 1st September) also includes the possibility to reimburse a specific pharmaceutical on the basis of an agreement between INFARMED (Portuguese Medicines Agency) and the company, if justified by public health and patients' interests. In this case, it is possible to set a maximum target of the pharmaceuticals' sales, and if this limit is exceeded the company has to pay back the difference to the NHS.

4.6.5 Reimbursement reviews

Within a period of 3 years after inclusion into reimbursement, INFARMED should undertake the re-assessment of pharmaceuticals with regard to the reimbursement status.

There are several criteria for delisting pharmaceuticals, including the excessive price of a pharmaceutical (cf. section 4.3).

Between 2000 and 2004, 353 International non-proprietary names (INN), corresponding to 536 brands underwent an evaluation, and as a result 381 have lost their reimbursement status due to lack of efficacy or unwillingness to prove absolute efficacy in comparison to placebo.

5 Rational use of pharmaceuticals

5.1 Impact of pharmaceutical budgets

In Portugal there are no pharmaceutical budgets being applied for doctors, which means there is no fixed monetary prescribing budgets for health care professionals.

Presently the prescription volume or prescription habits are not regularly monitored by the Portuguese Medicines Agency (INFARMED). There are few specific studies, in which the prescribing habits of doctors are evaluated for determined issues (e.g. general practitioners prescriptions of antibiotics) or policies adopted (e.g. monitoring the doctor's prescription by INN).

At regional level the prescription habits are monitored by the Regional Health Authorities (RHAs), this is done at Health Care Centres level.

Doctors have the obligation to prescribe by INN in case of pharmaceuticals that have generics approved (Decree-Law No. 271/2002, 2nd December). They have the responsibility to inform the patient about the existence of generics and their prices, but they may not allow the patient to choose a specific pharmaceutical, like a generic one (they may refuse generic substitution on the prescription).

5.2 Prescription guidelines

There are no obligatory prescription guidelines in Portugal. There are some guidelines but they are not mandatory, they are considered more as a useful tool to facilitate appropriate prescribing.

Since 2000 INFARMED has published a National Prescribing Formulary, which describes the benefits and side-effects of more than 4,000 POM, as well as indicating the price and reimbursement status. This formulary is an attempt to promote rational prescription, giving helpful information for prescribing to the health professionals, concerning the available pharmaceuticals in the outpatient sector.

INFARMED also publishes a National Hospital Pharmaceutical Formulary, which is an orientation document that supports wide range of pharmaceuticals with very different prices, but it is not obligatory prescription guidance.

In addition there are some doctors´ societies of specific specialities that publish treatment guidelines, which help doctors in choosing the appropriate pharmaceutical for prescription.

The General Directorate of Health also publishes informative documents that may include some guidelines.

5.3 Information to patients / doctors

Advertising of pharmaceuticals is regulated by law (Decree-Law no. 176/2006, 30th of August) in line with European Commission legislation. INFARMED is the institution responsible for supervising pharmaceutical advertising activities.

In Portugal direct advertising to public is not allowed for prescription-only-medicines (POM), for reimbursed pharmaceuticals and for pharmaceuticals with stupefacient and psychotropic substances. The exceptions are related to: vaccination campaigns and generic campaigns done by the industry, under the condition that they are approved by INFARMED. Direct distribution of pharmaceuticals from the industry to the public is also forbidden.

The advertising of POM can only be announced in technical publications or information supports, designed and accessible exclusively for doctors and other health professionals.

Direct advertising to the public is allowed for over-the-counter (OTC) pharmaceuticals. The advertisement should contain correct information about the pharmaceutical and promote the appropriate use (without extend the real properties) of the pharmaceuticals, and the information needs to be reliable.

The companies are responsible to keep complete registers of all advertising carried out by the company and to keep them available during a minimum period of five years so that they can be inspected by the national regulator entity (INFARMED). They are also responsible to assure that their representatives, who visit the doctors to promote their pharmaceuticals, have appropriate and up-to-date qualifications. The activities of the representatives of pharmaceutical companies are also regulated and restricted. The companies have to register their representatives at the site of INFARMED.

There are restrictions concerning the offers, bonus or any pecuniary benefits, from the industry to the health professionals, unless the objects are of insignificant value or are relevant to the medicine or pharmacy practice.

A National Advice of Medicine Advertising (Conselho Nacional de Publicidade de Medicamentos, CNPM) under the supervision of INFARMED was created. Experts are nominated by the Ministry of Health. They should be qualified to advise in the domain of the advertising of human use pharmaceuticals.

