Pharmaceutical Health Information System

PHIS Hospital Pharma Report

FRANCE

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

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Executive Summary

In France, hospital care is provided by the public or private sector. Patients have access to all hospitals working within the public service framework. However, private hospitals that do not work within the public service framework can select their patients.

Before the 2004 hospital payment reform, public and private hospitals were not funded the same way:

- Hospitals in the private sector were funded by a fee-for-service system,
- while the public hospital sector received funds from a global budget system.

This difference gave hospitals different incentives to provide care to patients. It encouraged specialisation: private hospitals tended to produce more surgical procedures and less medicine acts than public hospitals.

Furthermore, the public sector is composed of two kinds of hospitals: public hospitals and not-for-profit private hospitals contracted to the public service ("*établissements participant au service public hospitalier,* PSPH). The private sector includes only for-profit private hospitals.

Background

In France a hospital is a health care institution (*établissement de santé)* and its general mission is defined in article L.6111-1 in the Public Health Legislation (*Code la Santé Publique*, CSP)[1]. Whatever their status (public or private), a health care institution should:

- Diagnose, monitor and provide health care treatments to patients considering their psychological status;
- participate in public health activities (including for instance prevention).

Their activities are defined in article L.6111-2 of the CSP. A health care institution should provide (with or without overnight stay):

- Short term acute care in medicine, surgery, obstetrics, (Médecine, Chirurgie, Obstétrique, MCOs), odontology or mental health services;
- Rehabilitation;
- Long term care for patients needing special daily assistance (e.g. *Etablissement d'Hébergement pour Personnes Agées Dépendantes,* EHPAD*,* for the elderly).

The regional hospital agencies (ARH, soon to be replaced by regional health agencies (ARS) in spring 2010) are responsible for hospital planning (for both public and private hospitals), financial allocation to public hospitals and adjustment of tariffs for private for-profit hospitals

[1] http://www.legifrance.gouv.fr/affichCode.do;jsessionid=6C02EE194BAA3A325BB048570E4BA387.tpdjo03v_2?idSectionTA=LEGISCTA000006171442&cidTexte=LEGITEXT000006072665&dateTexte=20091109

(within the framework of national agreements). At regional level the health services of the state and health insurance funds, which previously shared management of this sector are brought together.

There are **five categories of public hospitals** (972 in 2007), excluding overseas departments:

- 29 regional and university hospital centres (*centres hospitaliers régionaux et universitaires*, CHR/CHU),
- 498 hospital centres (*centres hospitaliers généraux*, CH):
- 340 local hospitals (*hôpitaux locaux*, HL)
- 86 specialised hospit*al centres for* mental healthcare (*centres hospitaliers spécialisés en psychiatrie*, *CHS),*
- 19 others public hospitals which include army hospitals, penal establishments, sanitary hospitals.

*Public hospital*s ar*e legal en*tities usually owned by local administrative units such as municipalities or counties (departments). Still they are administratively autonomous and financially independent.

There are for-profit and not-for-profit private hospitals, among which in 2006[2]:

- 43% were not-for-profit hospitals
- 57% were for-profit private hospitals, commonly referred to as “cliniques”

Financing for-profit private hospitals is almost the same as financing public hospitals (hospitals are submitted to the same prospective payment system but tariffs are not calculated according to the same basis in the public and the private sector), but they do not have public service duties (they can refuse some patients and pathologies for example) and can choose their activities. They are usually specialised on acute care (MCOs) whereas public hospitals have to undertake all MCOs activities as well as rehabilitative care and long term care for patients needing special daily assistance.

Every year the parliament votes the national ceiling for health insurance expenditure (ONDAM) for the year to come. A separate budget is defined for public and private hospitals.

The State is responsible for the hospital sector, both public and private, as well as the medicines sector. The budget is divided between regions by the Ministry of Health and the **ARHs** (soon to be replaced by ARS). Individual budgets are allocated to each hospital in the framework of regional resource. The ARHs combines health services of the state and the health insurance funds at the regional level and are responsible for hospital planning (for

[2] „Les établissements de santé, Un panorama pour l'année 2006“, 2008 report, http://www.sante.gouv.fr/drees/donnees/es2006/es2006.htm

both public and private hospitals), financial resource allocation to public hospitals and adjustment of tariffs for private for-profit hospitals.

Hospital expense accounted for 37% (€ 77 billion in 2007) of the total health care expenditure.

Health expenditure accounted for 11% of the GDP in 2007 (€ 208,4 billion). France ranks second in the world behind the United States (16%) and is close to Switzerland (10.8%), in terms of health expenditure as a percentage of GDP.

Pricing

In the in-patient sector the **prices are freely set**.

In this framework, cost of medicines for hospital use have been regulated since 2003[3] according to article L 162-22-7 of the social security code (*Code de la Sécurité Sociale*, CSS), very expensive medicines**,** are under control of the Economic Committee for Health Care Procducts (*Comité Economique des Produits de Santé*, CEPS) by agreement with the industry or in case no agreement is found the health minister fixes a level of reimbursement. This is not a price regulation but a cost regulation. In fact the prices are not far from the reimbursement level because hospitals have no money to pay the gap between price and the base of reimbursement by social security.

Still medicine prices for the out-patient and in-patient sector are regulated by an "out-patient - in-patient" agreement (*Accord ville-hôpital*)[4], which has been in place since 25 September 2008 (until 31 December 2011). This agreement is signed between CEPS and the industry. Before 2008, the agreements for each sector, out-patient and in-patient, were different. The 2008 agreement is a merger of the previous out-patient and in-patient agreements so it regulates the cost of very expensive medicines for hospital use excluded from the hospital budget and reassigned medicines (*retrocession)*.

Hospitals decide on the products they want to purchase by means of creating formularies (in the frame of the official list of medicines that hospitals are authorised to buy). In hospitals a committee (*commissions du médicament et des dispositifs médicaux stériles,* COMEDIMS), composed of physicians, pharmacists and hospital managers, for establishing formularies and to decide on the type of products needed, is designed. The official list is registered by the Minister of Health and published in the official bulletin according to article L5123-2 of the Public Health Code (CSP). The purchase of products for hospitals is carried out by the hospital pharmacist.

The main purchasing policy is procurement by tendering however negotiation may also take place. The way of purchasing is either done individually by hospitals or together with other hospitals as better deals are expected this way.

[3] 2003 law n°2003-1199 du 18 December 2003 article 27-1 (in application as of 1 January 2005)

[4] http://www.leem.org/leem-image/leem/document/1372.pdf

In 2005 all 32 Regional University Hospitals and the 20 largest General Hospitals created a common structure called *Groupement de Coopération Sanitaire* "*Union des Hôpitaux pour les Achats* (UNI.H.A)[5]. UNI.H.A. negotiates various products and services from medicinal products to laundry.

Many other mutualised structures dedicated to procurement contracts have been created, some being based on geographical distribution of hospitals, others related to specialised care centers. The size of these procurement structures is variable; the minimal extreme is represented by a unique isolated hospital having chosen to manage by itself some of its purchases independently.

The procurement process takes place as needed but **usually on an annual basis**.

When required by regulation, the **tender is published** in the Official Journal of the European Union.

Partial **information on prices** is available for Health Insurance Funds and the Competent Authorities.

Reimbursement of medicines in hospital

In order to be commercialised a medicine must obtain **market authorisation** (*Autorisation de Mise sür le Marché*, AMM) delivered by the French Agency for the Health Safety of Health Products (*Agence Française de Sécurité Sanitaire des Produits de Santé,* AFSSAPS) upon advice from the Market Authorisation Commission (AMM Commission). The AMM Commission defines the **hospital reserve**, the list of medicines to be only used in hospitals.

In case a company applies for reimbursement by the sickness funds, the product may be marketed as soon as it obtains its AMM. However if it is to be reimbursed, a file must be completed for the transparency commission. The transparency commission is part of the French National Authority for Health (*Haute Autorité de Santé,* HAS). The transparency commission also advises the Ministry of Health on whether a medicine should be approved for use in primary care or hospitals; if a medicine is licensed for group use, it is authorised for purchase by and use in hospitals; if it is licensed for primary care use, it may be used in general practice and also in hospitals; however some products, either due to their packaging or their dosage, are only licensed for group use. Medicines classified in the hospital reserve when they obtain AMM may only request a group licence. All of this information is published in the Advice of the Transparency Commission; this advice is transmitted to the Economic Committee for Health Products (CEPS). At this point the administrative process ends for most hospital medicines which are not subject to price regulation (non reassigned and inexpensive medicines as described below).

In France there are two lists of reimbursable medicines, i.e. positive lists:

- one list of reimbursable medicines for out-patient care and for the sales by pharmacies (*liste des medicaments remboursables agrees aux assures sociaux*)

[5] https://www.uniha.org/

- and a list for the hospital sector, the hospital reserve (*liste des medicaments agréés aux collectivites* or *réserve hospitalière*).

Among the pharmaceutical expenditure in hospitals (HOSPE), **about 40% of medicines** used in hospitals are **integrated in the activity-based costing** system. A **supplementary list** (*liste en sus* or *non T2A* medicines), of **costly medicines excluded from the DRG system** has been developed and is reimbursed separately by the health insurance. A third group of medicines referred to reassigned (*retrocession)*, is not included in the DRG system either. In 2008 (cf. CEPS activity report 2008):

- reassigned medicines accounted for about € 1.2 billion with a growth rate of 5% compared to 2007;
- outside-DRG medicines, in-patient supplementary list, accounted for about 2.4 billion € with a growth rate of 16% compared to 2007.

