PHIS Pharma Profile

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Executive Summary

Health care system

The French health care system is a mix of a Bismarckian approach with Beveridge goals reflected in the single public payer model, the current increasing importance of tax-based revenue for financing health care and strong state intervention. The French public health insurance system currently covers almost 100% of the resident population. It was implemented in 1945. Coverage is based on a work-related basis and the system is divided into three main schemes:

- The general scheme for employees in the industry, business and services sectors covering 85% of the population.
- The agricultural scheme for farmers, about 7% of the population is covered.
- The scheme for self-employed workers, about 5% of the population covered.

The system also includes a number of other special schemes (sailors, miners, railway, etc.).

The financing of statutory health insurance varies from scheme to scheme. The financing of social security in general, and of health insurance in particular, depends on two main sources[1]: social contributions (48% of the funding) based on earnings and taxes (49%).

Health expenditure accounted for 11% of the GDP in 2008. Public total health expenditure (PE) accounted for 77% of the total health expenditure (HE) in 2008. The remaining 23% from private expenditure included 14% of expenses for private health insurance and 9% of out-of-pocket payments (OPP) (including co-payment and self-medication, cf. 3.2.4.2) of households.[2] Private health insurance in France corresponds to complementary health insurance which patients subscribe to on a (usually) voluntary basis. In 2008, a total of 94% of the population is covered by complementary health insurance, including 6% covered by the free Complementary Universal Health Insurance Coverage (CMUC), provided for people with low incomes[3].

In 2008, health expenditure accounted for € 122,2 billion in out-patient sector and € 89,2 billion in in-patient sector.

Primary care and secondary care are largely developed in France and offer a wide variety of services. Since 2005, a patient must choose a referring doctor, a GP or a specialist, called “médecin traitant” which acts as a gatekeeper for access to specialist care. If s/he refuses to do so, reimbursement will be decreased by 40%.

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[1] Figures from LFSS 2011, annex 4 : http://www.securite-sociale.fr/chiffres/lfss/lfss2011/2011_plfss_annexe_4.pdf

[2] National health accounts 2009 (CNS 2009) : http://www.sante.gouv.fr/comptes-nationaux-de-la-sante-2009.html

[3] IRDES, ESPS survey:
http://irdes.fr/EspaceEnseignement/ChiffresGraphiques/CouvertureComplementaire/DonneesGnles.html

In the in-patient sector, an performance-based payment is in place since 2004. Financing is based on diagnosis related groups (DRG) models, the so-called *T2A* system. It concerns both the private and public sector but excludes local hospitals, specialised hospitals centres for mental healthcare and army hospitals. It only applies to acute medical and surgical care, the so-called MCOs (Medicine, Chirurgy, Obstetrics) activities, dialysis and at home care. DRGs tariffs are different in the public and private sector and planned convergence was postponed to 2018. In addition, 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*).

Pharmaceutical system

The key actors of the pharmaceutical system are:

- The French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Produits de Santé, AFSSAPS), through a Market Authorisation Commission, is responsible for granting market authorisation. The agency is also in charge of classification, vigilance and advertisement control.
- The French National Authority for Health (Haute Autorité de Santé, HAS), through the Transparency Commission (Commission de la Transparence), is in charge of assessing therapeutic value and added therapeutic value of medicines and medical devices. The agency gives technical advice on including pharmaceuticals on the positive list of reimbursable medicines and issues recommendations. As of 2008, the HAS is also in charge of conducting pharmaco-economic evaluations.
- The Economic Committee for Health Care Products (CEPS) is in charge of negotiating prices for reimbursed medicines. The Economic Committee for Health Care Products (CEPS) sets reference prices (Tarif Forfaitaire de Responsabilité, TFR) and the prices of reimbursable medicines, as well as the prices of a list of hospital products (medicines outside performance-based costing system).
- The National Union of Health Insurance Funds (UNCAM) sets the reimbursement rates for reimbursable medicines.

In 2009 a total of 16,070 medicines were registered in France[4]. The increase of authorised medicines between 2000 and 2009 is mainly due to new market authorisation of generics.

The **industry's total sales** were € 50,013 Mio. in 2009: domestic sales accounting for € 21,000 Mio. and exports € 23,105 Mio. Domestic sales are broken down into € 19,538 Mio. of reimbursable products and € 1,912 Mio. of non-reimbursable products, which corresponds to an out-patient market of € 21,450 Mio. in total. Hospital sales amount to € 5,458 Mio.. **Parallel imports** of medicines are not significant in France with 52 market authorisations for 28 medicines in 2010.

[4] counting different pharmaceutical forms, dosages and pack sizes, but not including homeopathic products

There are 324 pharmaceutical companies based in France, which are all members of the Association of Pharmaceutical Industry (LEEM). This number includes 12 companies specialised in generics, members of the trade association Generic Producers Association (Association des Fabricants de Génériques, GEMME).

There are 7 wholesalers in France (excluding overseas departments) with 4 leading ones: OCP Celesio group (35.5% market share); Alliance Santé (26.5% market share); CERP: approximately 27% market share ; Phoenix Pharma (8.5% of market share).

By law, medicines in France are mostly sold through pharmacies which have de facto the monopoly. In 2009, the total number of pharmacies included 22,511 private pharmacies, about 120 dispensing doctors. Most hospital pharmacies may dispense medicines to out-patients.

