



Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2010

PORTUGAL

Commissioned by the European Commission, Executive Agency for Health and Consumers (EAHC) and the Austrian Federal Ministry of Health (BMG)

PHIS

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Executive Summary

In Portugal a hospital is considered a health establishment with both in- and out-patient care, and endowed with diagnostic and therapeutic resources, with the purpose of providing the population with treatment and rehabilitation medical assistance. It is also qualified for preventing disease, health care teaching and scientific research (INE, Statistics of Portugal). Hospitals are usually classified in accordance with type of care (general hospital or specialized hospital); geographic areas covered and services offered (central hospital, district hospital, district level-one hospitals and specialized hospitals) or ownership (*Public hospital* or *Private hospital*).

In this report only public hospitals included in the National Health Service are considered.

The National Health Service has an annual budget which is funded mainly through general taxation. The Central Administration of the Health System (ACSS) is the entity responsible for managing NHS providers funding, including hospitals.

In Portugal a mixture of more than one funding system is in place. Hospitals are financed prospectively through contracting of services (contract program) between ACSS, Regional Health Administrations and hospitals. According to these contracts hospitals commit to a certain level of activity (admissions, external consultations, emergency department episodes, etc), in return for an overall yearly budget. This funding is based on DRG system. The contract also includes special items like out-patient medicines dispensed exclusively in hospital pharmacies and subject to special legislation, and the new funding model concerning the HIV and Chronic Kidney Diseases (CKD).

Portuguese hospitals are also remunerated by own revenues via out-of pocket payments (OPP) charged to patients for admission charges. The health subsystems and private insurance schemes reimburse NHS hospitals retrospectively on a case-by-case basis for in-patient care and ambulatory surgery, according to a DRG price list (Barros and Simões, 2007).

In Portugal there is no explicit legal framework regarding pricing of medicines used in hospitals. In general, the hospital price corresponds to the maximum ex-factory price plus value added tax (VAT). Mark-ups are not relevant for public hospital pharmacies unless medicines are bought from a wholesaler or a community pharmacy.

Since January 2007, on approval by INFARMED, there has been a maximum price for HOM and restricted POM, considered appropriate according to the therapeutic added value and economic advantage compared to other medicines. If the Medicines Agency – INFARMED – decides positively, public hospitals are free to decide on the acquisition. If a medicine is not evaluated or not approved public hospitals cannot purchase it. The maximum price is settled – under supervision of Ministry of Health – by INFARMED and displayed on the INFARMED website. The new medicines introduced in public hospitals are also subject to budget control for (Decree-Law no. 195/2006, 3rd October).

In relation to medicines purchase, various scenarios are possible with a combination of centralised procurement by tendering and direct acquisitions and negotiations (by association of several hospitals or by each hospital individually).

Regarding reimbursement, the positive list used in the out-patient sector is not relevant for hospitals. However, there is a list of conditions for which medicines must be delivered in the hospital pharmacy and are fully reimbursed. The diseases and medicines under this reimbursement scheme are selected either due to the complexity/severity or the need to monitor the medicine intake. Medicines that are fully reimbursed and delivered to NHS users are funded separately in the contract program. Health Subsystems and voluntary private health-care insurance have to refund hospitals for the medicines dispensed.

Portugal has a National Hospital Pharmaceutical Formulary (NHPF) for several years (currently in its 9th edition), which is mandatory for all public hospitals. This NHPF was last updated in 2006 by a committee including experts from the Medicines Agency. If a medicine not included in the NHPF is needed for in-patient treatment, the Pharmaceutical and Therapeutic Committee (PTC) of a hospital will decide if this medicine should be included in the hospital-specific addendum to the NHPF. In fact, all public hospitals do have their own addendum in place supplementing the NHPF (PHIS Hospital Pharma Report 2010).

In 2007, a national hospital code was created to standardize the codification of medicines in hospitals and replace the different codes available in public hospitals (Decree No. 155/2007, 31st January). This measure allowed the implementation of a monitoring system of pharmaceutical consumption in hospitals.

It is now possible to monitor the public hospitals' pharmaceutical consumption. Monitoring can be done by different clinical areas (oncology, infection, internal medicine, etc) or services (external consultation, urgency, ambulatory surgery, etc). This monitoring is also possible by therapeutic classification, active substance or specific groups of medicines, such as orphan medicines.

Although most of hospitals can now link consumption to the individual patient that information is not yet available in the monitoring system at INFARMED.

In Portugal, interface management only exists in 6 Local Health Units (ULS). Additionally is also needed a closer cooperation between hospitals.

Table of content

Acknowledgements	III
Executive Summary.....	V
Table of content.....	1
Introduction	5
PHIS Hospital Pharma	6
Methodology of the general survey	6
1 Background	8
1.1 Definition and scope.....	8
1.2 Organisation.....	10
1.3 Funding	15
2 Pricing.....	19
2.1 Organization.....	19
2.1.1 Framework.....	19
2.1.2 Hospital prices	21
2.2 Pricing policies	22
2.2.1 Procurement	23
2.2.2 Others	23
3 Reimbursement.....	25
3.1 National hospital reimbursement procedure	25
3.2 Hospital pharmaceutical formularies.....	25
4 Consumption of medicines	28
5 Evaluation.....	30
5.1 Monitoring	30
5.2 Assessment.....	31
6 Interface management	33
7 Developments and outlook.....	34
8 References and data sources	35
8.1 Literature and documents	35

List of tables and figures

- Table 1.1: Portugal – Key data on in-patient care, 2000 and 2004–200911
- Table 1.2: Portugal – Medicines, 2000 and 2005–2010 12
- Table 1.3: Portugal – Health and pharmaceutical expenditure, 2000 and 2004–2009 18
- Table 4.1: Portugal – Pharmaceutical consumption in hospitals, 2000 and 2004-2009.....29
- Table 4.2: Portugal – Top 10 medicines by pharmaceutical expenditure and consumption in hospitals 2009.....29
- Figure 1.1: Portugal - flow-chart on the Portuguese delivery chain 13

List of abbreviations

Please add abbreviations used in your country and delete those you did not use!