A new mode of financing based on diagnosis related groups (DRG) models, **the T2A system**, was first introduced on 1 January 2004 according to the Hospital Plan 2007 *(Plan hôpital 2007).* This activity-based payment system concerns both the private and public sector but excludes local hospitals, specialised hospitals centres for mental healthcare and army hospitals. It only applies to the so-called MCOs activities, dialysis and at home care. The classification system is based on the principle of paying hospitals according to their activity in relation to homogeneous groups of patients (*Groupes Homogènes de Malades,* GHM). **DRGs tariffs** are different in the public and private sector and planned convergence was postponed to 2018. In not-for-profit and public hospitals all health professionals salaries are included in the GHM-system but doctors' fees are not included in the GHM-tariffs for for-profit hospitals.

In addition to the French DRG prospective payment tariffs, hospitals with general interest missions can benefit from an additional budget the so-called MIGAC (*Missions d'intérêt général et d'aide à la contractualisation*).

The institution responsible for updating and monitoring the french DRG system is the French Technical Agency for Hospital Information *(Agence Technique sur l'Information Hospitalière,* ATIH*)* which cooperates with a specific commission of experts. ATIH is in charge of conducting the national cost studies and reviewing the international literature.

Concerning the financial participation of the patient, hospitalisation-related expenses are covered at 80% by the social security system except in several circumstances where the level of reimbursement is 100% of eligible costs (e.g. if a technical act which value is over € 91 is realised on the patient during his/her stay - this exemption mechanism is called K50-, for length of stay over 30 days, for pregnancy, low income patients, long-term or major illness, hospitalised as a result of an accident at work etc.).

The other main co-payments for the patient are two fixed fees that may be reimbursed by voluntary health insurance:

- A charge of € 18 per day for any stay over 24 hours (*forfait journalier hospitalier*);

- A charge of € 18 for the stay if costs of hospital treatment exceed € 91, excluding radiologgy, biology, transport and stay over 30 days.

Consumption of pharmaceuticals in hospitals

The official source for consumption data is the French National Competent Authority for Safety of Health Products (AFSSAPS), which publishes the analysis of the fiscal declaration by each manufacturer every year. However, this publication is not detailed for each code.

The Economic Committee for Health Care Products (CEPS) also publishes statistics in its yearly activity report detailing estimations of in-patient and out-patient pharmaceutical consumption since 2007 at ex-factory price level[6].

Since 2005, the Directorate for Research, Analysis, Evaluation and Statistics (DREES) of the French Ministry of Health collects data on consumption of pharmaceuticals through a global survey in French hospitals. In each hospital, information on prices and quantities are collected for each medicine.

Evaluation

Nationwide statistics are available through aggregated data compiled by the AFSSAPS including medicines. These statistics are based on manufacturers' tax information and are published by active substances.

There is no public source on negotiated prices by medicines subject to procurement in the framework of hospital expenditures available.

Interface management

Production and distribution of therapeutic guidelines based on evidence-based medicine, with adequate appropriation through trainings represent an essential basis for a medically sound rationalisation of medicine use.

Beside appropriation of good practices by health professionals a key element for price negotiation is adequate evaluation of quality, safety and efficacy of medicines as well as quantification of medical progress (clinical added value). . Evaluation of the clinical added value is distinct from price negotiation. In addition these two activities need different professional competences. In France the clinical added value is evaluated by the French National Authority for Health and can be used during price negotiations.

In addition, the National Health Fund is acting through its local offices and dedicated teams of representatives to communicate and promote good clinical practices, in particular in hospitals, expecting results in better care and optimised expenses.

[6] http://www.sante.gouv.fr/ceps/doc/rapport_activite_ceps_2008.pdf

Developments and outlook

Since the nineties, hospital organisation in France has been under permanent and important evolution through successive reforms including new prospective payment system, new governing rules as well as new accounting rules (*Etat prévisionnel des recettes et des dépenses,* EPRD). Since then, this trend has been amplified.

Hospital, patients, health and territories (*Hôpital, patients, santé et territoire,* HPST*)* is the official name of a French bill presented on 22 October 2008 and which is now enforced. It was initially introduced to modernise the French hospital system, but in fact proposes a full reform of the health system, establishing full and complete State responsibility at regional level through the setting up of regional health agencies (ARS) that will have full authority over most health issues.

The HPST reform has the objective to set a global organisation of health care, in every compartment of public health. This reform includes the **development of a Regional Health Agency** (*Agences Régionales de Santé,* ARS) **in each of the 22 regions in France in 2010.** These agencies will be in charge of regulating health care organisations, specifically of the organisations of a new level of hospital organisation, the so called **local hospital communities** (*communités hospitalières de territoires*, CHT) as to facilitate sharing of advanced technology and medical expertise; this fits along the line of regional optimisation of care.

The **priority of ARS** agencies will be to improve the healthcare organisation by removing barriers between the out-patient, hospital and socio-medical sectors, and by promoting overall cross disciplinary patient management, especially in cross-disciplinary health institutes. These agencies will further supervise the implementation of regionalised public health policies.

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List of abbreviations

AFSSAPS	French Health Products Safety Agency / Agence Française de Sécurité Sanitaire des Produits de Santé
AIFA	Italian Medicines Agency / Agenzia Italiana del Farmaco
AMM	Market authorisation / Autorisation de Mise sur le Marché
ANAES	Former evaluation agency
AP-HP	Public assistance hospital of Paris / Assistance Publique – Hôpitaux de Paris
AP-HM	Public assistance hospital of Marseille / Assistance Publique – Hôpitaux de Marseille
ARH / RAH	Regional hospital agencies / Agences régionales de l'hospitalisation
ARS	Regional health agency / Agence Régionale de Santé
ASMR	Level of improvement of clinical benefit/ Amélioration du service médical rendu
ATC	Anatomic Therapeutic Chemical classification
ATIH	French Technical Agency for Hospital Information / Agence Technique sur l'Information Hospitalière
BMG	Austrian Ministry of Health
CEPS	Economic Committee for Health Care Products / Comité Economique des Produits de Santé
CH	Hospital centres / Centres Hospitaliers généraux
CHR/CHU	Regional and university hospital centres / Centres Hospitaliers Regionaux et Universitaires
CHS	Specialised hospital centres for mental healthcare / Centre Hospitalier Spécialisé en psychiatrie
CIVAS	Centralised Intravenous Admixtures Service
CLCC	Cancer institute / Centre de Lutte Contre le Cancer
CNAMTS	National Health Insurance Fund for Salaried Employees / Caisse Nationale d'Assurance Maladie des Travailleurs Salariés
COMEDISM	Sterile pharmaceutical and medical appliances hospital comittee / Commission du Médicament et des Dispositifs Médicaux Stériles
CSP	Public Health Code / Code de la Santé Publique
CSRP	Wholesalers Union / Chambre Syndicale des Répartiteurs Pharmaceutiques

CSS	Social security code / Code de la Sécurité Sociale
DDASS	Local social services direction / Direction départementale des affaires sanitaires et sociales
DDD	Defined Daily Doses / Doses Définies Journalières (DDJ)
DHOS	Department of hospital and health care organisation management of the Ministry of health and Solidarity / Direction de l'Hospitalisation et de l'Organisation des Soins
DG SANCO	Health and Consumer protection Directorate General
DRASS	Regional social services direction / Direction régionale des affaires sanitaires et sociales
DREES	Directorate for Research, Analysis, Evaluation and Statistics / Direction de la recherche, des études, de l'évaluation et des statistiques
DRG	Diagnosis-related group / Groupes Homogènes de Malades (GHM)
EAHC	Executive Agency for Health and Consumers
EHPAD	Care center for dependent elderly people / Etablissement d'Hébergement pour Personnes Agées Dépendantes
EU	European Union
FHF	Union of public hospitals in France / Fédération Hospitalière de France
GCSMS	Social and medico-social groups / Groupement de Coopération Sociale et Médico-Sociale
GDP	Gross Domestic Product / Produit national Brut
GERS	Pharmaceutical sales of wholesalers and industry to pharmacists / Groupement pour l'Élaboration et la Réalisation de Statistiques
GHM	Diagnosis-related group (DRG) / Groupes Homogènes de Malades
GHS	Homogeneous in-patient stay group / Groupe Homogène de Séjour
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HAS	French National Authority for Health / Haute Autorité de Santé
HCL	Civil hospitals of Lyon / Hospices Civils de Lyon
HE	Health Expenditure
HL	Local hospitals / hôpital local
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals

HPF	Hospital Pharmaceutical Formulary
HPST	Hospital, patients, health and territories / Hôpital, patients, santé et territoire
HTA	Health Technology Assessment
IHHII	International Healthcare and Health Insurance Institute
LEEM	Association of Pharmaceutical Industry / Les Entreprises du Médicament
LFSS	Finance Law of the Social Security System / Loi de financement de la sécurité sociale
MA	Medical assembly
MCO	Medicine, Chirurgy, Obstetrics / Médecine, Chirurgie, Obstétrique
MIG	Missions of General Interest / Missions d'Intérêt Général
MERRI	Missions for teaching, research and innovations / Missions d'Enseignement, Recherche, Référence et Innovation
MIGAC	Missions for general interest and contractual support / Missions d'intérêt général et d'aide à la contractualisation
NCU	National Currency Unit
NHS	National Health Service
Mio.	Million
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development
OPD	Out-patient department(s)
OPP	Out-of pocket payments
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
PHIS	Pharmaceutical Health Information System
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
PSPH	Participating to the public service

PUI	Internal pharmacy / Pharmacie à Usage Intérieur
SAE	Annual statistics for hospitals / Statistique annuelle des établissements de santé
SHI	Social Health Insurance
SMR	Clinical benefit/ Service médical rendu
SROS	Regional strategic health plans / Schéma Régional d'Organisation des Soins
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
T2A	Activity based payment / Tarification à l'activité (TAA)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UNCAM	National Union of Social Health Insurance Funds / Union Nationale des Caisses d'Assurance Maladie
UNI.HA	Union of hospital for purchasing / Union des Hôpitaux pour les Achats
VAT	Value Added Tax
WP	Work Package

Introduction

PHIS research project

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 of the PHIS project management 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 will be 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 the current knowledge of pharmaceutical policies in this sector is 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 conservations 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 France, a hospital is referred to as a health care institution (*établissement de santé*) and its general mission is defined in the Public Health Code (*Code la Santé Publique*, CSP) in article L.6111-1[7]. Whatever their status (public or private), the health care institution should:

- Diagnose, monitor and provide health care treatments to patients considering their psychological status;
- Participate in public health actions including for instance prevention.