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

Prices for reimbursable medicines are set by the Economic Committee for Health Care Products (CEPS), which is composed of representatives of the Ministry of Social Affairs (Ministère des Affaires Sociales, MAS), Ministry of Health, Ministry of Economy, Finance and Employement (Ministère de l'Economie, des Finances et de l'Emploi, MINEFE), compulsory Health Insurance Funds and complementary Health Insurance Funds.

Pricing policies in France include:

- statutory pricing for reimbursable products. Prices are negotiated between the Economic Committee for Health Care Products (CEPS) and pharmaceutical manufacturers, within a 3-year framework agreement known as "accord cadre", the current one being effective until 31 December 2012;
- free pricing for non-reimbursable medicines and most medicines approved for hospital use and for over-the-counter (OTC) medicines (Médicament en vente libre).

Prices are set at ex-factory level. Pharmacy retail prices (PRP) for reimbursable medicines (including wholesalers' and pharmacists' margins) are regulated as well.

Only medicines that provide an improvement in medical service or savings in the cost of treatment are eligible for reimbursement by the Health Insurance Funds (art. R 163-5 of the Social Security Code (Code de la Sécurité Sociale, CSS). The price of highly innovative medicines (Level of improvement of clinical benefit ("Amélioration du service médical rendu", ASMR) levels I to III) must be consistent with the prices of similar medicines in other European countries.

ASMR (Level of improvement of clinical benefit) has been rated on scale of levels I to V:

- ASMR I: major improvement (new therapeutic area, reduction of mortality)
- ASMR II: significant improvement in efficacy and/or reduction of side-effects
- ASMR III: modest improvement in efficacy and/or reduction of side-effects

- ASMR IV: minor improvement
- ASMR V: no improvement.

According to the framework agreement ("accord cadre") between the Economic Committee for Health Care Products (CEPS) and the Association of Pharmaceutical Industry (Les Entreprises du Médicament, LEEM), the price of medicines with Level of improvement of clinical benefit (ASMR) ≥ III should not be lower than the least expensive price observed in comparable European countries, i.e. Germany, Spain, Italy and the United Kingdom, over a period of five years starting from their inclusion in the positive list of reimbursable products.

For reimbursable medicines, wholesalers and pharmacists are remunerated through a regressive mark-up scheme. Both wholesalers' and pharmacists' margins are regulated. Margins are free for non-reimbursable medicines.

The standard value-added tax (VAT) rate in France is 19.6% on most products and services. The VAT rate is 2.1% on reimbursable medicines and 5.5% on non-reimbursable pharmaceuticals.

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

1. list of reimbursable medicines for out-patient care (i.e. for the sales by pharmacies)
2. list of hospital medicines for the hospital sector which included about 2,700 medicines in 2008.

- After assessment of medical service and improvement of medical service by the Transparency Commission, the Economic Committee for Health Care Products (CEPS) is in charge of the pricing procedure. Then the National Union of Health Insurance Funds (UNCAM) is in charge of setting the reimbursement rate.
- The positive list of reimbursable medicines which is determined by the Ministry of Health after receiving technical advice from the Transparency Commission and price decision from the CEPS. Only medicines that provide an improvement of medical service or savings in the cost of treatment are eligible for reimbursement.
- The National Union of Health Insurance Funds (UNCAM) has been in charge of defining the reimbursement categories since 13 August 2004 (Art. L322-2 and L182-2 of the Social Security Code (CSS). There are four reimbursement categories (cf. Table I). The reimbursement rate is based on HAS recommendation Clinical Benefit Assessment ("Service Médical Rendu", SMR) and seriousness of disease.

The following tables give an overview of the reimbursement categories and rates.

Table 0.1: France – Reimbursement categories of medicines, 2011

Reimburse-ment category	Reimbursement rate for		Description
	serious disease	non-serious dis-ease	
Major clinical benefit (SMR)	65%	30%	Normal rate determined by Minister of Health, UNCAM can modify it, +or - 5 points
Moderate clinical benefit (SMR)	30%		Normal rate determined by Minister of Health, UNCAM can modify it, +or - 5 points
Weak clinical benefit (SMR)	15%[5]		Rate determined by Minister of Health, UNCAM can modify it, +or - 5 points
Insufficient clinical benefit (SMR)	Not listed	Not listed	Not listed

SMR = clinical benefit, UNCAM = National Union of Health Insurance Funds

Source: Social Security Code (CSS)[6]

In France the reference price system (Tarif Forfaitaire de Responsabilité, TFR) in place concerns the generics sector, i.e. all medicines in a generic group[7] have the same level of reimbursement. The reimbursement limit called "tariff level" is often equal to the generic price[8] and the reimbursement rate is often based on this tariff. If a product under this scheme is more expensive than the "tariff" (reference price), the patient must make up the difference. The first list was implemented on 27 August 2003. A generic group is defined for all molecules of the same Anatomic Therapeutic Chemical (ATC) classification level 5, with the same dosage and the same packaging. The different reference price (TFR) level is modified by the Economic Committee for Health Care Products (CEPS). In 2010, 195 generic groups were under TFR among the 939 generic groups reffered to "le repertoire".

The list and the levels of tariffs are managed by the Economic Committee for Health Care Products (CEPS). The current policy of the Economic Committee for Health Care Products (CEPS) is to add a new group in the TFR list and the corresponding reference tariff each time a poor rate of substitution is observed for a generic group. This is combined with the actions of the National Union of Health Insurance Funds (UNCAM) upon generic substitution, through a convention with pharmacists.