ACSS	Administração Central do Sistema de Saúde / Central Administration of Health System
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
APFH	Associação Portuguesa de Farmácias Hospitalares / Portuguese Association of Hospital Pharmacists
BMG	Austrian Ministry of Health
CHNM	Código Hospitalar Nacional do Medicamento / National Hospital Code
CIVAS	Centralized Intravenous Admixtures Service
CKD	Chronic Kidney Disease
CMI	Case Mix Index
DGAE	Direcção- Geral das Actividades Económicas / Directorate-General of Economic Activities
DG SANCO	Health and Consumer protection Directorate General
DRG	Diagnosis-related group
EAHC	Executive Agency for Health and Consumers
E.P.E hospitals	Hospital subject to State entrepreneurial sector jurisdiction
EU	European Union
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HE	Health Expenditure
HIV	Human immunodeficiency virus
HOM	Hospital Only Medicines
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
IHHII	International Healthcare and Health Insurance Institute
INFARMED	Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. / National Authority of Medicines and Health Products, I.P.
IT	Information Technology

NCU	National Currency Unit
NHPF	National Hospital Pharmaceutical Formulary
NHS	National Health Service
Mio.	Million
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of pocket payments
OTC	Over-The-Counter medicines
PE	Pharmaceutical Expenditure
PHIS	Pharmaceutical Health Information System
POM	Prescription-Only Medicines
PPPs	Public-Private Partnerships
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PTC	Pharmaceutical and Therapeutic Committee
RHAs	Regional Health Administrations
SUCH	Serviço de Utilização Comum dos Hospitais / Common Use Service of Hospitals
S.P.A. hospitals	Hospital subject to public administrative sector jurisdiction
SPMS	Serviços Partilhados do Ministério da Saúde / Shared Services of the Ministry of Health
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
ULS	Local Health Units
VAT	Value Added Tax
WP	Work Package

Introduction

PHIS (Pharmaceutical Health Information System) is a research project commissioned under the call for proposals 2007 in the priority area “health information” of the European Commission, DG SANCO. It has been commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project aims at increasing knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union (EU) Member States, covering both the out-patient and the in-patient sector.

This will be done via different work packages (WP) resulting in the following deliverables:

- the PHIS Glossary with key terms related to pharmaceuticals,
- the PHIS Library offering country specific information on out-patient and in-patient pharmaceutical pricing and reimbursement for the EU Member States,
- the PHIS Indicators and the PHIS Database, containing major data for the developed indicators in the Member States,
- the PHIS Hospital Pharma Report with information on pharmaceutical policies in the in-patient sector in the EU Member States, including a price survey.

The PHIS project management is a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG), which is a research institute situated in Vienna, Austria, and four associated partners:

- the Italian Medicines Agency (AIFA),
- the International Healthcare and Health Insurance Institute (IHHII), Bulgaria,
- SOGETI Luxembourg SA., which is a services provider, and
- the State Institute for Drug Control (SUKL), Slovakia

SUKL is the WP leader of Hospital Pharma.

Further key stakeholders are the PHIS Advisory Board covering EU Commission services and agencies and other international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

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

PHIS Hospital Pharma

The aim of the work package “Hospital Pharma” is an in-depth investigation of the in-patient sector, as systematic knowledge of pharmaceutical policies in this sector has been rather poor.

The survey is divided in two phases:

- Phase 1: General survey

Country reports on pharmaceuticals in hospitals (“PHIS Hospital Pharma Reports”), designed to describe specific pharmaceutical policies in the in-patient sector in the EU Member States (spring 2009)

- Phase 2: Case studies

A specific survey, including a price survey, provided by means of case studies, in a limited number of hospitals in a few countries (autumn 2009).

The final PHIS Hospital Report, covering information from the general survey (phase 1) and the case studies (phase 2), is scheduled for February 2010.

Methodology of the general survey

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

1. Development of a uniform PHIS Hospital Pharma Report Template

The PHIS Hospital Pharma Report Template offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in-patient sector of a country. The Template was developed by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader) and further members of the PHIS project management. It is based on literature and internet reviews as well as interviews with experts in the hospital sector in the EU Member States. Members of the PHIS network received the draft Template for feed-back, and had an opportunity to discuss and provide personal feed-back during a meeting.

2. Collecting information and data and drafting the PHIS Hospital Pharma Report

The country-specific PHIS Hospital Pharma Reports were written by members of the PHIS network. In order to get the needed information and data, hospital experts were contacted and involved in several countries. They provided information and data in written form and during telephone conversations and personal talks. In some countries the reports (or parts of it) were written by hospital experts. In several countries, the preparatory work for drafting the PHIS Hospital Pharma Reports also included study visits of the authors to hospitals and hospital pharmacies. Information on persons and institutions involved can be found in the

“Acknowledgements” at the beginning of this PHIS Hospital Pharma Report and in section 8 “References and data sources”, listing “Literature and documents” (section 8.1) and “Contacts” (section 8.2).

3. Editorial process

The draft PHIS Hospital Pharma Reports were submitted to the project management for review, which was undertaken by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template and terminology (PHIS Glossary). In the course of the editorial process, the reviewers contacted the authors for providing feed-back on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

1 Background

1.1 Definition and scope

In Portugal a hospital is considered a health establishment with both in- and out-patient care, and endowed with diagnostic and therapeutic resources, with the purpose of providing the population with treatment and rehabilitation medical assistance. It is also qualified for preventing disease, health care teaching and scientific research¹ (INE, Statistics of Portugal).

This definition is very close to OECD definition², as it considers both in-patient and out-patient care and excludes nursery homes.

In Portugal, the subtypes of hospitals defined by OECD³ are also relevant, and are usually classified⁴ in accordance with:

1) Type of care:

- *general hospital* (a hospital that provides care in several medical fields):
- *specialized hospital* (a hospital in which the majority of beds are reserved for a specific medical field or which simply provides assistance to or specializes in patients of a specific age group). Mental health and substance abuse hospitals are considered as specialized hospitals.

¹ According to the approved definition by High Statistical Council INE, Statistics Portugal, *INE concepts and definitions database*

² OECD definition of a hospital: „This item comprises licensed establishments primarily engaged in providing medical, diagnostic, and treatment services that include physician, nursing, and other health services to in-patients and the specialised accommodation services required by in-patients. Hospitals may also provide out-patient services as a secondary activity. Hospitals provide in-patient health services, many of which can only be provided using the specialised facilities and equipment that form a significant and integral part of the production process. In some countries, health facilities need in addition a minimum size (such as number of beds) in order to be registered as a hospital.” Please be aware that nursing homes, which primarily provide long term care services particularly for the elderly, would not normally be considered as “hospital” of the purpose of this PHIS Hospital Pharma Report Template.