Their activities are defined in article L.6111-2 of the CSP. A health care institution should provide, with or without overnight stay:

- Short term acute care in medicine, surgery, obstetrics, (*Médecine, Chirurgie, Obstétrique*, MCO), odontology or mental health services;
- Rehabilitation care;
- Long term care for patients needing special daily assistance (e.g. *Etablissement d'Hébergement pour Personnes Agées Dépendantes*, EHPAD*,* for the elderly).

According to these definitions of health care institutions, the classification of hospital activity is:

- Acute care (MCO) activities;
- Mental health hospitals;
- Rehabilitation care;
- Long-term care.

The French definition of a hospital is close to the OECD definition[8].

[7]http://www.legifrance.gouv.fr/affichCode.do;jsessionid=6C02EE194BAA3A325BB048570E4BA387.tpdjo03v_2?idSectionTA=LEGISCTA000006171442&cidTexte=LEGITEXT000006072665&dateTexte=20091109

1.2 Organisation

Hospital planning

The regional hospital agencies (ARH, soon to be replaced by regional health agencies (ARS) in spring 2010) are responsible for hospital planning (for both public and private hospitals), financial allocation to public hospitals and adjustment of tariffs for private for-profit hospitals (within the framework of national agreements). At regional level the health services of the state and health insurance funds, which previously shared management of this sector are brought together.

Within the health care sectors, the chief executive of the ARH decides on the quantitative parameters, in terms of bed/population ratios, for each discipline: medicine, surgery, obstetrics, psychiatry, follow-up care and rehabilitation and long-term care. All proposals for establishing new beds or changing the use of existing ones, whether in public or in private hospitals, are subject to authorisation by the ARH.

Since 2003 the government has been using a planning tool called **regional strategic health plans** (*Schéma Régional d'Organisation des Soins,* SROS). The SROS can be considered as an instrument of a qualitative approach. They set out the goals for the development of regional provision over a five-year period, in areas corresponding to national or regional priorities. For example for the 1999–2004 period the SROSs defined who is in charge of the provision of emergency care, perinatal care and cancer. The focus on these three areas illustrated a trend in hospital policy promoting networks of hospitals within a region, in which each hospital cooperates to provide care at the level most appropriate to its technical capacity.

The SROS for each health care area sets up objectives to improve the organisation of care and proposes the development of activities, restructuring and cooperative measures. It also provides the ARHs with a framework for granting authorisations, approving proposals submitted by institutions and negotiating the contracts that ARHs must enter into with every hospital in the region – whether public, private non-profit or private for-profit.

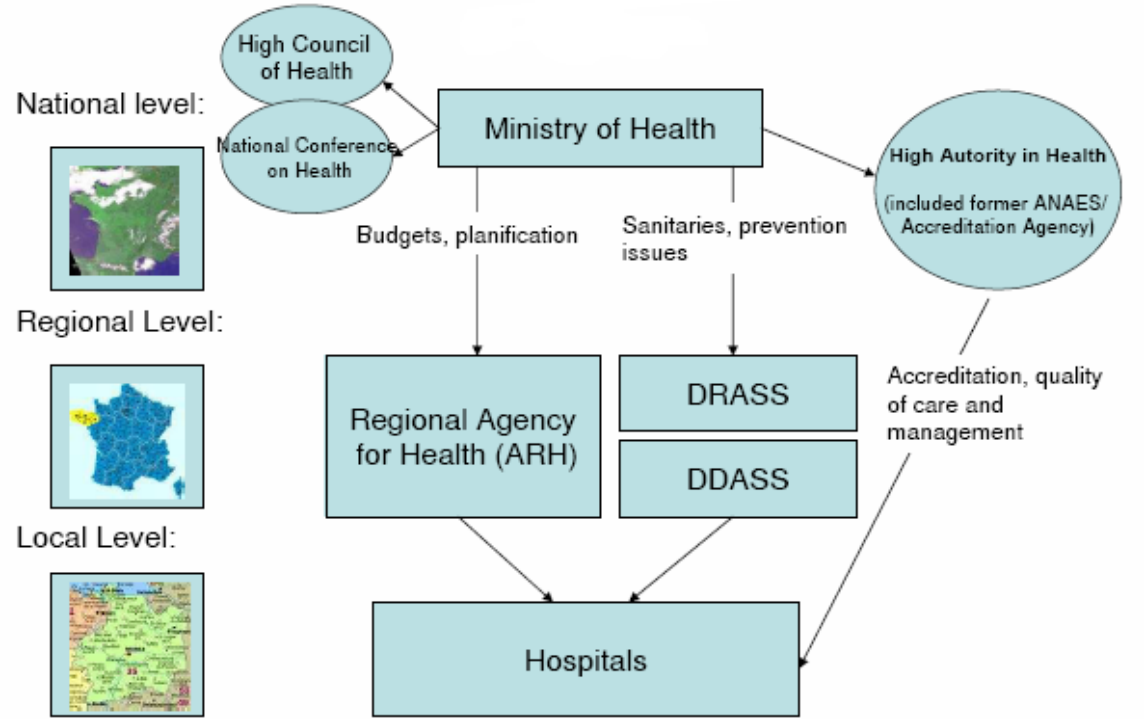
ARH contracts with public hospitals set out goals and commitments for the hospital for three to five years. Some commitments relate to the provision of medical services, which should be

[8] 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.

consistent with the SROS, but they may also concern the quality of care, information systems, management efficiency, etc. The contract determines the way in which hospital projects will be funded. If the hospital is not considered efficient enough, it will have to generate resources by increasing its productivity; if it is considered to be very efficient it will be allocated additional resources by the ARH.

The **National Authority for Health** (*Haute Autorité de Santé,* HAS) is in charge of granting the **accreditation** process for all hospitals, both public and private. The institution is also responsible for quality of care management.

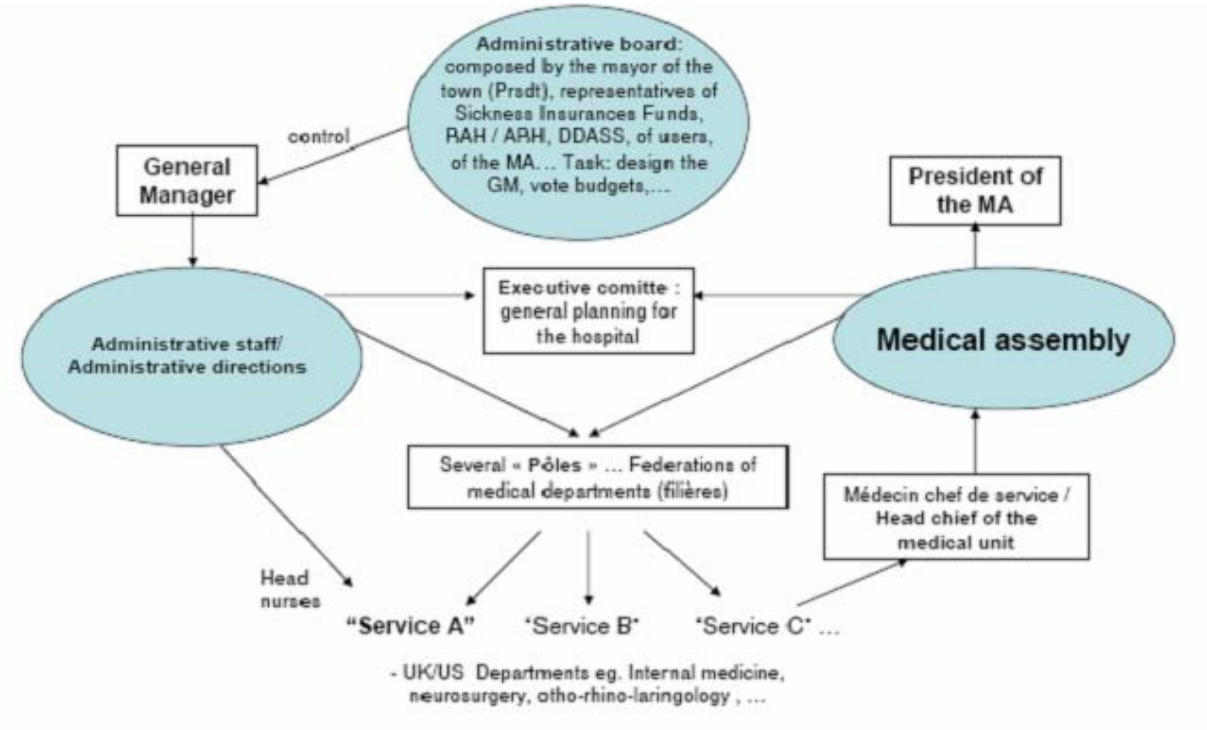
Figure 1.1: France – Governance and regulation of public hospitals, 2007



ANAES = Former evaluation agency, ARH = Regional agency for health, DDASS = Local social services direction / Direction départementale des affaires sanitaires et sociales, DRASS = Regional social services direction / Direction régionale des affaires sanitaires et sociales

Source: http://www.europhamili.org/protect/media/127.pdf

Figure 1.2: France – Example of the organisation of a public hospital, 2007



RAH/ARH = Regional Hospital Agencies, DDASS = Local social services direction / Direction départementale des affaires sanitaires et sociales, MA = Medical assembly

Source : http://www.europhamili.org/protect/media/127.pdf

Counting of hospitals

It is important to note that the public hospitals are counted regarding their legal status not regarding their facilities or as geographical entities, meaning a public hospital may group several hospitals not located close by each other. So the number of public hospitals is underestimated of about 1% compared to the private ones[9].