Patients have access to information on authorised and reimbursed pharmaceuticals (printed version publications and online data) through INFARMED. Publications such as the “Pharmaceuticals Generics Guide” and the “Reference Price System Guide” contribute to a more rational use of pharmaceuticals (cf. section 2.1.3.6). There have been also several campaigns concerning the use of generics (television, radio, billboards, Internet) to inform patients about these pharmaceuticals.

5.4 Pharmaco-economics

Since 1998 pharmaco-economic evaluations have played an important role in the assessment of reimbursement applications in Portugal.

The Portuguese Medicines Agency (INFARMED) has a unit of Economic Evaluation and Health Results which deals with health economic issues and is responsible for the reimbursement process.

When submitting a reimbursement application companies have to send to INFARMED evidence based information that proves the therapeutic added value (ATV) related to the alternatives already reimbursed (pharmacotherapeutic and pharmacoeconomic information). They also propose a price for reimbursement.

After the pharmacotherapeutic evaluation the application is analysed by economists in order to demonstrate economic advantage. If the product does not demonstrate an ATV compared to the alternative, the economic evaluation is only based on the comparison of prices (the product under evaluation should present a lower daily price than the alternative).

In case of a pharmaceutical demonstrating an ATV or in case of a totally new product without alternatives, the economic advantage should be demonstrated by an economic evaluation study supplied by the manufacturers. INFARMED then assesses pharmaco-economic evaluations. The result of economic evaluation is an economic report. When needed companies are asked by INFARMED to provide clarifications on doubts related to the economic evaluation study.

In 1998 INFARMED developed and published the Methodological Guidelines for Economic Evaluation Studies (Orientações Metodológicas para estudos de Avaliação Económica de Medicamentos), to help companies in performing studies. These guidelines explain how to conduct and present a study. They were drawn up by an expert working group at the request of INFARMED.

In 2007 pharmaco-economic criteria were also introduced for the hospital-only medicines. Reimbursement legislation requires the reimbursement evaluation for new pharmaceuticals for inpatient use, based on their therapeutic as well as the economic effectiveness.

5.5 Generics

The share of generics in Portugal had an enormous increase over the years. While in 2000 the generic market share was less than 1% of the total number of prescribed packages, in 2007 this market share amounted to 14.86%. In terms of value, at the reimbursement market, the generics market shares are slightly higher, reaching 19.50% in 2007 (expenditure at retail price).

This market share relation between volume-value is opposite to the one observed in other European countries. The increase in generics market share in Portugal might thus be a result of expensive substances or the utilization of higher packages.

Table 5.1 and Figure 5.1 give an overview of the development of the Portuguese market share of generics, in volume (number of packages) and value (expenditure at pharmacy retail price level), at the National Health Service market (reimbursement)

Table 5.1: Portugal – Development of the generic market in the NHS outpatient sector, 2000–2007

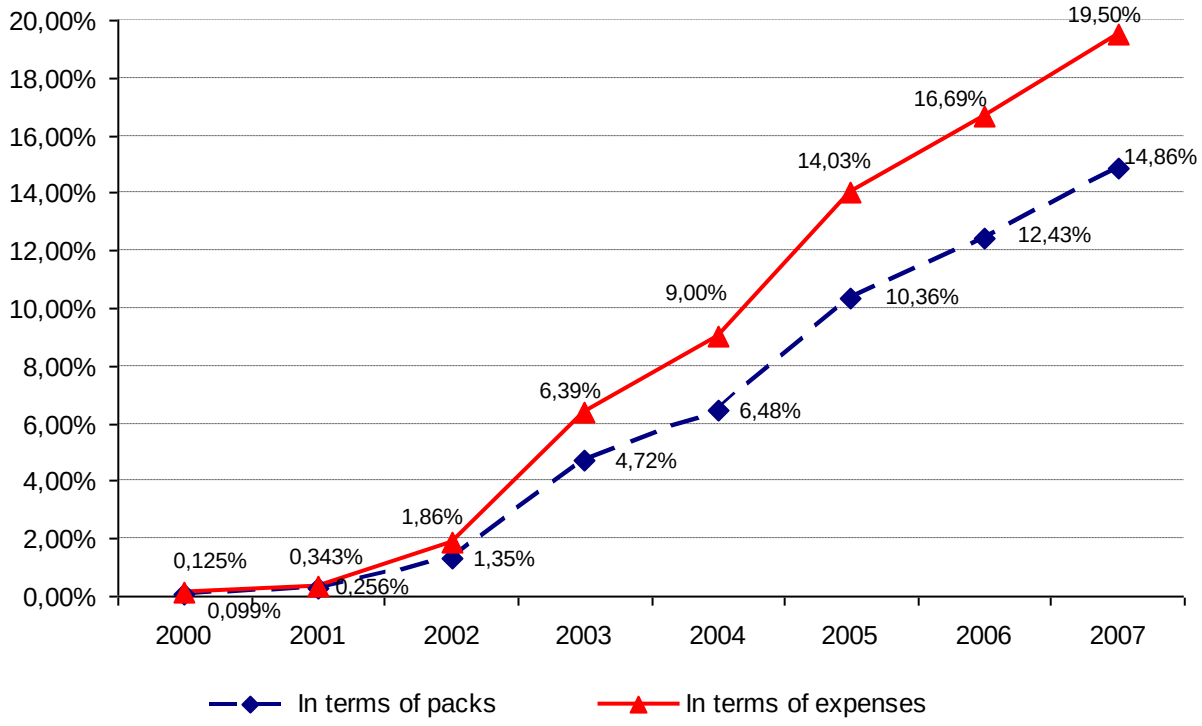
Generic market share	2000	2001	2002	2003	2004	2005	2006	2007
Share of number of generic prescriptions as number of total prescriptions (a)	0.099%	0.256%	1.35%	4.72%	6.48%	10.36%	12.43%	14.86%
Share of expenditure for generics as percentage of total pharmaceutical ex-penditure (b)	0.110%	0.344%	1.86%	6.39%	9.00%	14.03%	16.69%	19.50%