³ a. general hospitals, b. mental health and substance abuse hospitals, c. speciality (other than mental health and substance abuse) hospitals; for a definition see the Glossary

⁴ <http://portalcodgdh.min-saude.pt/index.php/Hospitais>

2) Geographic areas covered and services offered:

- *central hospital (a public hospital characterized by possessing highly specialized human and technical resources, with national or inter-regional scope);*
- *district hospital (a public hospital characterized by possessing resources equivalent to the basic medical fields, though it may have, when necessary, intermediate, specialized and, in exceptional circumstances, highly specialized care. It covers the district in which it is located);*
- *district level-one hospitals (district hospital with limited in-patient facilities, providing the most basic specialties: Internal Medicine, General Surgery, Obstetrics/Gynecology, Pediatrics. Exceptionally, there may be cases where Orthopedics is included);*

3) Ownership:

- *Official hospital (hospital under the administrative supervision of the State, regardless of the ownership of the facilities). It can be under the supervision of the Ministry of Health or Regional Departments of Health - *public hospital*; under the supervision of the Ministry of Defense - *military hospital*; under the supervision of the Ministry of Internal Affairs - *paramilitary ; hospital* or under the supervision of the Ministry of Justice -*prison hospital*.*
- *Private hospital (a hospital owned and managed by a private institution, whether a profit or non-profit entity).*

NHS hospitals can also be classified according to their *juridical status* in:

- S.P.A. Hospitals – hospital subject to public administrative sector jurisdiction
- E.P.E Hospitals - hospital subject to State entrepreneurial sector jurisdiction

This Hospital Pharma Report will not cover the information from private hospitals due to the lack of information on this area.

1.2 Organisation

The Portuguese Health system is a mix of public and private care delivery and financing. In the public sector, health care is assured by the National Health Service (NHS) which is mainly financed by general taxation. The Ministry of Health receives a global budget for the NHS, which is then allocated to Regional Health Administrations (RHAs) and public hospitals.

Hospital budgets are established and allocated by the Ministry of Health through the Central Administration of the Health System (ACSS), which is also in charge of the management of financial and human resources, facilities and equipment, systems and information technology of the NHS. ACSS is also responsible for the definition of policy, regulation and planning of health, along with the RHAs, namely in the area of health service contracting.

In the last decade hospitals have been undergoing several structural reforms. In 2003, 40% of the public hospitals received an entrepreneurial-like statute “E.P.E Hospitals” (public enterprise), with a change in management rules and financial responsibility. The hospitals that did not go through this transformation process continued to be managed by civil service rules, and are known as “S.P.A Hospitals” (Barros and Simões, 2007).

At the same time some hospitals belonging to the same Health Administrative Region have been merged in hospital centers in order to improve health care delivery efficiency.

Another structural measure was the creation of Local Health Units (ULS), which integrate primary and secondary care and are responsible for the delivery of health care in a specified geographical area. In 2010 there were 6 ULS implemented (ULS Baixo Alentejo, ULS Norte Alentejo, ULS da Guarda, ULS de Matosinhos, ULS do Alto Minho and ULS Castelo Branco).

Public-Private partnerships (PPPs) were established to build, maintain and operate new hospitals (Decree-Law n.º 185/2002). In 2010 two hospitals were operating in this scheme (Hospital of Cascais and Hospital of Braga).

Table 1.1: Portugal – Key data on in-patient care, 2000 and 2004–2009¹

In-patient care	2000	2004	2005	2006	2007	2008	2009
No. of hospitals²	219	209	204	200	198	189	186
<i>Classified according to ownership³</i>							
- thereof public hospitals	114	105	100	96	88	81	n.a.
- thereof private hospitals	94	93	93	93	99	97	100
- thereof other hospitals	11	11	11	11	11	11	n.a.
<i>Classified according to subtypes³</i>							
- thereof general hospitals	153	148	144	141	140	139	n.a.
- thereof mental health and substance abuse hospitals	43	41	41	42	42	36	n.a.
- thereof speciality (other than mental health and substance abuse) hospitals	23	20	19	17	16	14	n.a.
No. of acute care beds⁴	33,208	32,400	31,489	30,759	30,209	n.a.	n.a.
- thereof in the public sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof in the private sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Average length of stay in hospitals⁴	9.2	8.6	8.7	8.6	8.5	n.a.	n.a.
No. of hospital pharmacies⁵	114	105	100	96	88	81	n.a.
thereof no. of hospital pharmacies that serve out-patients ⁶	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 31 December

² according to OECD definition and its subtypes

³ Source: INE, Statistics Portugal, Hospitals survey

⁴ Source: OECD HEALTH DATA 2009, June 09

⁵ Only public hospitals; all public hospitals have their own hospital pharmacy, sometimes one hospital pharmacy provides medicines to more institutions in one owner organization (hospital centre)

⁶ Not applicable because hospital pharmacies are not allowed to serve out-patients in normal circumstances

The number of public hospitals decreased in the last years probably due to the assemblage of different hospital, operating in nearby areas, in hospital centers. At the same time it is noticeable that the number of private hospitals has increased.

The number of acute care beds decreased from 33,208 beds in 2000 to 30,209 beds in 2007 as well as the average length of stay in hospitals decreased from 9.2 days in 2000 to 8.5 days in 2007.

Medicines

Table 1.2: Portugal – Medicines, 2000 and 2005–2010¹

Number of medicines	2000	2005	2006	2007	2008	2009	2010
Authorised medicines in total	17,791	33,998	36,432	38,481	41,659	44,192	50,118
- thereof hospital-only medicines	n.a.	1,381	1,624	1,820	1,995	2,404	3,314

n.a. = not available

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

Source: INFARMED, Medicines Statistic Yearbook 2009

In Portugal, medicines for exclusive use in hospital are classified as hospital-only medicines (HOM). However, besides HOM a greater variety of medicines may be used in hospitals, a fact which has an impact on the out-patient sector as the in-patient treatment influences the choice of medicines used in the consecutive out-patient treatment (PHIS Hospital Pharma Report 2010).