Classification of hospitals

There are **five specific categories of public hospitals** (972 in 2007), excluding overseas departments; (cf. article 711-6 of CSP):

- 29 regional and university hospital centres (*centres hospitaliers régionaux et universitaires*, CHR/CHU) which are in charge of four important missions: teaching and research, general hospital vocation for the population of the local area and more specialised care; they were introduced in 2004 in the field of the prospective payment system.
- 498 hospital centres (*centres hospitaliers généraux*, CH): hospital care activity for neighbourhood population;

[9] Source: L'hospitalisation et l'organisation des soins en France: enjeux et perspectives: données statistiques 2006 report

- 340 local hospitals (*hôpitaux locaux*, HL) which provide basic hospital care;
- 86 specialised hospital centres for mental healthcare (*centres hospitaliers spécialisés en psychiatrie*, CHS): one per county (*department*) with special vocation;
- 19 others public hospitals which include army hospitals, penal institutions and sanitary hospitals.

Public hospitals are public legal entities usually owned by local administrative units such as municipalities or counties (departments). Still they are administatively autonomous and financially independent.

There are for-profit and not-for-profit private hospitals, among which in 2006[10]:

- 43% were not-for-profit hospitals including:
  - 30% contracted to the public service (PSPH). Private hospitals contracted to the PSPH are private hospitals financed as public hospitals and as for the public sector, they are not allowed to refuse any patient;
  - and 13% are not participating to the PSPH; and
- 57% were for-profit private hospitals, commonly referred to as “cliniques”

For-profit private hospitals are specialised on acute care referred to as MCOs.

Among the private hospitals the subtypes of hospitals are (1,800 of entities in 2007):

- 751 acute care hospitals *(Établissement de soins de courte durée);*
- 20 cancer institutes *(Centre de Lutte Contre le Cancer,* CLCC*);*
- 240 mental health hospitals *(Établissement de lutte contre les maladies mentales);*
- 662 institutions for rehabilitation *(Établissement de soins de suite et de réadaptation);*
- 95 long-term care *(Établissement de soins de longue durée);*
- 32 other hospitals which include 85 radiotherapy hospitals (2004), 106 dialysis hospitals (2004) and 42 home care (2004).

[10] „Les établissements de santé, Un panorama pour l'année 2006“, 2008 report, http://www.sante.gouv.fr/drees/donnees/es2006/es2006.htm

Table 1.1: France – Key data on in-patient care, 2000 and 2004–2007

In-patient care	2000	2001	2004	2005	2006	2007
No. of hospitals[1]	n.a	3,025	2,890	2,854	2,813	2,772
Classified according to ownership						
- thereof public hospitals	n.a	1,011	994	987	977	972
- thereof private hospitals (incl. not-for-profit)	n.a	2,014	1,896	1,867	1,836	1,800
Classified according to subtypes						
- thereof general hospitals	n.a	1,821	1,706	1,681	1,646	1,618
- thereof mental health	n.a	332	327	327	326	326
- thereof speciality (other than mental health) hospitals	n.a	872	857	846	841	828
No. of acute care beds[1]	**240,817**	**235,933**	**226,803**	**224,030**	**224,168**	**222,194**
- thereof in the public sector	n.a	n.a	150,322	149,565	148,767	148,518
- thereof in the private sector	n.a	n.a	76,481	76,465	75,401	73,676
Average length of stay in hospitals (in days)	**13.2**	**13.5**	**13.4**	**13.4**	**13.2**	**13.2**
No. of hospital pharmacies	**n.a**	**n.a**	**n.a**	**n.a**	**n.a**	**2,639**
thereof no. of hospital pharmacies that serve out-patients	n.a	n.a	n.a	n.a	n.a	~90%

n.a = not available

[1] = excludes overseas departments if not stated otherwise

Source: Number of hospitals excluding overseas territories: INSEE[11], DREES [12]; number of hospitals, Acute care beds total and by sector from SAE for 2004-2007 [13] and OECD Health Data 2009 for 2000-01; Average length of stay : OECD Health Data 2009; Hospital pharmacies: CNOP[14]

In 2005 public hospitals accounted for about three quarters of the overall number of hospital beds[15], providing 81% of the general medicine beds and 63% of the gynaecology-obstetrics beds. Surgery beds are almost evenly divided between private and public hospitals (44% for the for-profit hospitals and 10% for private not-for-profit hospitals).

On the one hand, the number of acute care hospital beds has decreased over the last 18 years, reflecting the general decrease in the length of stay and the development of alternatives to usual hospitalisation. On the other hand, beds in long-term care institutions have

[11] http://www.insee.fr/fr/themes/tableau.asp?reg_id=0&ref_id=nattef06106&id=125

[12] http://www.insee.fr/fr/ffc/figure/NATTEF06106.xls

[13] http://www.sae-diffusion.sante.gouv.fr/Collecte_2007/usr%5C../usr/es2006.pdf

[14] http://www.ordre.pharmacien.fr/fr/bleu/index3.htm

[15] See DREES "Données sur la situation sanitaire et sociale en France en 2005", Annexe A au Projet de la loi de financement de la Sécurité Sociale pour 2005.

increased in recent years, in response to the needs of a growing number of dependent elderly people[16].

Compared activity public and private for-profit sectors

The private for-profit sector realises about 55% of the surgery activity and more than 75% of the out-patient surgeries. Their activity is concentrated on the least "heavy" 50 diagnosis related groups (GHM) (e.g. tonsillectomy, dental extractions, ligatures of veins, liberation of the carpal channel, etc.), as complicated and more cost predictable surgeries are handled by the for-profit private sector amounting to 70% of these cases.

While the public sector, including private non-for-profit hospitals, realises about 80% of the medicines, 66% of the obstetrics, and more than 90% of the emergency admissions (heaviest 50 GHM e.g. transplantations, grave multiple traumatism, cardio-thoracic interventions, pointed leukemia, etc.) are taken care in 71% cases by the public hospitals.

Hospital-only medicines

Table 1.2: France – Pharmaceuticals, 2000 and 2005–2009

Number of pharmaceuticals	2000	2004	2005	2006	2007	2008
Authorised pharmaceuticals in total	11,470	14,110	14,990	14,391	15,341	14,110
- thereof hospital-only medicines	n.a.	n.a.	n.a.	n.a.	n.a.	~2,700

n.a. = not available

Source: CNAMTS, AFSSAPS, hospital-only medicines estimate from theriaque database

Hospital-only medicines are defines by the Market Authorisation Commission (AMM Commission) (cf. section 3.1.).

Hospital pharmacies

According to Table 1.1 nearly all hospitals have a hospital pharmacy. About 90% of the hospital pharmacies are allowed to serve out-patients.

In France a specific list of reassigned medicines (retrocession) delivered by hospital pharmacies to out-patients (including medicines not available in out-patient pharmacies) exists. This restricted list of pharmaceutical specialties authorised for sale to the public from pharmacies in health institutions is defined in a decree by the Minister of Health at request of the phar-

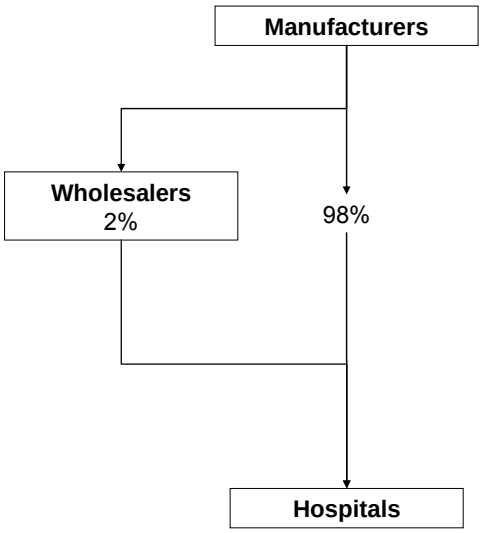
[16] According to the memo DHOC/O/n. 44 of February 4th 2004 on home-hospitalisation, in terms of handling capacity, the closure of 70,000 hospital beds over the past 10 years was accompanied by the creation of 48,000 part-time beds, to which we can add 4,200 spaces for home care. Beds for long term care represented, in 2002, 17.5% of total beds, compared to 10% in 1987. See DREES "Données sur la situation sanitaire et sociale en France en 2005", Annexe A au Projet de la loi de financement de la Sécurité Sociale pour 2005.

maceutical companies. It takes into account the risks associated with using the products and makes it easier to control stocks (see section 3.1 for further details).

Delivery chain

Pharmaceutical provision in hospitals is mainly managed directly between manufacturers and hospitals (98%); provision through wholesalers is rare (2%).