Public pharmaceutical expenditure (PE) (social security and state or local funds) accounted for 66% of the out-patient pharmaceutical expenditure (PE) in 2009. The remaining 34% from

[5] New reimbursement rate since 16 april 2010 according to the list of medicines published in the official bulletin

[6] http://legifrance.com/affichCode.do?cidTexte=LEGITEXT000006073189&dateTexte=20080723

[7] A generic group is defined at Anatomic Therapeutic Chemical (ATC) classification level 5 for products with the same dosage and the same packaging.

[8] the price of the generic is regulated in France and is based on the price of the originator

private expenditure included 17% of expenses for private health insurance and 17% of out-of-pocket payments (OPP) (including co-payment and self-medication, cf. 3.2.4.2) of households.[9]

Regarding co-payment, the patient pays for a doctor visit € 1 out-of pocket with an annual maximum threshold of € 50. The patient also pays a fixed co-payment of € 0.50 for each pack of medicines with an annual ceiling of € 50. Children under 18 years old, socially disadvantaged patients covered under the Universal Health Insurance Coverage (CMU) or the State Medical Aidby (AME), and pregnant women under maternity coverage (begins at the 6th month of pregnancy) are exempted of these out-of pocket contributions. There is also a percentage co-payment for medicines, which is the difference between the rate of reimbursement and 100% reimbursement, but mostly reimbursed by complementary health insurances.

In France there are no pharmaceutical budgets being applied for doctors or other health care providers. Still, the **prescription volumes** or prescribing habits of general practitioners (GPs) and specialists are monitored by health insurance funds, after consultation with the French National Authority for Health (HAS). Since 2007, doctors have been able to see their prescription profile on the health insurance funds' website.[10]

Generic substitution has been allowed in France since 1999. The French Health Products Safety Agency (AFSSAPS) monitors the positive list of generic products and establishes groups which contain the original product and its generics. Within each group, substitution by a pharmacist is possible. Generic substitution is **voluntary**. Both doctor and patient may oppose generic substitution. However in that case, the patient will have to pay the price difference out-of-pocket. Generic substitution is promoted through:

- a financial incentive to pharmacists (higher margin);
- an agreement between the UNCAM and the union of pharmacists to increase the rate of substitution;
- the non-exemption of initial payment of the patient to the pharmacist (the system of direct payment by the health insurance fund to the pharmacist known as "tiers-payant" and applied in most situations);
- and through television (TV) advertising campaigns intended for consumers.

Since 1999, all manufacturers of medicines are possibly affected by the **claw-back system**. However, if they sign in an agreement with the Economic Committee for Health Care Products (CEPS), they are not affected by the clawback but have to pay a contribution, negotiated with the CEPS according to the "accord cadre". Under this agreement, the CEPS obtains the same amount of money as it is possible through the application of the law relating to claw-backs. If the turnover increases faster than a predetermined rate, the companies must pay part of this amount back to health insurance fund.

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9 National health accounts 2009 (CNS 2009)

10 http://www.ameli.fr/

Pharmacoeconomic studies are not required by law for including a product in the positive list. Since 2008, HAS has been in charge of conducting pharmaco economic studies. A new commission, the Economic and Public Health Evaluation Commission (CEESP- Commission d'Evaluation Economique et de Santé Publique) was created and pharmaco-economic reevaluations of statins, ACE inhibitors, angiotensin II antogonists and PPI were planned. This process is ongoing, HAS conducted a public consultation during the first quarter or 2011 on the methodology.

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

Prices of medicines in the out-patient and expensive medicines in-patient sector are regulated by a joint out-patient-in-patient" agreement (*Accord ville-hôpital*)[11]. Since 2003 **the Economic Committee for Health Care Products** (CEPS) has been regulating the **cost (expenses) of very expensive medicines by an agreement with the industry.** If no agreement is found the health minister fixes a level of reimbursement. This is not a price regulation but a cost (expenses) regulation.

Hospitals decide on the products they want to purchase by means of creating formularies (based on 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. 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/

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 as explained above.

In this framework, most hospital medicines are freely priced. There is, however, a list of particularly innovative pharmaceuticals for which prices are regulated. Hospitals carry out their own procurement, either through negotiations with the pharmaceutical industry, or through tendering. Some hospitals, usually operating in the same geographical area, group together in bulk-buying organisations to negotiate cheaper purchase prices. Since 2007 a public tendering procedure has been gradually implemented at national level for public hospitals. The prices granted by the pharmaceutical companies are significantly lower than those in the out-patient sector. It is up to each hospital to decide whether they want to publish their prices. Communication on prices is not compulsory.

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

1. one list of reimbursable medicines for out-patient care, i.e. for the sales by pharmacies (*liste des medicaments rembursables agrees aux assures sociaux, see section 3.2.2.2*)

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

2. and a list of hospital medicines for the hospital sector (*liste des medicaments agréés aux collectivites*). It includes about 2,700 medicines in 2008 (estimate from Theriaque database) which includes out-patient medicines use for in-patient care. There also exists a hospital-only medicines list (Médicament de la réserve hospitalière, HOM) which medicines can only be delivered for in-patient stay.

Since 2004, the transparency commission of the French National Authority for Health (HAS) 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 so-called "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".

About 40% of medicines used in hospitals are **integrated in the performance-based costing** system "*T2A"*. 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 DRG system** has been developed and is reimbursed separately by the health insurance (see below for details). A third group of medicines referred to reassigned, "*rétrocession*", is not included in the DRG system either.