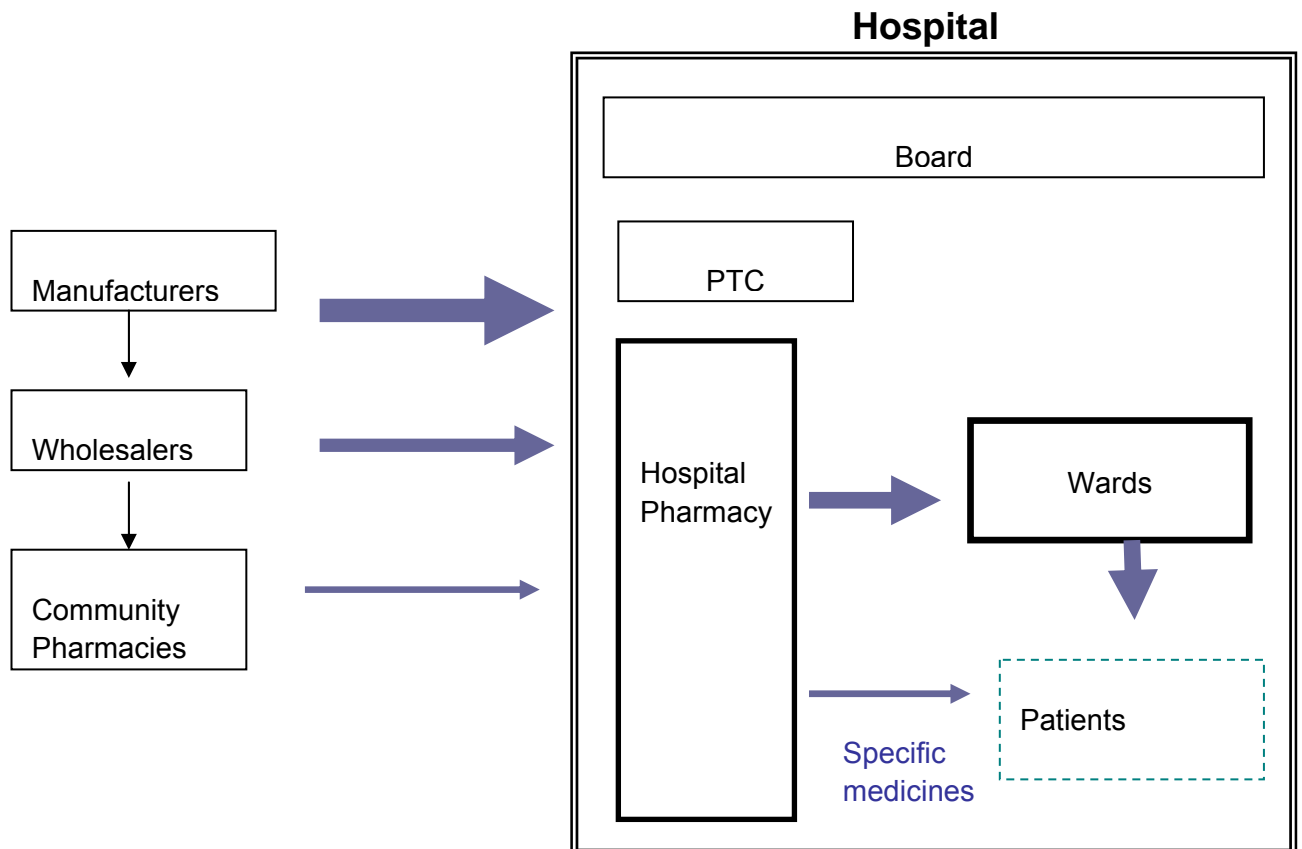
In Portugal, there were a total of 50 118 medicines authorized in 2010 (counting different pharmaceuticals forms, strengths and pack sizes). Of these, 3 314 (6%) were hospital only medicines (HOM). The National Hospital Pharmaceutical Formulary (NHPF), which serves as guidance to each hospital own formulary (addendum), has a total of 619 active substances (cf. section 3.2).

Delivery Chain

Pharmaceutical industry following negotiation/procurement processes is the main actor responsible for delivering medicines to hospitals, while wholesalers and community pharmacies have a minor role in this process.

In Portugal each hospital or hospital center has its own pharmacy responsible for delivering medicines to in-patients (wards). Hospital pharmacies can also deliver medicines to out-patients for specific conditions (e.g. HIV, hepatitis C, Amyotrophic lateral sclerosis, etc) that are not allowed to be dispensed in community pharmacies (cf. section 3.1). These patients are obliged to go to the hospital pharmacy of the institution which is following them. Figure 1.1 provides an overview of the Portuguese delivery chain.

Figure 1.1: Portugal - flow-chart on the Portuguese delivery chain



Hospital Pharmacies

In Portugal all public hospitals have a hospital pharmacy. However, in some cases several hospitals were pooled together to one hospital centre as a result of the re-structuring of hospitals occurred in the last years. These hospital centers with joint management have only one hospital pharmacy which provides medicines to all hospitals within this centre (PHIS Hospital Pharma Report 2010).

In Portugal, hospital pharmacy is responsible, among other activities, for:

- Selection and purchase of pharmaceutical products and medical devices;
- Ensuring medicines are stored appropriately;
- Delivery of medicines to in-patient including experimental medicines and other health care products;
- Preparation of intravenous medications, when provided with adequate facilities and equipments.

Hospital Pharmaceutical Services are led by a pharmacist and staff includes pharmacists, pharmacy technicians, administrative and assistants. However the number of people working in the hospital pharmacies is variable, depending on the number of beds and on hospital activity. In 2009 there were 446 pharmacists and 515 pharmacy technicians working in NHS Hospital pharmacies.⁵

Hospital pharmacies are entitled to dispense medicines to out-patient in three conditions:

1. Medicines under special reimbursement schemes that can only be delivered in hospital pharmacies like HIV treatment, Hepatite C, Lennox- Gastaut syndrome, etc (cf. section 3.1).
2. Patients undergoing ambulatory surgery are entitled to free oral medication for a maximum period of 5 days after discharge (Decree-Law n. ° 13/2009, 12th January).
3. Under exceptional circumstances that may hamper the regular access to medicines hospitals pharmacies may be authorized by the ministry of health to dispense medicines to

⁵ Programa do Medicamento Hospitalar: <http://www.acss.min-saude.pt/Projectos/ProgdoMedicamentoHospitalar/Apresentação/tabid/171/language/pt-PT/Default.aspx>

the public (Decree-Law No. 206/2000, 1st September) or for clinical reasons in the emergency services, though it has never been translated to practice.