Figure 1.3: France – Pharmaceutical distribution channels in % of turnover at ex-factory price level (excluding overseas territories), 2006



Source: CSRP/LEEM

1.3 Funding

Since 1996 the parliament has annually voted on a **national ceiling for health insurance expenditure (ONDAM)** for the year to come, in the context of the debate on the Social Security Funding Act. Within the ONDAM, a **separate budget is defined for public hospitals** since the overall ONDAM ceiling once set is split by the government into four subtargets:

- health care in private practice, including:
  - payment for treatment provided in private practice (mainly out-patient care, but also private for-profit hospitals) by doctors, dentists, medical auxiliaries and biologists (that is, the fees of all self-employed professionals and professionals employed by private institutions); to this the fees of doctors practising privately in public hospitals are added;
  - prescriptions issued in private practice (for medicines, transport etc.) and disability allowances paid in case of inability to work;
- health care in **public hospitals**

- health care in **private for-profit hospitals** (apart from fees, included in the first part)
- social care (that is the cost of institutions and services for elderly and disabled people).

The State is responsible for the hospital sector, both public and private, and the medicine sector.

The budget is then divided between regions by the Ministry of Health, and the regional hospital agencies (ARH), allocate individual budgets to each hospital in the framework of regional resource allocation (see section 1.2 Organisation section for more details on planning and ARHs' role). At regional level the ARHs bring together the health services of the state and the health insurance funds and are responsible for

- hospital planning (for both public and private hospitals),
- financial resource allocation to public hospitals
- and adjustment of tariffs for private for-profit hospitals.

Table 1.3: France – Health and pharmaceutical expenditure, 2000 and 2004–2008

Expenditure (in million €)	2000	2004	2005	2006	2007	2008
Total health expenditure (THE)	**145,182**	**182,707**	**191,610**	**199,228**	**208,441**	n.a
- thereof THE public	115,252	144,843	151,864	157,649	164,649	n.a
thereof THE private	29,930	37,864	39,746	41,579	43,792	n.a
THE in hospitals (HOSHE)	**55,673**	**67,204**	**70,833**	**73,909**	**77,144**	**n.a**
thereof HOSHE public	52,537	63,469	66,817	69,498	72,392	n.a
thereof HOSHE private	3,136	3,735	4,016	4,411	4,752	n.a
Total pharmaceutical expenditure (TPE)	**23,948**	**30,723**	**32,047**	**32,568**	**34,055**	**n.a**
- thereof TPE public	16,026	21,265	22,256	22,576	23,625	n.a
- thereof TPE private	7,922	9,458	9,791	9,992	10,430	n.a
Pharmaceutical expenditure in hospitals (HOSPE)[1]	**n.a**	**n.a**	**n.a**	**4,800**	**4,900**	**5,450**
- thereof HOSPE public	n.a	n.a	n.a	n.a	n.a	n.a
- thereof HOSPE private	n.a	n.a	n.a	n.a	n.a	n.a

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

[1] at ex-factory prices

Source: OECD Health Data 2009 - Version: June 2009, HOSPE from CEPS activity report 2008[17]

Hospital expenses accounted for 37% (€ 77 billion in 2007) of the total health care expenditure.

[17] http://www.sante.gouv.fr/ceps/doc/rapport_activite_ceps_2008.pdf

Health expenditures accounted for 11.0% of the GDP in 2007 (€ 208,4 billion). France ranks second in the world behind the United States (16.0%) and Switzerland (10.8%), in terms of health expenditures as a percentage of the GDP.

Activity-based costing of hospitals in France

A new mode of budgeting based on Diagnosis Related Groups (DRG) models, **the T2A system**, was first introduced on 1 January 2004 according to the Hospital Plan 2007 *(Plan hôpital 2007).* This activity-based payment system concerned both the private and public sectors. It only applies to the acute care activity, the so-called medicine, surgery and obstetrics (MCOs), dialysis and at home care. It was enlarged to all acute care which came into effect in 2008. This prospective payment directly links the medical activity to the financial support, instead of the global budget which was previously attributed to each hospital. The classification system is based on the principle of paying hospitals according to their activity in relation to homogeneous groups of patients (*Groupes Homogènes de Malades,* GHM).

DRGs tariffs are different in the public and private sector and planned convergence was postponed to 2018. The tariffs of not-for-profit hospitals can be multiplied by a geographical adjustment factor (e.g. + 7% for Paris and its region, + 5% for Corsica island and + 25 or 30% for outermost regions) and the tariffs of for-profit hospitals are multiplied by each hospitals' individual correction factor. It also includes specific financial mechanisms for outliers, critical care and expensive medicines.

In not-for-profit and public hospitals all health professionals salaries are included in the *Groupes Homogènes de Malades* (GHM) system but doctors' fees are not included in the GHM-tariffs for for-profit hospitals.

The French DRG/GHM version 11 release includes four levels of severity and over 2,300 groups.

In addition to the French DRG prospective payment tariffs, hospitals that undertake for example prevention, research and training activities can benefit from an additional budget called *Missions d'intérêt général et d'aide à la contractualisation* (MIGAC) and that can be divided in three parts:

- A budget for the Missions of General Interest (MIG), about 7% of the total budget for a general hospital (7%) compared to the part of GHM payment;
- A budget for university hospital, for teaching, research and innovations called *Missions d'Enseignement, Recherche, Référence et Innovation* (MERRI);
- A budget called contractual support (*aide à la contractualisation*) that corresponds to a policy of setting up contract-based links between ARH and hospitals.

The institution responsible for updating and monitoring the French DRG system is the French Technical Agency for Hospital Information *(Agence Technique sur l'Information Hospitalière,*

ATIH*)* which cooperates with a specific commission of experts. ATIH is in charge of conducting the national cost studies and reviewing the international literature.

Co-payments for medicines in hospital care

The basic rule is that hospital treatment costs are reimbursable through the social security system at a rate of 80% of official rates. Still full coverage (100%) concerns situations in which a technical act which value is over € 91.- is realised on the patient during his stay, length of stay over 30 days, pregnancy, low income patients, long-term or major illness or hospitalised as a result of an accident at work. In fact, most medicines used during hospital stay are fully covered.

The other main ineligible costs are caused by two fixed fees, that may be reimbursed by complementary health insurance:

- A charge of € 18.- per day for any stay over 24 hours (*forfait journalier hospitalier*), that is the responsibility of the patient;
- A charge of € 18.- per stay in case the costs of the hospital treatment exceeds € 90.- excluding radiology, biology, transport and stay over 30 days.

Among the pharmaceutical expenditure in hospitals (HOSPE), **about 40% of pharmaceuticals** used in hospitals are **integrated in the activity-based costing** (T2A) system. Basically, they are included in the lump sums which can be generated for reimbursement of the procedure and diagnosis-orientated case groups (DRG) in hospitals. A **supplementary list** (*liste en sus* or *non T2A* medicines), of **costly medicines excluded from the GHM system** has been developed and is reimbursed separately by the health insurance (cf. Table 1.4 and section 3.1 for further details). A third group of medicines referred to reassigned (*retrocession)*, is not included in the DRG system either.

Table 1.4: France – In-patient supplementary list of pharmaceuticals expenditure, 2000 and 2004–2008

Expenditure (in million €)	2000	2004	2005	2006	2007	2008
Supplementary list of pharmaceuticals expenditure in hospitals[1]	**n.a**	**n.a**	**n.a**	**1,785**	**2,075**	**2,400**
Share of supplementary list in HOSPE	n.a	n.a	n.a	37%	42%	44%
- thereof HOSPE public	n.a	n.a	n.a	1,338	1,575	1,850
- thereof HOSPE private	n.a	n.a	n.a	0,447	0,500	0,550

For medicines excluded from the DRG system (costly medicines on the supplementary list "*liste en sus*")

Source: CEPS activity report 2008[18]

[18] http://www.sante.gouv.fr/ceps/doc/rapport_activite_ceps_2008.pdf

2 Pricing

2.1 Organisation

2.1.1 Framework

This section presents the organisational structure and framework for purchasing medicines in hospitals and setting their prices in the in-patient sector.

In the in-patient sector in general the **prices are freely** set.

Between 1987 and 2003 there was no regulation of hospital medicine prices. Prices were unregulated and subject only to the regulatory framework of the public sector. Hospitals issued invitations to tender which were concluded within the law of supply and demand with pharmaceutical companies.

The law No. 2003-1199 from 18 December 2003 article 27-1 (in application as of 1 January 2005) regulates the **cost (expenses) of medicines** which is defined in article L 162-22-7 of the social security code (CSS), and **very expensive medicines are under control of the Economic Committee for Health Care Products** (CEPS) **by an agreement with the industry** or if no agreement is found the health minister fixes a level of reimbursement. This is not a price regulation but a cost (expenses) regulation. In fact the prices are not far from the reimbursed level because hospitals have no money to pay the gap between price and base of reimbursement by social security.

From 25 September 2008 until 31 December 2011 pharmaceuticals prices in the out-patient and in-patient sector are regulated by an "out-patient-in-patient" agreement (*Accord ville-hôpital*)[19]. Before 2008 the agreements for each sector, out-patient and in-patient, were distinct. The 2008 agreement is a merger of each previous out-patient and in-patient agreement so it regulates the cost of very expensive medicines for hospital use excluded the hospital budget and reassigned medicines (*rétrocession*) (cf. section 3.1.).