The idea of this **supplementary financing for costly** medicines is to guarantee equitable access to the most innovative medicines which would distort the DRG cost either because of the very expensive nature of these medicines, or because the number of patients consuming these medicines is marginal within the DRG. In 2008 this list of costly medicines contained about 120 active molecules[12], particularly anticancer medicines, blood products, orphan medicines and some treatments for rheumatoid arthritis. This list is regularly updated, with new entries as innovative and expensive medicines reach the market; in theory medicines 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 2009, these medicines accounted for about € 2.5 billion with a growth rate of 4% compared to 2008[13].

"Reassigned" medicines are delivered by hospital pharmacies to out-patients since these pharmaceuticals are not available from out-patient pharmacies. This is a restricted list of pharmaceutical specialities authorised for sale to the public from pharmacies in health institutions. The establishment of this list was completed by setting a price ceiling for reimbursement of these products by Sickness Insurance. In 2009, reassigned medicines accounted for about € 1.45 billion with a growth rate of 11% compared to 2008[14].

The regulation of reimbursement (basis) price for in-patient medicines is as follows. The price is proposed by the company, this price then serves as a ceiling for reimbursement by Social

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12 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/

13 CEPS 2009

14 CEPS 2009

Security (price notification procedure). This notified price may be opposed by CEPS during the following 15 days. In cases of non declaration or of opposition by CEPS, 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"**. Reassigned and costly medicines cannot be charged to Sickness Funds above the cession price. If a health institution (e.g. hospital) buys a medicine on the reassigned list or supplementary list of medicines 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 notified price, it can charge for it on the basis of the notified sale price. In the case of reassigned medicines, the cost differential is borne by the institution. For expensive medicines, the excess 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% in 2005).

The basic rule is that hospital treatment costs are reimbursable through the social security system at a rate of 80%. Still full coverage (100%) is granted for situations in which a technical act which value is over € 120.- 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 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 € 24.- per stay in case the costs of the hospital treatment exceeds € 120.- excluding radiology, biology, transport and stay over 30 days.

The Commission in charge of medicines and sterile medical devices (*commission du médicament et des dispositifs médicaux stériles,* COMEDIMS) is responsible to elaborate a list of medicines and medical devices, the *Livret Thérapeutique* (further referred to as hospital pharmaceutical formulary, HPF) of relevant use in the corresponding hospital. This commission is established in all public and private hospitals. 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). Each hospital has its own HPF. In these formularies all medicines available for use on a routine basis in the hospital appear.

According to 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.

Table of content

List of tables and figures

List of abbreviations

ACE	Cngiotensin-Converting Enzyme / inhibiteur de l'enzyme de conversion
AESGP	Association of the European Self-Medication Industry
AFSSAPS	French Health Products Safety Agency / Agence Française de Sécurité Sanitaire des Produits de Santé
AFSSET	French Agency for Environmental Health and Safety / Agence Française de la Sécurité Sanitaire Environnementale et de Sécurité au Travail
AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ALD	Long-term illness / Affection de longue durée
AME	State Medical Aid / Aide Médicale de l'Etat
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
ARS / RHA	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
ATU	Temporary use authorisation / Autorisation temporaire d'utilisation
BMG	Bundesministerium für Gesundheit / Austrian Ministry of Health
CCAM	Common medical act classification / Classification Commune des Actes Médicaux
CEPS	Economic Committee for Health Care Products / Comité Economique des Produits de Santé
CERP	French wholesaler

CGPME	General Confederation of Small and Medium-sized Enterprises / Confédération Générale des Petites et Moyennes Entreprises
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
CHT	Local hospital communities / communités hospitalières de territoires
CIVAS	Centralized Intravenous Admixtures Service
CLCC	Cancer institute / Centre de Lutte Contre le Cancer
CMU	Universal Health Insurance Coverage / Couverture Maladie Universelle
CMUC	Fund for the Complementary Universal Health Insurance Coverage
CNAF	French National Fund for Family Allowances / Caisse Nationale d'Allocations Familiales.
CNAMTS	National Health Insurance Fund for Salaried Employees / Caisse Nationale d'Assurance Maladie des Travailleurs Salariés
CNAVTS	French National Elderly Insurance Fund for Elderly Salaried Employees Caisse Nationale d'Assurance Veillesse des Travailleurs Salariés
CNOP	Pharmacist professional board / Conseil National de l'Ordre
COG	Management and Objectives Agreement / Convention d'Objectifs et de Gestion
COMEDISM	Sterile pharmaceutical and medical appliances hospital comittee / Commission du Médicament et des Dispositifs Médicaux Stériles
CPG	Pluriannual Management Contracts / Contrats Pluriannuels de Gestion
CRDS	Social debt tax / Contribution pour le remboursement de la dette sociale
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
DAM	Health insurance representatives / Délégués d'Assurance Maladie