In all other situations hospital pharmacies are not entitled to dispense medicines to patients as happens in a community pharmacy.

Establishment of 24 hours community pharmacies in NHS hospitals facilities in order to increase access to medicines was approved in 2006 (Decree-Law No. 235/2006, 6th December and Decree-Law n.º 241/2009, 16th September). These 'community' pharmacies do not have any interaction with the hospital pharmacy and its activities of delivering medicines to in-patients.

Although each hospital is responsible for proposing the establishment of a community pharmacy inside the hospital the approval of public procurement by tendering of these pharmacies is made by the Ministry of Health. In 2009, there were six community pharmacies located in public hospitals being contracted out to private management.

1.3 Funding

The National Health Service has an annual budget which is funded mainly through general taxation. The Central Administration of the Health System (ACSS, IP) is the entity responsible for managing NHS hospital funding.

In Portugal a mixture of more than one funding system is in place for NHS hospitals. Hospitals are mainly financed prospectively through contracting of services (contract program), however there are other sources of funding namely user-charges and payments made by health subsystems and private insurers.

Contract Program

Hospitals are financed prospectively through contracting of services (contract program) between ACSS, Regional Health Administrations and hospitals. According to these contracts hospitals commit to a certain level of activity (admissions, external consultations, emergency department episodes, etc), based on DRG system, in return for an overall yearly budget.

Since 1997 hospital funding has taken into account Case-Mix Index (CMI). In-patient and ambulatory surgery were classified using Diagnosis-related Groups (DRG) and a growing portion of the budget is now based on the predicted hospital activity (from 10% in 1997 to 50% in 2002).

These contracts include the following hospital services:

- Hospital services for out-patients:
 - Medical appointments [First medical appointments (episode) and Subsequent medical appointments (episode)];
 - Ambulatory DRG [Medical DRG (episode) and Surgical DRG (episode)];
 - Day Hospital [Haematology; Imuno-hemotherapy; Infections Diseases; Psychiatry; Others (episode)];
 - Dialyses (Comprehensive price);
- In-patient services:
 - Surgical (CMI * Patient equivalent; DRG) ;
 - Surgical Emergency (CMI * Patient equivalent; DRG);
 - Medical (CMI * Patient equivalent; DRG);
- Emergency episode;
- Health Plans: HIV/AIDS; Pre-natal Diagnosis (Comprehensive price);
- Home care (episode).

Besides the activities mentioned above the contract includes additional funding concerning the following items:

- Out-patient medicines dispensed exclusively in hospital pharmacies and subject to special legislation (cf. section 3.1).

- Medicines and medical procedures to HIV patients and CKD patients, which are subsidized according to the predicted the number of new patients.

Hospitals integrated in Local Health Units (ULS) (primary healthcare services plus secondary care) are remunerated on an adjusted capitation basis.

Other sources of financing

The health subsystems and private insurance schemes reimburse NHS hospitals retrospectively on a case-by-case basis for in-patient care and ambulatory surgery (according to a

DRG price list), and on a fee-for-service basis for ambulatory services provided to their beneficiaries (Barros and Simões, 2007).

Hospitals can also generate their own revenue through payments received from patients for special services, private donations or user-charges (Barros and Simões, 2007). User charges are applied on some NHS services, including services delivered at hospital level. Flat rate charges in hospitals exist for consultations, emergency visits, diagnostic tests and therapeutic procedures. In 2007 user charges were introduced for in-patient services and out-patient surgery, but were revoked in 2009 (Decree-Law n.º 322/2009, 14th December).

Exemptions to user charges are applied to people with annual income of less than 14 minimum wages, children under 12, pregnant women, people with some chronic diseases, etc. (Decree-Law n.º 173/2003, 1st August, Decree-Law n.º 201/2007, 24th May and Decree-Law n.º 38/2010, 20th April).

Health and Pharmaceutical Expenditure

The Portuguese health sector has been characterized by a substantial increase in expenditure since the beginning of the 1990s (Table 1.3). Total pharmaceutical expenditure (TPE) (hospitals and ambulatory) amounted to € 4206 mio. in 2006, corresponds to 27,2% of the total health expenditure (THE). The pharmaceutical expenditure in hospitals (HOSPE) rose by 33% between 2004 and 2006.

The increase in expenditure with medicines in hospitals could be explained, among others factors, by an increase in expenditure with antineoplastic and medicines to HIV. This is due to an increase of incidence/prevalence of the associated diseases and also to the introduction of new and more expensive medicines.

Table 1.3: Portugal – Health and pharmaceutical expenditure, 2000 and 2004–2009

Expenditure (in million €)	2000	2004	2005	2006	2007	2008	2009
Total health expenditure (THE)	10,815 ¹	14,377	15,163	15,437	n.a.	n.a.	n.a.
- thereof THE public	7,846 ¹	10,356	10,880	11,041	n.a.	n.a.	n.a.
thereof THE private	2,969 ¹	4,021	4,283	4,396	n.a.	n.a.	n.a.
THE in hospitals (HOSHE)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof HOSHE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total pharmaceutical expenditure (TPE)²	n.a.	3,806	4,063	4,206	n.a.	n.a.	n.a.
- thereof TPE public	n.a.	2,488	2,670	2,723	n.a.	n.a.	n.a.
- thereof TPE private	n.a.	1,318	1,393	1,483	n.a.	n.a.	n.a.
Pharmaceutical expenditure in hospitals (HOSPE)²	n.a.	665	783	844	n.a.	n.a.	n.a.
- thereof HOSPE public	n.a.	666	783	844	n.a.	n.a.	n.a.
- thereof HOSPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

HOSHE = health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, NCU = National Currency Unit, PE = Pharmaceutical Expenditure, THE = Total Health Expenditure, TPE = Total Pharmaceutical Expenditure; n.a.= not available

¹ break in series

² ACSS data, does not include HOSPE private.

Source: OECD HEALTH DATA 2009, June 09 and ACSS

On average nearly 72% of the health expenditure is covered by public sector. 25% of public health expenditure is spent on medicines of which less than one third (30%) is spent in the hospital sector.

2 Pricing

2.1 Organization

2.1.1 Framework

Whereas pricing of prescription only medicines (POM) used in the out-patient sector is highly regulated, there is a lack of a legal framework regarding medicines used in hospitals.