Hospitals decide on the products they want to purchase by means of creating formularies (in the frame of the official list of medicines that hospital are authorised to buy). In hospitals a committee is designed to establish formularies and to decide the type of products they need (cf. section 3.2). The official list is registered by the Minister of Health and published in the official bulletin according to article L5123-2 of the Public Health Code (CSP). This list is available at: http://www.medicfrance.sante.gouv.fr/

[19] http://www.leem.org/leem-image/leem/document/1372.pdf

The main purchasing policy is procurement by tendering however negotiations may also take place. Exceptions exist for very expensive medicines for which the level of reimbursement is defined by CEPS or the Minister (see above).

2.1.2 Hospital prices

There are no mark-ups because the prices are freely set.

There are no specific discounts. They are included in the free price level which means that commercial discounts may be freely negotiated between supplier and purchaser.

2.2 Pricing policies

2.2.1 Procurement

Public and private hospitals' purchases through calls of tenders comply with EU Directive No. 2004/17 and 2002/18 adopted on 31 March 2004. Local implementation is based on two regulations depending on the public or private status of the hospital:

- Public hospitals: Decree No. 2006-975 of 1 August 2006 applicable for public procurement contracts
- Private hospitals: Order (*ordonnance*) of 6 June 2005 and its application decrees related to procurement contracts for which the decree no. 2006-975 of 1 August 2006 mentioned above is not applicable.

Before adoption of the Directives 2004/17 and 2002/18, legal references were based on the Code for Procurement Contracts and the Decree No. 2001-210 of 7 March 2001. In addition, an explanatory text was published by the Ministry of Health and specifically aimed at hospitals' managers: *Circulaire DHOS[20] /F4 no. 2000-474 du 15 septembre 2000 relative à l'organisation de la fonction achat et à la maîtrise de la commande publique dans les établissements publics de santé*.

Procurement scope

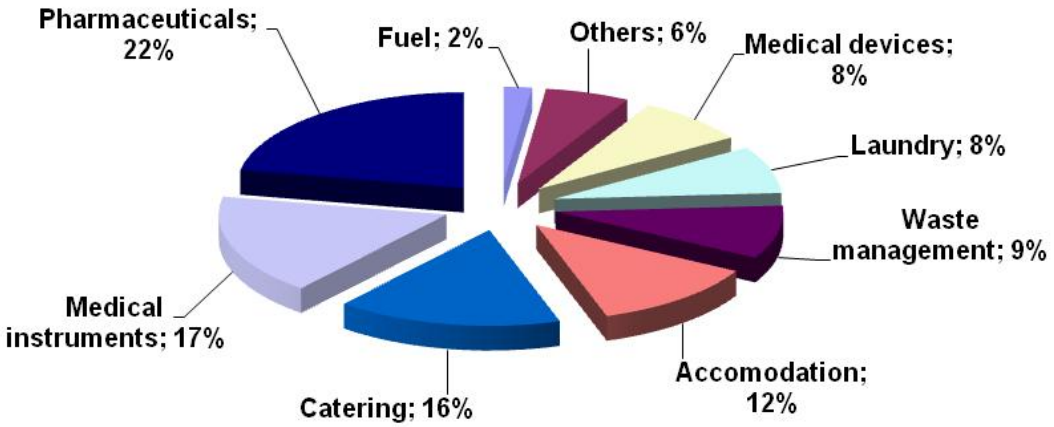
EU Directives 2004/17 and 2004/18 define financial thresholds for mandatory calls for tendering procedures.

[20] Department of hospital and health care organisation management of the Ministry of health and Solidarity / Direction de l'Hospitalisation et de l'Organisation des Soins

Cumulative value of purchases of public and private French hospitals (excluding rehabilitation, psychiatry and geriatric hospitalisation structures) was estimated to € 27 billion in 2007. The public sector represents about half of this amount (€ 13 billion), the biggest actors being represented by the Assistance Publique – Hôpitaux de Paris (AP-HP), Assistance Publique – Hôpitaux de Marseille (AP-HM), Hospices Civils de Lyon (HCL) and the University Hospital of Nancy.

Medicines represent the first budget with a value of 22% of the total expenses, percentage reaching 30% when medical devices are added (statistics from public hospitals).

Figure 2.1: France – Public hospitals expenditures shares, 2007



Source: Union of public hospitals in France, FHF

Procurement organisation

Hospitals commonly use procurement by tendering for medicines. The way of purchasing is either done individually by hospitals or together with other hospitals as better deals are expected this way. A hospital can participate in different mutualised procurements for different products and services and can in parallel decide to initiate an independent call for tenders for other services or products by itself.

All thirty two Regional University Hospitals and the twenty largest General Hospitals created in 2005 a common structure called *Groupement de Coopération Sanitaire* "*Union des Hôpitaux pour les Achats" (*UNI.H.A)[21]. UNI.H.A. negotiates various products and services from medicines to laundry.

Many other mutualised structures dedicated to procurement contracts have been created, some being based on geographical distribution of hospitals such as *Réseau des acheteurs hospitaliers d'Ile de France* (RESAH-IDF)[22], others related to specialised care centers such

[21] https://www.uniha.org/

[22] http://www.resah-idf.com/

as for the Regional Cancer Centers (by federation of the *Centres de Lutte Contre le Cancer,* CLCC). The size of these procurement structures is variable; the minimum is represented by a unique isolated hospital having chosen to manage by itself some of its purchases independently.

Process

According to article L.592-2 of the French Public Health Code, pharmacists of hospital pharmacies are responsible for purchasing medicines and medical devices. This article specifies that the hospital pharmacy (*pharmacie à usage intérieur,* PUI) is in charge of managing, providing, controlling and dispensing medicines within the hospital.

The choice of medicines and medical devices is based on the hospitals' need of essential medicines chosen for their activities and listed in their therapeutic booklet (*Livret Thérapeutique*). Specific committees are established in all hospitals (*commissions du médicament et des dispositifs médicaux steriles,* COMEDIMS)) and are responsible for establishing this reference list (cf. section 3.2).

Criteria for accepting a tender

After marketing authorisation and validating the quality, safety and efficacy of the medicines (through the centralised, the mutual recognition or national procedures), marketing authorisation holders seek access to the hospital or ambulatory market by means of submitting a specific application to the French National Authority for Health *(Haute Autorité de Santé,* HAS). This Authority evaluates in particular both the actual clinical benefit (*service médical rendu*) and the clinical added value of the medicine (*amélioration du service médical rendu,* ASMR) vs. already marketed comparators.

Criteria for defining the list of medicines are related first to clinical needs, taking into account the clinical added value previously mentioned. Practicalities related to the use of medicines by nurses or their handling at the pharmacy can for example be also taken into account. Other elements such as the level of risk related to the supply chain can be considered during the selection process. All specifications should be transparently published when initiating a call for tender. An essential element to the final choice will eventually be based on the price.

Frequency

Procurement process takes place as needed but **usually on an annual basis**.

Publication

When required by regulation, the **tender is published** in the Official Journal of the European Union. Results of the procurement process can be shared, de facto when the procurement is a common mutualised process involving more than one hospital. Contractual provisions can introduce confidentiality of data due to commercial interests. The results of the procurement process are however published.

Information on prices

Partial **information on prices** is available for Health Insurance Funds and the Competent Authorities.

When considering the so-called medicine, surgery and obstetrics (MCOs) activities (cf. section 1.3), payments of hospitals are based on activities (DRG-derived system): each hospitalisation corresponds to a specific and predefined economical value depending in particular on the pathology causing the hospitalisation, medical acts performed and the duration of the hospitalisation. Costs of medicines are included in this value except for the so-called expensive products which can then be additionally reimbursed. Although in limited number (120 different products in 2008)[23], these medicines represent more than 60% of total expenses related to medicines in public and private hospitals.

At local level, total expenses are quarterly available by "expensive medicine" for each public hospital. For private hospitals, statistics on the use and expenses related to these expensive medicines are fully available in detail at local level (cf. sections 4 and 5).

In both public and private hospitals, these data are used to calculate differences between the maximum theoretical amount which could be reimbursed and the real price which could be negotiated by individual hospitals. In case of differences, and as an incentive measure to encourage price negotiations by hospitals, the benefit is equally shared between the hospital and the Health Insurance Fund.

2.2.2 Negotiations

Purchases of medicines which are not subject to procurement can be acquired independently by a hospital through unspecific commercial negotiation (after selection of products in hospitals' formularies).

[23] DREES Etudes et Résultats, N° 653, August 2008, « *Les médicaments hors tarification à l'activité dans les établissements de santé* », http://www.sante.gouv.fr/drees/etude-resultat/

3 Reimbursement

3.1 National hospital reimbursement procedure

In order to be commercialised a medicine must obtain **market authorisation** (AMM). In France the French Agency for the Health Safety of Health Products (AFSSAPS) is in charge of market authorisation upon advice from the Market Authorisation Commission (AMM Commission). This Commission, made up of scientific experts and directors from the different commissions of AFSSAPS, carries out a scientific and technical analysis of the data submitted by the pharmaceutical company filing the request with the AMM. The AMM defines the **hospital reserve**, the list of medicines to be only used in hospitals.

If a company applies for reimbursement by the sickness funds, the product may be marketed as soon as it obtains its AMM. However if it is to be reimbursed, a file must be completed for the transparency commission. The transparency commission is a consultative scientific entity composed of independent experts: general practitioners and medical specialists, pharmacists, methodological and epidemiological experts.

Since 2004, the transparency commission has been part of the French National Authority for Health (*Haute Autorité de Santé*, HAS). It gets involved following the initial request for inclusion of a product in the list of reimbursable medicines, for extensions of indications of products already included and for five yearly reviews. The transparency commission reviews data submitted by the manufacturer as well as existing literature.