DDASS	Local social services direction / Direction départementale des affaires sanitaires et sociales
DDD	Defined Daily Doses / Doses Définies Journalières (DDJ)
DGOS	Department of health care supply of the Ministry of health and Solidarity / Direction Générale de l'Offre de Soins
DG SANCO	Health and Consumer Protection Directorate General
DHOS	Health care organisation directorate / Direction de l'hospitalisation et de l'organisation des soins
DMP	Patient medical record / Dossier Medical Personnel
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
EAHC	Executive Agency for Health and Consumers
EC	European Commission
EGOS	Meetings on health organisation / Etats Généraux de l'Organisation des Soins
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
FIT	Therapeutic information leaflet / Fiche d'Information Thérapeutique
FMF	Federation of Doctors in France / Fédération des Médecins 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
HTA	Health Technology Assessment
ID	Identification / Numéro d'identification personnel
IHHII	International Healthcare and Health Insurance Institute
INN	International Non-proprietary Name
INVS	National Institute for Monitoring Public Health / Institut National de la Veille Sanitaire
GDP	Gross domestic product
GEMME	Trade association Generic Producers Association / Association des Fabricants de Génériques
GP	General practitioner
HiT	Health systems in transition
HOM	Hospital-only medicine
HPF	Hospital pharmaceutical formularies
HPST	Hospital, patients, health and territories / Hôpital, patients, santé et territoire
LAP	Computer-assisted prescription software / Logiciels d'Aide à la Prescription
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
MAS	Ministry of Social Affairs / Ministère des Affaires Sociales
MCO	Medicine, Chirurgy, Obstetrics / Médecine, Chirurgie, Obstétrique
MEDEF	French Business Confederation / Mouvement des Entreprises Françaises
MERRI	Missions for teaching, research and innovations / Missions d'Enseignement, Recherche, Référence et Innovation
MIG	Missions of General Interest / Missions d'Intérêt Général
MIGAC	Missions for general interest and contractual support / Missions d'intérêt général et d'aide à la contractualisation
MINEFE	Ministry of Health and Social Security, Minister of Economy, Finance, and Employment / Ministère de l'Economie des Finances et de l'Emploi
NCU	National currency unit
NHS	National health service
NMEs	New molecular entities
Mio.	Million
OCP	French wholesaler
OECD	Organisation for Economic Co-operation and Development
ONDAM	National Target for Health Insurance Expenditure / Objectif National des Dépenses d'Assurance Maladie
OPD	Out-patient departments
OPP	Out-of-pocket payment
OTC	Over-the-counter medicine
PHIS	Pharmaceutical Health Information System
PE	Pharmaceutical expenditure
POM	Prescription-only medicine
PPI	Proton pump inhibitors

PPP	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
QALY	Quality adjusted life year
RESAH-IDF	In-patient procurement network for the Ile-de-France region / Réseau des acheteurs hospitaliers d'Ile de France
SAE	Annual statistics for hospitals / Statistique annuelle des établissements de santé
SEL	Practice in private professional corporation (company formed by self-employed practitioners) / Sociétés d'Exercice Libéral
SHI	Social health insurance
SML	Union of Self-employed Doctors / Syndicat des Médecins Libéraux
SMR	Clinical benefit / Service médical rendu
SROS	Regional strategic health plans / Schéma Régional d'Organisation des Soins
SUKL	Štátny ústav pre kontrolu liečiv / State Institute for Drug Control
SOGETI	SOGETI Luxembourg SA
T2A	Activity based payment / Tarification à l'activité (TAA)
TFR	Reference price system / tarif forfaitaire de responsabilité
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
VHI	Voluntary health insurance
WHO	World Health Organisation
WP	Work package

1 Health care system

This chapter provides an overview of the France's health care system as of 2011.

1.1 Demography

In 2009, the French population accounted for 62.1 million inhabitants. The life expectancy at birth was 81 years.

As a result of decreasing rates of fertility and increasing life expectancy, the French population is ageing. Today, one in six is over 64 years of age, compared with one in eight 30 years ago. Population ageing is set to continue as the "baby boomers" born after the Second World War reach old age.

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

Demography	2000	2005	2006	2007	2008	2009
Total population (million)	59,049	60,996	61,353	61,707	61,840	62,149
Population aged 0-14 (million)	11,121	11,234	11,270	11,318	11,308	11,366
Population aged 15-64 (million)	38,446	39,736	39,997	40,228	40,329	40,466
Population aged > 64 (million)	9,483	10,025	10,085	10,162	10,203	10,318
Life expectancy at birth	79.0	80.3	80.7	80.9	81.0	81.2
Life expectancy at age 65	19.34	20.07	20.68	20.92	21.01	21.19

Source: OECD health data (as of october 2010), EUROSTAT for life expectancy at age 65

1.2 Organisation

French social security system

The French social security system was first implemented in 1945. It aimed at providing compulsory protection against the risks of old age, illness, maternity, occupational accidents and family responsibility for trade and industry employees, funded by contributions collected from wages. In 1961, a compulsory health insurance scheme for farmers was implemented. In 1967, social security was split up into three separate branches, as shown here.

- Health branch: French National Health Insurance Fund for Salaried Employees (CNAMTS).

- Elderly branch: French National Elderly Insurance Fund for Elderly Salaried Employees (Caisse Nationale d'Assurance Veillesse des Travailleurs Salariés, CNAVTS).
- Family branch: French National Fund for Family Allowances (Caisse Nationale d'Allocations Familiales, CNAF).

In 1996, a social security reform plan implemented a "universal health insurance scheme" enabling the automatic right to social security for all people aged 18 and over who regularly live in France. Control of health expenditure (Dépenses de santé, HE) was also implemented. A new tax for funding public expenses of social care, the "contribution for reimbursement of social debt" (Contribution pour le remboursement de la dette sociale, CRDS) was levied on all types of income (not only wages) to ensure additional funding.