Before 2007 prices of medicines used in hospitals were established by pharmaceutical companies (except if already established by DGAE for the out-patient sector) or, in some cases, by public procurement. The only exception occurred in medicines fully reimbursed dispensed to out-patients at hospital pharmacies which were subject to previous economic evaluation and in those cases prices were established.

However, since 2007 (Decree-Law no.195/2006, 3rd October) it was established, by INFARMED, a procedure for the preliminary assessment of HOM and restricted POM.

Pharmaceutical companies have to demonstrate the therapeutic added value and the economic advantage for these medicines through comparison with other products or by health economic study evaluations.

In accordance with Decree-Law no.195/2006 hospitals are not allowed to acquire new HOM and restricted POM (or with new indications) that were not subject to evaluation or that have not been approved. Since its implementation (2007), maximum prices have been established for all HOM and restricted POM approved, though hospitals are free to decide on their acquisition. On approval these medicines are also subject to a budget control by INFARMED.

Hospitals cannot decide directly on prices, but can influence them indirectly through negotiations.

Purchasing can be done in different ways (cf. section 2.2):

- public procurement process by tendering (ACSS);
- joint purchasing (SUCH, that was replaced on March 2010 by SPMS).
- acquisition by association of several hospitals;
- acquisition by each hospital individually.

Most medicines can be purchased through a national catalogue managed by ACSS (available online at: https://www.catalogo.min-saude.pt/caps/publico/pub_consulta.asp). In case medicines are not included in the catalogue, purchase can be done directly with pharmaceutical industry. Even if the medicine is included in the national catalogue providers are entitled to negotiate, though prices must be below the ones defined by ACSS.

If the hospital purchases one medicine that was subject to evaluation by INFARMED (Decree-Law no.195/2006, 3rd October) prices must be equal or lower to the price defined by INFARMED.

The actual hospital price achieved during the purchasing process might be lower as no limitations on the discounts or rebates are in place in the in-patient sector.

Each hospital has its own list of medicines available for use (called addendum to the NHPF-section 3.2) and purchasing/negotiation of these medicines can be done by:

- Purchasing departments;
- Hospital pharmacy;
- Hospital management services.

Usually there is collaboration between the three services mentioned above.

To sum up, in Portugal there is no legal framework regarding pricing of medicines used in hospitals. Before 2007 medicines prices were established by pharmaceutical companies or, in some cases, by public procurement. The only exception occurred in medicines fully reimbursed dispensed at hospital pharmacy which were subject to previous economic evaluation and in those cases prices were established.

Since 2007 new medicines and medicines with new indications are subject to an economic evaluation and a maximum price is also established. Hospitals can not decide directly on prices, but can influence them indirectly through negotiations.

2.1.2 Hospital prices

Structure of Hospital Prices

There is no legislation imposing rules on prices of hospital medicines. In general the “hospital price” corresponds to the maximum ex-factory price plus value added tax (VAT). For all medicines sold to hospitals is applied VAT at standard rate (5% changed to 6% from 1st July 2010).

Despite the existence of specific legislation for POM pricing (dispensed at the community pharmacies) these medicines in hospitals have lower prices due to negotiations and non-existence of margins to wholesalers and pharmacies.

In fact, since most of the pharmaceutical purchases are directly made to industry mark-ups are not relevant for public hospital pharmacies. Mark-ups are relevant if in exceptional cases medicines are acquired from wholesaler or pharmacies. Wholesale mark-ups for the in-patient sector are not regulated, but when applied usually the out-patient mark-ups are taken. In these cases, for POM, margins cannot exceed the margins established by law (the wholesale and pharmacy margins are regulated via a percentage of the net pharmacy retail price according the Decree-Law No. 65/2007, 14th March, of 8% and 20% respectively).

There is no mandatory discount policy though most hospitals have rebates (“rappel” due to a negotiation process, usually granted at the end of the year, if the hospital purchases a certain quantity or type of medicines.

Availability and transparency of pharmaceutical prices

The INFARMED website makes available information about the maximum price for the new medicines for hospital use (Decree-Law No.195/2006, 3rd October). ACSS website offers information about the prices of public procurement process. However, there is no legal obligation for hospitals to publish actual pharmaceutical prices or to notify prices to a competent authority.

In general, public hospitals do not share information on purchasing medicines in a systematic and organized way. Furthermore, prices including discounts and rebates are neither publicly available nor shared among hospitals.

However, there's always place for some flow of information and on request from official entities hospitals usually provide this information.

To sum up, the hospital price corresponds to the maximum ex-factory price plus value added tax (VAT). Mark-ups are not relevant for public hospital pharmacies unless medicines are bought from a wholesaler or a community pharmacy.

2.2 Pricing policies

In purchasing various scenarios can be considered:

- public procurement process (managed by ACSS);
- Joint purchasing (SUCH);
- acquisition by association of several hospitals;
- acquisition by each hospital individually.

The major pricing policies are the public procurement process (cf. section 2.2.1) and the negotiation directly with the suppliers (cf. section 2.2.2). Joint purchasing by SUCH was residual and in 2010 this entity was replaced by SPMS (cf. section 2.2.2).

In Portugal the prices of medicines were also reduced in an administrative way. In 2005 and 2007 medicines purchased by the NHS had a 6% price reduction (Order n.º 618-A/2005, 27th July and n.º 2496/2007, 31st January).

For several medicines, a two step procurement process is applied, involving direct negotiations by hospitals following centralised tendering.

2.2.1 Procurement

NHS hospitals may purchase medicines through public procurement. Public procurement procedure is managed by ACSS and processed according to European Legislation (European Directives 2004/17/CE and 2004/18/CE transposed to portuguese law through Decree-Law n.º 18/2008).

Public procurement covers the most common medicines (include 3216 pharmaceutical products⁶ taking into account different dosages) and medical devices used in NHS hospitals.

Tenders usually cover a bundle of products included in the same therapeutic group and favorable prices are important criteria in the decision process. These tenders usually run for 3 years.

The tender prices of these centrally procured medicines are displayed in a publicly accessible catalogue. The catalogue is available online at: https://www.catalogo.min-saude.pt/caps/publico/pub_consulta.asp, and includes information not only on the price but also on other factors like time to deliver the product, storage conditions, etc.

Hospitals may enter afterwards into negotiations with pharmaceutical companies (c.f. section 2.2.2).