(a) % of generics in the NHS market (no. of packages)

(b) % of generics in the NHS market (expenditure at pharmacy retail price)

Source: INFARMED Medicines Statistic Yearbook 2007

Figure 5.1: Portugal – Development of the generic market in the NHS outpatient sector, 2000–2007



Source: INFARMED Medicines Statistic Yearbook 2007

The generic market shares in the total pharmaceutical market (and not only in the NHS segment) represent the same growing evolution but with lower annual percentages.

The analyses of the generics market is frequently evaluated by the Portuguese Medicines Agency (INFARMED) and is available on its website through monthly reports.

It is difficult to specify which policy had the strongest impact on the development of generics market because they were numerous and mixed. There were three major measures with significant impact on generics market share: the implementation of several information campaigns, the procedures simplification and the introduction of an additional 10% reimbursement level on generics.

The pricing of generics is explained in section 3.4.2.

5.5.1 Generic substitution

In Portugal generic substitution was introduced in September 2000. Pharmacists were obliged to dispense the cheapest generic, unless the doctor explicitly states the dispensing of another pharmaceutical, in particular the original products, on the prescription form (Decree-Law No. 271/2002, 2nd December).

Physicians and pharmacists have the responsibility to inform the patient about the existence of generics and their prices, but which pharmaceutical the patient gets depends if the doctor authorises or excludes generic substitution.

In 2002 the obligation to prescribe by International Non-proprietary Name (INN) for pharmaceuticals that have generics approved was approved (Decree-Law No. 271/2002, 2nd December). A new prescription form was also introduced giving the doctors the choice to authorise or not authorise the generic substitution:

- If the doctor prescribes generically (by INN only) and does not tick any of the boxes, then the pharmacists are allowed to dispense any generic medicine with that active ingredient, strength and pharmaceutical form;

- If the doctor prescribes by the brand name (by INN plus brand name) and ticks the box prohibiting substitution, then the pharmacists are not allowed to substitute;

- If the doctor prescribes by the brand name (by INN plus brand name) and ticks the box allowing substitution or does not tick the box to prohibit substitution, then the pharmacists are allowed to substitute for generic medicine;

There are no incentives to pharmaceuticals for generics substitution. Moreover pharmacists earn a fixed percentage mark up, so they benefit from dispensing expensive pharmaceuticals.

5.5.2 Generic prescription

As already mentioned (cf. section 5.5.1) since 2002 doctors have had the obligation to prescribe by INN for pharmaceuticals that have generics approved (Decree-Law No. 271/2002, 2nd December). However they may add the brand name or the company name and thus exclude the generic substitution.

Doctors have neither financial incentives nor budgets for pharmaceutical prescription and there is few monitoring of their prescription practice.

5.5.3 Generic promotion

In the last few years there were several actions in Portugal trying to increase the level of knowledge about generics. These were not only targeted to the general public but also to the health professionals involved in the prescription and dispense action of these pharmaceuticals.