In 2000, a Universal Health Insurance Coverage (Couverture Maladie Universelle, CMU) was created for low-income people who cannot afford to become a member of a voluntary health insurance (Assurance complémentaire, VHI) scheme. The Carte Vitale (individual health ID smart card for all people aged 16 and over) was introduced.

In 2004, the particularly worrying financial situation of the health insurance system led the Government to take action regarding the organisation of the health care and the control of health expenditure (HE), as well as changes in the National Insurance Fund for Salaried Employees' (Caisse Nationale d'Assurance Maladie des Travailleurs Salariés, CNAMTS) managerial bodies. The overall objective of the reform was called "better care through better expenditure".

The French health insurance system is based on three main principles:

- equal access to treatment for all citizens, regardless of their place of residence and income;
- quality of treatment;
- solidarity – everyone must contribute to the health insurance scheme according to their income and receive care according to their needs.

The health insurance system is divided into three main schemes, as listed here.

- The general scheme, which covers employees in the industry, business and services sectors, covers 85% of the French population. It is managed by the National Insurance Fund for Salaried Employees (CNAMTS).
- The agricultural scheme, which covers farmers and farm employees (about 7% of the popluation covered), is managed by the Agricultural Mutual Insurance Fund (Mutualité Sociale Agricole, MSA).
- The scheme for non-salaried and non-farming, self-employed workers (about 5% of the popluation covered), which covers craftspeople, retailers and independent professions, is managed by various organisations belonging to the National Insurance Fund for Self-employed Workers (Régime Social des Indépendants, RSI).

The system also includes a number of other special schemes (sailors, miners, railway employees, Paris public transport employees, employees from the Electricity and Gas Board, etc.)

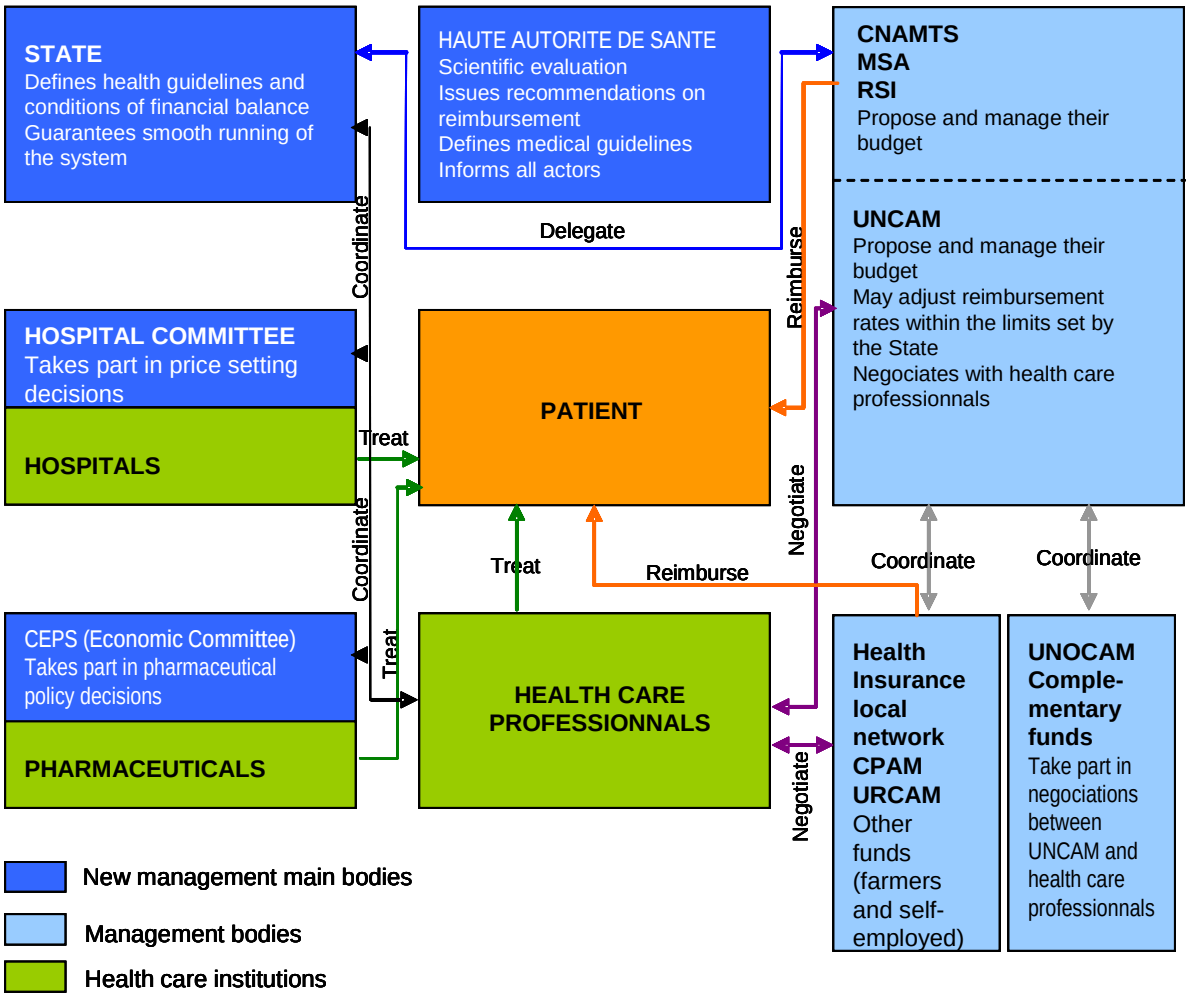
The new organisation mechanism for steering the health insurance system involves (as of 13 August 2004) the steps set out here.