2.2.2 Others

Negotiations

Hospitals may enter into negotiations with the companies for acquiring medicines. Depending on the economic relevance of the medicines for the hospital budget, hospital start competitive negotiations asking several manufacturers to submit a proposal, while in case of low-priced medicines they might decide to refrain negotiations and purchase the medicine at ACSS price (PHIS Hospital Pharma Report 2010).

In this process there is usually collaboration between purchasing departments, hospital pharmacy and hospital management services. Hospital pharmacists can be either advisory or decision makers.

⁶ Data accessed at August 2010.

The hospital price might be lower due to different kinds of reductions such as discounts (i.e. price reductions under specific conditions), rebates (i.e. price reductions after the transaction has occurred), bundling (i.e offering several products for sale as one combined product) or cost free products (i.e given to hospitals without payment) (PHIS Hospital Pharma Report 2010).

Hospitals can also take advantage of the bargaining power resulting from larger acquisition volumes.

Nevertheless, even if the medicine is included in the national catalogue providers are entitled to negotiate, though prices must be below the ones defined by ACSS. Or if the medicine was subject to prior evaluation assessment by INFARMED, prices must also be lower than the ones defined by INFARMED.

Joint Purchasing

Joint purchasing by a central structure (SUCH) has been non-significant. In 2010, The Ministry of Health created a new structure “SPMS - Serviços Partilhados do Ministério da Saúde”, which aims to provide common services in health - as purchases of medicines and medical material, financial services and human resource management - to entities belonging to the ministry of health. However it is still in an initial phase.

3 Reimbursement

3.1 National hospital reimbursement procedure

The positive list used in the out-patient sector is not relevant for hospitals. In NHS hospitals medicines are administered free of charge to all patients admitted in a clinical ward or emergency service during their stay in the hospital.

However, there is a list of conditions for which medicines must be delivered by the hospital pharmacy and are fully funded under a special scheme, which is included in the contract program. The diseases and medicines under this special reimbursement scheme are selected either due to complexity/severity or need of monitoring. The group of conditions includes Multiple Sclerosis, Hepatitis C, Lennox-Gastaut Syndrome, Cystic fibrosis, etc. The complete list is available online at the INFARMED website: http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AVALIACAO_ECONOMICA_E_COMPARTICIPACAO/MEDICAMENTOS_USO_AMBULATORIO/MEDICAMENTOS_COMPARTICIPADOS/Dispensa_exclusiva_em_Farmacia_Hospitalar .

3.2 Hospital pharmaceutical formularies

There is a National Hospital Pharmaceutical Formulary (NHPF) which is the result of the work of a specific committee, consisting of medical experts, pharmacists and technicians from the National Regulatory Agency (INFARMED). This committee is responsible for preparing, reviewing, updating and monitoring the NHPF publication as well as advising on related issues. The 1st edition of the NHPF was in 1972. Currently the NHPF is on its 9th edition and includes 619 active substances and also the brand name and is published in paper by INFARMED and available online at: <http://www.infarmed.pt/formulario/frames.php?fich=iab2&letra=b>. NHPF updating process does not occur in a regular/periodic way and since 2006 is not updated.

Funding and reimbursement of medicines used in hospitals does not depend on the inclusion in the national formulary.

In general, public hospitals should only use medicines on the NHPF. If a medicine not included in the NHPF is needed for in-patient treatment, the Pharmaceutical and Therapeutic Committee (PTC) of a hospital will decide if this medicine should be included in the hospital-specific addendum to the NHPF. In fact, all public hospitals have their own addendum in place supplementing the NHPF (PHIS Hospital Pharma Report 2010).

The number and type of medicines included on the hospital addendums, which are equivalent to a hospital own formulary, are highly dependable on the hospital (e.g. general or specialized).

The Pharmacy and Therapeutic Committees play an important role in the hospital regarding the rational use of medicines and are considered decision-makers in relation to the introduction/exclusion of medicines. The Pharmacy and Therapeutic Committee consists of a maximum of six members, 3 physicians and 3 pharmacists and is responsible for:

- Addition and exclusion of medicines from the hospital addendum;
- Ensure compliance with the NHPF and its addendum;
- Promote the elaboration and use of clinical guidelines;
- Issue opinions and reports about the use of medicines inside the hospital;
- Act as a liaison between the medical departments and pharmaceutical services;
- Revise the treatment prescribed for patients without breaking ethical standards;
- Assess costs of hospital treatment;
- Develop the list of emergency medicines that should exist in the medical services (Order No. 1083 /2004, 1st December 2003).

The decision on inclusion of new medicines in the hospital addendum is based on the therapeutic added value, safety, administration, economic value and budget impact, disease-specific criteria like severity of illness, patient-specific criteria like chronically or terminally ill patient.

The exclusion of pharmaceuticals is usually due to the introduction of new medicines with a better therapeutic profile, either due to efficacy, safety or administration or due to economic criteria.

At the Pharmacy and Therapeutic Committees level there's a continuous process of updating the hospital addendum which is usually available on hospital intranet.

In hospitals the prescription of medicines is made according to the international common denomination and should be in accordance with the hospital addendum. However physicians can prescribe medicines not included in the addendum with a clinical justification, which may or may not be accepted by the Pharmacy and Therapeutic Committee. The pharmacy delivers the active substance which is prescribed and regardless its status of brand or generic medicine.

4 Consumption of medicines

This section provides information and data on consumption (utilization) of medicines in hospitals at a national level and informs on data availability at hospital level.

In 2007 a Medicine National Hospital Code (CHNM) was created in order to standardize the codification of medicines in hospitals and replace the different codes in existence in public hospitals (Decree No. 155/2007, 31st January). This measure was important not only because it allowed the implementation of a monitoring system of pharmaceutical consumption in hospitals but also because all public hospitals were using the same codes after the introduction of the CHNM. Additionally hospitals can have access to INFARMED medicine database (they can upload monthly INFARMED database in a web platform) which provides information about new medicines introduced in the market, medicines withdrawn, reimbursement schemes, product information, etc.

The monitoring system requires that all NHS hospitals report to INFARMED monthly the information on pharmaceutical consumption (volume and expenditure) and for which clinical services were the medicines delivered. Although most of hospitals can now link consumption with individual patient that information is not yet available in the monitoring system at INFARMED.

It is now possible to monitor the public hospitals' pharmaceutical consumption regarding different areas (oncology, infection, internal medicine, etc) and departments (external consultation, urgency, ambulatory surgery, etc). This monitoring is also possible by therapeutic classification and by active substance as well on specific groups of medicines, such as the orphan medicines.