Since 2000 several information campaigns were made to promote generics trough television, radio, billboards and Internet. Different information leaflets were distributed to hospitals, health care centres and pharmacies.

Initially the Portuguese Medicines Agency (INFARMED) carried several information campaigns to the doctors at regional level, to be precise in the health care centres, hospitals and Regional Health Authorities. These information sessions were made by specific technicians with qualifications and the necessary professional formation, concerning the quality of generics and their role in the control of pharmaceutical expenditure.

INFARMED periodically publishes the “Pharmaceuticals Generics Guide” that contains information concerning prices and reimbursement levels of all available generics on the market. This Guide is available quarterly in printed version and monthly in online version. Since 2007 it has also been available through Personal Digital Agenda.

Others policies (already referred) had also contributed to the generics promotion, such as: the additional 10% generics reimbursement level in 2000; the introduction of the reference price system in 2002, the obligation to prescribe by INN and the obligation for pharmacists to dispense the least expensive generic authorised; the incentives to convert “copies” to generics; the simplification of the reimbursement process in 2006; and the price revision in 2007 (the generic price changed from a difference of 35% to 20% related to the original price for new generics where the originals have the maximum ex-factory price of 10 Euros in all packages).

The promotion of generics is an important issue to ensure access of patients to a greater variety of pharmaceuticals, to enhance local generic manufacturers and to contain costs.

More information is available at INFARMED website: www.infarmed.pt/genericos.

5.6 Consumption monitoring

The consumption of pharmaceuticals in Portugal is regularly monitored by INFARMED, through the Medicine and Health Products Observatory. INFARMED publishes on its website monthly reports about the consumption and expenditure development of pharmaceuticals in the reimbursable, generics, OTC pharmaceuticals (outside the pharmacies), and public hospitals market (cf. section 2.5).

Occasionally INFARMED also publishes development studies concerning the evaluation of a specific pharmacotherapeutic group, the prescription habits of doctors or the adopted government policies.

6 Current challenges and future developments

6.1 Latest changes

The most important changes regarding the pharmaceutical system since 2005 are summarised in Table 6.1.

Table 6.1: Portugal – Changes in the pharmaceutical system, 2005–2008

Year	Pricing	Reimbursement	Not attributable to Pricing or Reimbursement
2005	General price reduction (6%) for reimbursed pharmaceuticals	Reduction (5%) in the higher reimbursement rate (100% → 95%)	
		Ending of the increment of 10% in generics reimbursement level	
	Liberalisation of OTC prices and mark ups		OTC pharmaceuticals sell outside pharmacies, in authorised establishments
2006		Use of electronic communication for reimbursement applications	
2007	General price reduction (6%) for reimbursed pharmaceuticals	Reduction in reimbursement rates	
	New methodology of price formation		
	Price revision with new methodology, for authorised price		
		Beginning of reimbursement evaluation for new hospitals pharmaceuticals	
			Pharmacies allowed to dispense pharmaceuticals through the internet and home deliveries
2008	Price reduction (30%) for generics	-	-

Source: INFARMED

6.2 Current challenges

In Portugal one of the main challenges facing the pharmaceutical system is, as in many other countries, the rising pharmaceutical expenditure in outpatient and inpatient sectors. The major reasons for the growing expenditures are an ageing population, the increase of patients with chronic diseases and the uptake of new and more expensive pharmaceuticals.

Several measures have been implemented in Portugal over the years aiming to ensure, the access to an effective, safe and high quality therapy, with rationality and equity, and trying to be financially sustainable for the growth of public expenditure on pharmaceuticals.

Therefore, the government has implemented quite a few policies and campaigns to promote the generics market, to reduce the prices of pharmaceuticals and adopted legislation in 2007 that requires the reimbursement evaluation for new pharmaceuticals for inpatient use, based on its therapeutic as well as the economic effectiveness, like what happened before in the outpatient sector.

6.3 Future developments

Like it was mentioned before future developments have to face cost-containment problems, especially in the light of affordability and access to pharmaceuticals.

Consequently measures to promote the rational and sustainable use of pharmaceuticals are desirable, but it is not possible yet to report future plans. This can represent several policy measures, including the continuation of generics market promotion, the approval of price cuts of reimbursed pharmaceuticals, the promotion of prescription guidelines or reviewing the methods used for determining therapeutic added value.