- The creation of the National Union of Health Insurance Funds (Union Nationale des Caisses d'Assurance Maladie, UNCAM), which is a new body bringing together the three major health insurance schemes in order to:
  - run the conventional policy (i.e. the agreements between the Health Insurance Funds and the health care providers);
  - define the scope of services eligible for reimbursement;
  - set up the health care reimbursement rate.
- Extended powers for the National Insurance Fund for Salaried Employees (CNAMTS) Managing Director, who:
  - is also the Managing Director of the National Union of Health Insurance Funds (UNCAM) and carries out National Union of Health Insurance Funds (UNCAM) missions within the framework of adopted guidelines and within the given term of office;
  - appoints managers and accountants for the bodies;
  - takes the necessary measures for the successful organisation and steering of the network;
  - negotiates the Management and Objectives Agreement (Convention d'Objectifs et de Gestion, COG) with the State and the resulting Pluriannual Management Contracts (Contrats Pluriannuels de Gestion, CPG) with the bodies;
  - may suspend or cancel the decision of a Council or of a local or regional body which would not be aware of the commitments concluded in the Management and Objectives Agreement (COG) or a Pluriannual Management Contract (CPG).
- The reorganised National Insurance Fund for Salaried Employees (CNAMTS) Council:
  - is marked by the return of employers' representatives and open to representatives of mutual insurance companies and other institutions in the health insurance sector
  - has been set up to define the risk management policy guidelines and to clarify the modalities for implementing the health care policy and organisation of the health care system.
- The creation of the French National Authority for Health (Haute Autorité de Santé, HAS):
  - as the body created to propose the scope of reimbursable treatments;
  - which conducts periodic evaluations of medical services, draws up recommendations for good medical practices and conducts on pharmaco-economic evaluations,
- Better representation of the Health Insurance System within the Economic Committee for Health Care Products (Comité Economique des Produits de Santé, CEPS), which:
  - sets up the price of medicines;

- establishes the “Tarif forfaitaire de responsabilité” (fixed amount on the basis of which Health Insurance Funds reimburse some groups of generic medicines, “reference price”).

For further information, please refer to the document entitled “The General Health Insurance Scheme”, published by the National Insurance Fund for Salaried Employees (CNAMTS) in 2006.

Figure 1.1: France - Main actors in the health care system, 2009/2010



CEPS = Comité Economique des Produits de Santé (Economic Committee for Health Care Products), CNAMTS = Caisse Nationale d’Assurance Maladie des Travailleurs Salariés (National Health Insurance Fund for Salaried Employees), CPAM = Caisse Primaire d’Assurance Maladie (Local health insurance of CNAMTS) HAS = Haute Autorité de Santé (National Authority for Health), MSA = Mutualité Sociale Agricole (Agricultural Mutual Health Insurance Fund Health (for farmers and farm employees), RSI = Régime Social des Indépendants (National Insurance Fund for Self-employed Workers), UNOCAM = Union Nationale des Organismes d’assurance maladie Complémentaires (National Union of Complementary Health Insurance and Mutual Funds), URCAM = Union Régionale des Caisses d’Assurance Maladie (Regional Union of Health Insurance Funds (equivalent of UNCAM at regional level)

Health care organisation

The regional health agencies – RHAs (*Agences Régionales de Santé* – ARS) created in spring 2010) are responsible for in-patient and out-patient organisation for both public and private sectors. The implementation of these agencies being on-going, we describe their legal framework only.

In France, since the nineties, hospital organisation has been under permanent and important development through successive reforms. Since then, this trend has been amplified: first by the the "Hôpital 2007" reform and then by the "Hôpital 2012" reform.

The on-going reform of health care organisation being implemented is based on hospitals, patients, health and territories (Hôpital, patients, santé et territoire, HPST), bill presented on 22 October 2008 by the Minister of Health and Sports. The bill was initially introduced to modernise the French hospital system, but in fact is 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 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[15, 16]:

1- to **create in each of the 22 regions in France implemented in spring 2010, a Regional Health Agency** (*Agences Régionales de Santé,* ARS) in charge of regulating care organisation. ARS are 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.

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

[16] 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

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)*.

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** are being **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** are 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 oversee a large number of health services, currently run by several agencies, including public health insurance funds. There is one ARS per region in France.

ARS are able to negotiate and sign conventions (i.e. agreements) with private health groups to share facilities such as research labs, scanners and emergency wards. Beside hospitals and government functions, the ARS are also be in charge of retirement homes, primary doctors and disease prevention projects.

Each hospital will have to sign an annual contract with the RHA of its region to secure funding and setting out specific activity and quality objectives.

Since 2003 the government has been using a planning tool called **regional strategic health plans** (*Schéma Régional d'Organisation des Soins,* SROS). The SROS could be considered as an instrument of a qualitative approach. They set out the goals for the development of regional provision over a three-year or 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 care. 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. ARS 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 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.

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.

1.3 Funding

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

1.3.1 Health expenditure

In 2008, total expenditure on health in France was estimated at € 217 billion which included € 169 billion of public expenditure. The out-patient expenditure accounted for € 122 billion in 2008 while hospital expenses accounted for 41% (€ 89 billion in 2008) of the total health care expenditure.