The transparency commission also advises the Ministry of Health on whether a medicine should be approved for use in primary care or hospitals; if a medicine is licensed for group use, it is authorised for purchase by and use in hospitals; if it is licensed for primary care use, it may be used in general practice and also in hospitals; however some products, either due to their packaging or their dosage, are only licensed for group use. Medicines classified in the hospital reserve when they obtain AMM may only request a group licence. All of this information is published in the Advice of the transparency commission; this advice is transmitted to the Economic Committee for Health Products (CEPS). At this point the administrative process ends for most hospital medicines which are not subject to price regulation (non reassigned and inexpensive medicines as described below).

In France there are two lists of reimbursable medicines, i.e. positive lists:

- one list of reimbursable medicines for out-patient care and for the sales by pharmacies (*liste des medicaments rembursables agrees aux assures sociaux*)
- and a list for the hospital sector, the hospital reserve (*liste des medicaments agréés aux collectivites* or *réserve hospitalière*).

Pharmaceuticals sub-groups for reimbursement status

About 40% of pharmaceuticals used in hospitals are **integrated in the activity-based costing** system. Basically, they are included in the lump sums which can be generated for reimbursement of the procedure and diagnosis-orientated case groups (DRG) in hospitals. A **supplementary list**, "*liste en sus*" or ""*non T2A*" pharmaceuticals, of **costly medicines excluded from the DRG system** has been developped and is reimbursed separately by the health insurance (see below for details). A third group of pharmaceuticals referred to reassigned, "*rétrocession*", is not included in the DRG system either.

The idea of this **supplementary financing for costly pharmaceuticals** is to guarantee equitable access to the most innovative pharmaceuticals which would introduce considerable variation in the distribution of DRG costs, either because of the very expensive nature of these pharmaceuticals, or because the number of patients consuming these pharmaceuticals is marginal within the DRG.

In 2008 this list of costly medicines contained about 120 active molecules[24], particularly anticancer pharmaceuticals, blood products, orphan pharmaceuticals and some treatments for rheumatoid arthritis. This list is regularly updated, with new entries as innovative and expensive pharmaceuticals reach the market; in theory pharmaceuticals should be removed from this list and put back into the DRG system when they begin to be used more widely and/or their cost decreases. In 2008, these pharmaceuticals accounted for about 2.4 billion € with a growth rate of 16% compared to 2007 (CEPS activity report 2008).

Reassigning pharmaceuticals are delivered by hospital pharmacies to out-patients for pharmaceuticals not available from out-patient pharmacies. This restricted list of pharmaceutical specialities authorised for sale to the public from pharmacies in health institutions is defined in a decree by the Minister of Health at request of the pharmaceutical companies. It takes into account the risks associated with using the products and makes it easier to control stocks. Companies commercialising hospital medicines[25] not included in this list and which are used frequently in general practice are obliged to request certification for general practice and therefore have a price fixed by CEPS. In 2008, this list contained about 120 molecules. The establishment of this list was completed by setting a price ceiling for reimbursement of these products by Sickness Insurance. In 2008, reassigned pharmaceuticals accounted for about 1.2 billion € with a growth rate of 5% compared to 2007 (CEPS activity report 2008).

Pharmaceuticals reimbursement

The regulation of reimbursement basis price for medicines is as follows. The price is proposed by the company, this price then serves as a ceiling for reimbursement by Social Security (price registration procedure). This registered price may be opposed by CEPS during the following 15 days. In cases of non declaration or of opposition by CEPS (the main

[24] DREES Etudes et Résultats, No. 653, August 2008, *Les médicaments hors tarification à l'activité dans les établissements de santé*, http://www.sante.gouv.fr/drees/etude-resultat/

[25] Medicines included in the list of medicines being authorised for use in hospitals

reasons for refusal by CEPS are prices that are too high compared to the comparator medicines or prices elsewhere in Europe), the price is fixed by Ministerial decree. These specialties are then **reimbursed on the basis of this fixed price, known as the "cession price" or the "responsibility price"** (article R.5126-110 of the Public Health Code).

Reassigned and costly medicines cannot be charged to Sickness Funds above the cession price. If a health institution buys a medicine on the reassigned list or on the non T2A list at a higher price than the cession price, the difference in expenses is covered by the health institution. If a health institution buys one of the medicine specialties at a lower price than the declared price, it can charge for it on the basis of the declared sale price. In the case of reassigned medicines, the cost differential is absorbed by the institution. For expensive medicines, the bonus is shared between Sickness Funds and the institution: the institution is reimbursed by Sickness Funds on the basis of the amount billed by the hospital with a profit mark-up of part of the difference (profit sharing margin fixed at 50% by the decree of May 9 2005).

3.2 Hospital pharmaceutical formularies

Scope

At hospital level and according to article R.5126-48 of the French Code of Public Health, the Commission in charge of medicines and sterile medical devices is responsible to elaborate a list of medicines and medical devices (further referred to as hospital pharmaceutical formulary, HPF) of relevant use in the corresponding hospital (*commission du médicament et des dispositifs médicaux stériles,* COMEDIMS).

This commission is established in all public and private hospitals. The HPF locally defined is the reference list of medicines and devices which will be available on a routine basis in the hospital pharmacy.

Medicines appearing in the HPF are subject to marketing authorisation and must be cleared for hospital use by the National Competent Authority (*Haute Autorité de Santé*, HAS) (cf. section 3.1).

Payers

Except for a limited list of expensive products (cf. sections 3.1), funding is not based on medicines` consumption but on DRG basis. The National Health Fund, a mandatory and universal public insurance scheme applicable for all French legal residents and if applicable optional complementary private insurance scheme provides the main financial resources for public and private hospitals in France.

Decision-taking bodies/persons and process

According to article R.5126-48 of the Public Health Code, the hospitals' commission in charge of medicines and sterile medical devices, COMEDIMS, is composed of physicians, pharmacists, hospital managers, the chair of the committee in charge of nosocomial infections, a representative of the nurses, the local correspondents for pharmacovigilance, biovigilance and medical devices vigilance and a representative of the assistants to internal dispensing chemists.

Process and criteria

Criteria for defining the HPF are first related to clinical needs, taking into account previously defined clinical added value and clinical guidelines. Practicalities related to the use of medicines can be taken into account. The costs represent an important element of choice.

Medicines on the HPF

Each hospital has its own HPF. In these formularies all medicines available for use on a routine basis in the hospital appear. The use of the cheapest or generic products should be preferred. Special request which must remain exceptional could however allow availability of other products if clinically justified.

Updates

As a minimum a yearly update is recommended.

Publications and binding character

Such HPFs are widely available on paper and electronic format within hospitals. Prescription of medicines not included in the list should be properly justified on clinical grounds when equivalent products are not available in the HPF.

4 Consumption of pharmaceuticals

The only official source for pharmaceutical consumption data is the French National Competent Authority for Safety of Health Products (AFSSAPS), which every year publishes the analysis of the fiscal declaration by each manufacturer. But this publication publishes figures for the first fifty most sold pharmaceuticals on ATC level 2[26].

The Economic Committee for Health Care Products (CEPS) also publishes statistics in its yearly activity report detailing estimations of in-patient and out-patient pharmaceutical consumption since 2007 at ex-factory price level[27].

Some hospitals publish some data but no legal framework exists. Sometimes it is possible to see the top ten products by name or the top ten products at ATC5 level. Since 2005, the Directorate for Research, Analysis, Evaluation and Statistics (DREES) of the French Ministry of Health has been collecting data on consumption of pharmaceuticals through a global survey in French hospitals. In each hospital, information on prices and quantities are collected for each medicine.

Table 4.1: France – Pharmaceutical consumption, 2000 and 2004–2008

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008
Annual pharmaceutical consumption for the out-patient sector						
in packs (billions)	3.01	3.02	3.12	3.0	3.0	3.0
in DDD (Defined Daily Doses)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units (e.g. unit doses, please specify	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Annual pharmaceutical consumption in hospitals						
in packs (billions)	n.a.	n.a.	n.a.	n.a.	n.a.	0.4
in DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In other measures units (e.g. unit doses, please specify	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = Defined Daily Doses, n.a. = not available

Source: CNAMTS estimation

Table 4.1 shows the pharmaceutical consumption in the out-patient sector in France per year. In general pharmaceutical consumption is stable throughout the years and amounted to 3 billion packs in 2008.

[26] Afssaps report for 2008 : http://www.afssaps.fr/var/afssaps_site/storage/original/application/4f3d4a5ef9ebec8bf8feb4bff44ffdb2.pdf

[27] http://www.sante.gouv.fr/ceps/doc/rapport_activite_ceps_2008.pdf

Table 4.2 shows the top 10 pharmaceuticals by pharmaceutical expenditure and consumption in the year 2007.

Table 4.2 France – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption 2007

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure
1	PARACETAMOL	1	TRASTUZUMAB
2	DEXTROPROPOXYPHENE+PARACETAMOL	2	DOCETAXEL
3	FUROSEMIDE	3	RITUXIMAB
4	ELECTROLYTES SOLUTION	4	INFLIXIMAB
5	HEPARINE	5	OXALIPLATINE
6	POTASSIUM	6	OCTOCOG ALPHA
7	OMEPRAZOLE	7	IMMUNOGLOBULINE HUMAINE
8	PHLOROGLUCINOL	8	TRINOCETAN
9	MACROGOL	9	BEVACIZUMAB
10	ASPIRINE	10	CETUXIMAB

Source: CNAMTS estimation

5 Evaluation

5.1 Monitoring

Monitoring in the in-patient sector

Nationwide statistics on medicines are available at the French National Competent Authority for Safety of Health Products (AFSSAPS). These statistics are based on manufacturers' tax information and are published by active substances. Figures are published for the first fifty most sold pharmaceuticals only on ATC level 2.