The data available refers to consumption of medicines, measured in units, covered by the CHNM and refers to 60 NHS hospitals, which represent about 90% of the public HOSPE.

Table 4.1: Portugal – Pharmaceutical consumption in hospitals, 2000 and 2004-2009

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008	2009
Annual pharmaceutical consumption in the hospitals							
in units ¹	n.a.	n.a.	n.a.	n.a.	223,653,999	223,084,103	225,218,143

n.a= not available

¹ data measures in unit doses counted including different pharmaceutical forms, strength, and size

Source: INFARMED, “Medicines Market Analysis in the NHS hospitals”, 2007-2009 (refers to 60 NHS hospitals, which represent about 90% of the public HOSPE)

Table 4.2: Portugal – Top 10 medicines by pharmaceutical expenditure and consumption in hospitals 2009

Position	Top medicines used in hospitals, indicated by active ingredient, ranked with regard to consumption	Position	Top medicines used in hospitals, indicated by active ingredient ranked with regard to expenditure
1	Sodium Chloride	1	Emtricitabine + Tenofovir
2	Paracetamol	2	Trastuzumab
3	Lopinavir + Ritonavir	3	Imunoglobulin normal Human
4	Furosemide	4	Lopinavir + Ritonavir
5	Mycophenolate mofetil	5	Imatinib
6	Ethinylestradiol + Gestodeno	6	Docetaxel
7	Tacrolimus	7	Interferon beta-1a
8	Tamoxifen	8	Efavirenz
9	Potassium Chloride	9	Rituximab
10	Metoclopramide	10	Darbepoetin alfa

Source: INFARMED, “Medicines Market Analysis in the NHS hospitals”, 2009

5 Evaluation

5.1 Monitoring

Monitoring at national level

The consumption of medicines used in NHS hospitals is regularly monitored by INFARMED, through the Medicine and Health Products Observatory. This monitoring in the in-patient sector is made on a country-wide level.

INFARMED publishes monthly reports which are sent to Ministry of Health, hospitals and are made available online to the public on: http://www.infarmed.pt/portal/page/portal/INFARMED/MONITORIZACAO_DO_MERCADO/OBSERVATORIO/ANALISE_MENSAL_MERCADO/ANALISE_MERCADO_MEDICAMENTOS_CHNM

In monthly reports INFARMED provides data on expenditure of medicines:

- Annual evolution;
- Evolution by hospital;
- Evolution by therapeutic areas and delivery services;
- Main factor for the observed variations (Active substances, therapeutic groups, hospitals, etc);
- Monitoring of special groups like orphan medicines, medicines without formal "Market Introduction Authorization".

Monitoring at hospital level

Most public hospitals monitor the expenditure and consumption of medicines used in hospitals. It's possible to quantify the hospital expenditure on medicines for instance via DRG, although it's not a routine. Usually the data are provided by the pharmaceutical services and are discussed at the Pharmacy and Therapeutic Committees, at the clinical services and board of administration.

IT support

All public hospitals use computerized systems in supply. The level of its use can differ from hospital to hospital, but in general includes the purchase order, inventory control, stock-taking, units of care supplies, record systems.

The majority of hospitals have e-prescribing systems linking prescribing, pharmaceutical validation and dispensing. Hence, it is possible to link type and quantity of medicines dispensed to an individual patient.

Role of Hospital Pharmacist

Hospital pharmacists play an important role in hospitals, in particular with regard to rational use and monitoring. The profile of hospital pharmacist is defined in law, according the Decree No. 414/91, 22nd October. They are responsible, among other activities, for:

- Purchasing;
- Prescribing validation and supply of medicines to wards;
- Preparation of sterile products, non-sterile products and Centralized Intravenous Admixtures Service (CIVAS);
- Some hospital pharmacists are also responsible for clinical pharmacy activities, pharmacokinetics, pharmacovigilance and medicine information;
- Promotion of scientific investigation and education activities.

The NHS hospitals and the other services of NHS should report monthly, to INFARMED, the information on pharmaceutical consumption (cf. section 4).

5.2 Assessment

In 2007 prior evaluation assessment for new medicines for intramural/hospital use was introduced (Decree-Law No. 195/2006, 3rd October): the companies have to demonstrate the therapeutic added value and the economic advantage for these medicines demonstrated through comparison with other products or by health economic study evaluations.

INFARMED decides on the approval / exclusion of these medicines for use in hospitals and then informs hospitals about its decisions. If a medicine is not evaluated or is not approved,

hospitals cannot purchase it. On approval, Infarmed establishes a maximum price though hospitals are free to decide on their acquisition. The INFARMED website offers information on medicines assessed and the information is available online at: http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/AVALIACA_O_ECONOMICA_E_COMPARTICIPACAO/MEDICAMENTOS_USO_HOSPITAL/DL_N_195_2006_3_OUT/PROCESSOS_DIFERIDOS

Some hospitals promoted the use of clinical guidelines in order to improve rational use and hence cost-containment.

6 Interface management

With the exception of six Local Health Units there is no interface between primary and secondary care. However, it has been recognized the need to take into account the impact of hospital prescribing on primary care.

7 Developments and outlook

The most recent and significant reforms to the hospital pharmaceutical sector in the NHS include:

- New funding model based on contracting services – contract program;
- Pool together nearby institutions into a hospital centre;
- Implementation of e-prescribing and wider automation;
- Establishment of a maximum level of growth for hospital medicine's expenditure (2,8%).

In terms of initiatives planned for the near future:

- Stimulate price negotiations with pharmaceutical companies;
- Development of clinical guidelines in order to improve rational use of medicines;
- Increase comparative analysis between hospital's medicine use.

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INFARMED website - National Hospital Pharmaceutical Formulary (NHPF):
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INFARMED website - medicines delivered by the hospital pharmacy and funded under a special scheme :
http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/A_VALIACAO_ECONOMICA_E_COMPARTICIPACAO/MEDICAMENTOS_USO_AMBULATORIO/MEDICAMENTOS_COMPARTICIPADOS/Dispensa_exclusiva_em_Farmacia_Hospitalar

INFARMED website – prior evaluation assessment of medicines to be used in hospitals:
http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/A_VALIACAO_ECONOMICA_E_COMPARTICIPACAO/MEDICAMENTOS_USO_HOSPITAL/D_L_N_195_2006_3_OUT/PROCESSOS_DIFERIDOS

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