7 Appendixes

7.1 References

APIFARMA 2007
Pharmaceutical Industry in Figures 2007

Bentes, M; Dias, CM; Sakellarides, C; Bankauskaite, V. 2004
Health Care Systems in Transition: Portugal. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2004

Directorate-General of Health, Ministry of Health 2007
Health in Portugal 2007. Lisbon, July 2007

INFARMED 2008
Medicines Statistic Yearbook 2007. Lisbon

INFARMED 2008
Monthly Market Reports
http://www.infarmed.pt/portal/page/portal/INFARMED/MONITORIZACAO_DO_MERCADO/OBSERVATORIO/ANALISE_MENSAL_MERCADO

Ministry of Health 2005
Manual da Farmácia Hospitalar. Conselho Executivo da Farmácia Hospitalar, 2005

National Centre for Pharmacoeconomics 2005
European Pharmaceutical Pricing and Reimbursement Strategies. March 2005

ÖBIG 2006
Surveying, Assessing and Analyzing the Pharmaceutical Sector in the 25 EU Member States. Commissioned by European Commission - DG Competition

OECD 2007
OECD Health Data 2007. Organization for Economic Co-operation and Development

OPSS 2008
Relatório Primavera 2008 - Sistema de Saúde Português – Riscos e Incertezas. Coimbra

7.2 Further reading

EUROMEDSTAT 2004
The Library of European Union Pharmaceutical Indicators.
http://www.euromedstat.cnr.it/indicators/indicators_price.asp

Europe Economics 2005.
Study of Portuguese Medicines Reimbursement System and its adjustment to Health Reform http://www.infarmed.pt/pt/noticias_eventos/noticias/2005/nt_24_05_2005/relatorio_extras_en.pdf

Eurostat 2007
Eurostat Yearbook 2006-2007

7.3 Web links

National Authority of Medicines and Health Products, I.P. (INFARMED): www.infarmed.pt

Information on Portugal Laws and Enactments of pharmaceutical system may be accessed at: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO

Information on Portugal pharmaceutical statistics may be accessed at: http://www.infarmed.pt/portal/page/portal/INFARMED/PUBLICACOES/TEMATICOS/ESTATISTICA_MEDICAMENTO

Information on Portugal pharmaceutical consumption and expenditure studies: http://www.infarmed.pt/portal/page/portal/INFARMED/MONITORIZACAO_DO_MERCADO/OBSERVATORIO/ESTUDOS_REALIZADOS

Ministry of Health / Health Website: http://www.min-saude.pt/portal/

Directorate-General of Economic Activities: http://www.dgae.min-economia.pt/

Portuguese Pharmaceutical Industry Association: http://www.apifarma.pt/default.aspx

Pharmaceuticals Professional Organization: http://www.ordemfarmaceuticos.pt/scid/ofWebInst/

General Directorate of Health: http://www.dgs.pt/

High Commissioner for Health: http://www.acs.min-saude.pt/

Central Administration of Health System: http://www.acss.min-saude.pt/homepage

Institute Statistics Portugal: http://www.ine.pt/xportal/xmain?xpid=INE&xpgid=ine_main

Portuguese Health Economics Association: http://www.apes.pt/

World Health Organization: http://www.who.int/classifications/apps/icd/icd10online/

7.4 Detailed description of authors

Inês Teixeira is a health economist at the National Authority of Medicines and Health Products, I.P. (INFARMED) working in pharmaceutical utilization studies and economic impact evaluations on price and reimbursement systems; national representative in international projects “European Surveillance of Antimicrobial Consumption” and “Pharmaceutical Pricing and Reimbursement Information”; INFARMED´s representative in groups regarding National Programs of Diabetes and Antibiotics. She has a Master’s degree in Health Services Management, with a thesis on “Cardiovascular pharmaceuticals: the impact of recent policies in the use and expenditure of pharmaceuticals in Portugal“, and also specializations in Methodology Epidemiological and in Pharmaceuticals Economic Evaluation. She is co-author in articles published in scientific magazines, made several oral communications and poster presentations in national and international conferences in subjects of Health Economics.

Isaura Vieira is the Director of the Medicinal and Health Products Economics Department at the National Authority of Medicines and Health Products, I.P. (INFARMED), and is responsible for the coordination of activities related with pharmaceutical pricing and reimbursement, and monitoring economic data concerning pharmaceuticals consumption and impact estimation of political measures. She is a health economist in the field of pharmaceuticals, post-graduated in Medicines Economic Evaluation, also with specialization on Medicines Economic Evaluation (Evidence, Money & Drug Selection - OMS, University of Newcastle; Health Economics of Pharmaceuticals - Stockholm School of Economics). Currently she is starting her master’s thesis on European Pharmaceutical Industry Competition related with Innovation.