There is no public source available on negotiated prices by medicines subject to procurement in the framework of hospital expenditures.

Monitoring at hospital level

Hospital internal budget management allows computing data available of the hospitals pharmacies precise volumes and expenses specific to individual medicines.

The link to precise patients and consequently disease(s) is possible at hospital level but not systematically and with various levels of difficulty depending on choices related to data management of electronic medical information. This link is always technically feasible for expensive medicines (although sometimes cumbersome).

Pharmacists are responsible for monitoring pharmaceutical consumption.

The information collected is particularly used by the pharmaceutical and therapeutic committee (PTC) in charge of medicines and sterile medical devices but also by finance directors and structures in charge of procurements.

IT support

It is variable depending in particular on the size, the variability of diseases treated and the processes applicable in the hospitals.

Role of hospital pharmacists

All the activities mentioned are in the spectrum of competences of the pharmacists in French hospitals. One of the main activity of pharmacists consists in validating the relevance of the prescription for which he/she will ensure delivery of the medicine. Unfortunately, many other activities such as daily management of the pharmacy, accountability duties, time consuming procurement procedures etc. do impact direct patients' health related activities (analysing the prescription, delivery of advice for promotion of good clinical practice, treatment compliance...) and should be subject to adequate time sharing and risk management.

Traceability / tracking of medicines

Hospital pharmacies ensure full tracking of their medicines.

5.2 Assessment

Cost-effectiveness / HTA reports

Health Technology Assessments for medicines are realised by the French National Authority for Health (*Haute Autorité de Santé*; HAS). After marketing authorisation, validating the quality, safety and efficacy of the medicines (through the centralised, the mutual recognition or purely national procedures), marketing authorisation holders seek access to the hospital or out-patient market. In order to do that they need to submit a specific application to the HAS. HAS is in particular in charge of evaluating both the actual clinical benefit (*service médical rendu*, SMR) and the clinical added value of the medicinal product (*amélioration du service médical rendu*, ASMR) vs. already marketed comparators. This evaluation based on predefined rules results in scaled values used in particular for defining the level of reimbursment by the National Health Fund and the medicines' prices[28].

Audit reports

Both public and private hospitals are subject to audits and certification (accreditation) procedures. The certification reports which include in particular information on the use of medicines are publicly available on the website of the French National Authority for Health.

Cost-containment

A national price cap is defined per medicines through a national convention between the pharmaceutical industry and the national authorities (*Accord cadre entre le comité économique des produits de santé et les entreprises du médicament*).

Moreover, there are several measures for cost-containment of expenditures related to the use of medicines in hospitals:

- The main source of revenues of both public and private hospitals is based on payments from the National Health Fund calculated on the basis of a predefined set of about 2,300 standard groups of patients (*Groupes Homogènes de Séjour,* GHS). These GHS represent a specific financial value. A specific and complex predefined algorithm allows to calculatefrom information such as disease characteristics, medical surgical or non-surgical acts performed during the hospitalisation, specific risk factors presented by the patient, etc. to evaluate the GHS applicable and by consequence the amount of money which will be transferred from the National Health Fund to the

[28] http://www.has-sante.fr/portail/jcms/c_5443/english?cid=c_5443

hospital after the end of the patient´s hospitalisation. As a majority of medicines' costs are included in the GHS value, hospitals are self-encouraged to negotiate prices.

- For specific expensive products officially listed[29], it is possible for hospitals to send additional bills to the National Health Fund in order to be reimbursed for the costs they have represented in patient's care. Their official price is published in the Official Journal. This price represents the maximum amount of reimbursement. In case the purchasing price is below the maximum level of reimbursement, the difference is equally shared between the hospital and the National Health Fund. This is another incentive to measure which should encourage price negotiation.

The negotiation power is very variable depending on the level of competitiveness in the specific pharmacological class. For some expensive recent and innovative products, cost of purchase by the hospital can be above the reimbursment limit, the difference being on the hospitals' charge, the latter being viable in large hospitals only, within certain limits.

Savings and other benefits

Results of savings evaluation are very variable depending on the volumes, the products, etc. but prove in all cases to be substantial for hospitals. Prices of medicines could drop to nearly half of initial ones in case of highly competitive markets zero indispensable medicines in monopolistic positions.

[29]http://www.afssaps.fr/Dossiers-thematiques/Tarification-a-l-activite-T2A-medicaments/Accueil-T2A/(offset)/0#med

6 Interface management

Need for interface management

There is a need for interface management and the HPST reform effective in 2010 should help improve it (see next section for more details on HPST reform). For example, in some cases of chronic diseases, expensive products are offered for free to hospitals in order that hospital doctors will initiate treatments which will last for years in the out-patient sector at high costs.

Interface management

Production and distribution of therapeutic guidelines based on evidence-based medicine are an essential basis for the rational use of medicines. Beside the use of good practices by health professionals, adequate evaluation of not only quality, safety and efficacy of medicines but also assessment of medical progress (clinical added value) is a key element for price negotiations. The evaluation of the clinical added value is distinct from price negotiations. In addition these two activities need different professional competences. In France the clinical added value is evaluated by the French National Authority for Health and can be used during price negotiations.

In addition, the National Health Fund is acting through its local offices and dedicated teams of representatives to communicate and promote good clinical practices, in particular in hospitals, expecting results in better care and optimised expenses.

7 Developments and outlook

In France, since the nineties, hospital organisation has been under permanent and important evolution through successive reforms. Since then, this trend has been amplified: first by the the “Hôpital 2007” reform and then by the “Hôpital 2012” reform, now conducted by the present Minister of Health.

Hospital, patients, health and territories (*Hôpital, patients, santé et territoire,* HPST*)* is the official name of a French bill presented on 22 October 2008 by Roselyne Bachelot-Narquin, Minister of Health and Sports. The bill was initially introduced to modernise the French hospital system, but in fact proposes a full reform of the health system, establishing full and complete State responsibility at regional level by means of the setting up regional health agencies (ARS) that will have full authority over all health issues.

The HPST reform has the objective to set a global organisation of health care, in every sector of public health. It has started with an in depth reappraisal of the national situation based upon four reports: hospital organisation (Rapport Larcher), primary care (*Etats Généraux de l’Organisation des Soins*, EGOS), equality of access to the care system (Rapport Flajolet), personnal medical record (*Dossier Medical Personnel*, DMP).

Afterall, the main lines and planned objectives of the reform are as follow[30], [31]:

1- to **create in each of the 22 regions in France in 2010, a Regional Health Agency** (*Agences Régionales de Santé,* ARS) in charge of regulating care organisation. ARS will be specifically in charge of the organisation of a new level of hospital organisation, the so called **local hospital communities** (*communités hospitalières de territoires*, CHT) as to facilitate sharing of advanced technology and medical expertise; this fits along the line of regional optimisation of care. The idea is to concentrate complex interventions in high volume hospitals and transfer small local hospitals to take care of less complex medical and medico-social care by regrouping a range of small and big hospitals on the basis of complementarity of competencies.

2- to **redefine the care objectives of each hospitals** according to their technical competence and flow of activity. Each hospital will receive accreditation to precise objectives depending on the safety of care which can be ideally provided to the patient population. Small local hospitals will be closely linked to larger reference centers and devoted to primary prevention, tertiary care and eldery persons´ housing.

3- to **reformulate the governance inside the hospital** by the creation of a “*Directoire*” composed of medical doctors and administrative directors, working under the authority of a president (*Président du Directoire)*.

[30] European association of senior hospital physicians http://www.aemh.org/pdf/AEMH08-040NationalReportFrance_000.pdf

[31] Or, Zeynep. "New regional health governance". *Health Policy Monitor*, October 2008. Available at http://www.hpm.org/en/Surveys/IRDES_-_France/12/New_regional_health_governance.html

4- to modify the functions and organisation of the "*Conseil d'administration*" towards a "*Conseil de Surveillance*", according to the new transversal inter-institutional territorial organisation. This council is responsible for the hospital budget and the local mayor will no longer automatically be part of the "*conseil de surveillance*".

5- Moreover, the **rules of management in public hospitals** will be **simplified** and hospital directors will have real autonomy in management with better defined objectives and result-based evaluation. One novelty is that they will have more flexibility in recruitment decisions with the possibility of establishing part time contracts with private practitioners. The modes of remuneration for doctors will also be more flexible.

The **priority of ARS** will be to improve the healthcare organisation by removing barriers between the out-patient, hospital and socio-medical sectors, and by promoting overall cross-disciplinary patient management, especially in cross-disciplinary health institutes. These agencies will further supervise the implementation of regionalised public health policies.

The ARS will oversee a large number of health services, currently run by several agencies, including public health insurance funds. There will be one ARS per region in France and will be headed by the region's prefect. This will rearrange the facilities of several hospitals to respond to the needs of the local population - with many becoming specialist facilities.

ARS will be able to organise conventions with private health groups to share facilities such as research labs, scanners and emergency wards. Besided hospitals and government functions, the ARS will also be in charge of retirement homes, primary doctors and disease prevention projects.

Each hospital will have to sign an annual contract with RHAs to secure funding and setting out specific activity and quality objectives.

The latest planned project of the Finance Law of the Social Security System 2010 (LFSS) is to allow the development of shared hospital pharmacies (*pharmacie à usage intérieur,* PUI) for care centers for dependent elderly people (EHPAD) without an internal pharmacy from 1 January 2011. These pharmacies will be managed by the social and medico-social groups (*Groupement de Coopération Sociale et Médico-Sociale,* GCSMS), on behalf of the EHPAD.

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