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

Health expenditure in million Euro	2000	2005	2006	2007	2008	2009
GDP	1,441,372	1,726,068	1,806,430	1,895,284	1,948,511	1,907,145
THE	145,182	191,610	200,257	209,059	217,352	n.a.
- *thereof public HE*	115,252	151,864	157005	163,651	169,061	n.a.
- *thereof private HE*	29,930	39,746	43,252	45,407	48,291	n.a.
HE in the out-patient sector[1]	82,664	108,158	112,872	117,994	122,213	n.a.
- *thereof public*	55,727	73,411	76,070	79,481	81,003	n.a.
- *thereof private*	26,937	34,747	36,802	38,513	41,210	n.a.
HE in the in-patient sector[1]	59,052	78,023	81,584	85,204	89,193	n.a.
- *thereof public*	56,059	73,883	76,902	80,080	83,924	n.a.
- *thereof private*	2,993	4,140	4,682	5,124	5,269	n.a.

GDP = gross domestic product, HE = health expenditure, THE = total health expenditure

n.a. = not available

[1] out-patient and in-patient data according to SHA Table HPxHF: Providers and Financing agents/schemes. Note that out-patient and in-patient expenditure does not sum up exactly to THE. Indeed, THE includes investment on medical facilities which is not included in out-patient and in-patient expenditure. The sum of out-patient and in-patient expenditure equals to total current health expenditure.

Source: OECD health data (as of October 2010)

1.3.2 Sources of funds

The public financing of social, and in particular health care, depends on two main sources (shares refer to health care which falls under the sickness scheme)[17]:

- social contributions (48% of the funding) based on earnings from employees, employers and those on benefits (retired people, those on early retirement benefit and unemployed people) as a proportion of wages and salaries;
- taxes (49%) including
  - mainly (36%) the "general social contribution" (contribution sociale généralisée, CSG) based on total income (the general social contribution (CSG) rate varies depending on the source of income);
  - other taxes: 14%;
- and other sources of funding: 3%, including state contribution and transfers.

Public health expenditure (PE) (social security and state or local funds) accounted for 77% of the total HE expenditure (PE) in 2008. The remaining 23% from private expenditure included 14% of expenses for private health insurance and 9% of out-of-pocket payments (OPP) (including cost-sharing and self-medication, cf. 3.2.4.2) of households.[18]

Private health insurance in France refers to complementary health insurance which patients subscribe to on a (usually) voluntary basis. In 2008, a total of 94% of the population is covered by complementary health insurance, including 6% covered by the free Complementary Universal Health Insurance Coverage (CMUC), provided for people with low incomes[19]. In 2009, 4.186 million people[20] were registered under the CMUC coverage system, among which 36%[21] belong to the universal health coverage (CMU) - cf. section 1.2.

The financing of statutory health insurance varies from scheme to scheme. In France, there are three types of complementary health insurers:

- mutual insurance associations ("mutuelles");
- private insurance companies;
- provident institutions, co-managed by representatives of employers and employees.

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17 Figures from LFSS 2011, annex 4 : http://www.securite-sociale.fr/chiffres/lfss/lfss2011/2011_plfss_annexe_4.pdf

18 National health accounts 2009 (CNS 2009) : http://www.sante.gouv.fr/comptes-nationaux-de-la-sante-2009.html

19 IRDES, ESPS survey: http://irdes.fr/EspaceEnseignement/ChiffresGraphiques/CouvertureComplementaire/DonneesGnles.html

20 Fonds CMUC 4th report : http://www.cmu.fr/userdocs/RAPPORT%20EVALUATION%204.pdf

21 CNAMTS[21]

The mutual insurance associations play a dominant role in providing complementary health insurance coverage, financing 7.7% of total pharmaceutical expenditure (TPE), while private insurance companies account for 3.6%, and the provident institutions for 2.5%.

For the most part, employees do not subscribe on a voluntary basis in the context of employment, where the employer/professional organisation enters into a collective (group) contract with an insurance provider on behalf of all its employees or a specific professional group. A total of 44% of employees are covered by a complementary health insurance scheme subscribed by their employers and 32% subscribe to one individually on a voluntary basis.[22]

Self-medication, defined as medicines bought without a medical prescription, represented 6.5% of the pharmaceutical sales in France in 2009 (14% in volume), accounting for € 1.9 billion[23, 24].

1.3.3 Out-patient care

Methods of paying health care professionals vary according to whether the professionals concerned are self-employed (that is, independent professionals engaged in private practice) or employed by institutions. However, it is common for specialists to have mixed activities, so their total remuneration is likely to be a composite sum.

Most self-employed professionals work within the terms of an agreement with the health insurance fund. Self-employed health professionals provide the vast majority of out-patient service. These self-employed professionals are all paid directly for the services they provide at the time of the provision of the service by the patient.

Out-patient doctors, general practitioners (GP) or specialists, are remunerated on a fee-for-service which tariffs are set according to agreements with the health insurance fund. Under the health insurance fund agreement, they can choose between 2 types of sectors with different remuneration rules:

sector 1: statutory fees in return of reduced social security contributions

sector 2: can charge fees higher than statutory fees

Fees are defined according to the common medical act classification (*classification commune des actes médicaux* – CCAM) available online[25]. More details and main fees amounts are also available online[26].

[22] Workplace provided supplementary health insurance, Health economics letter 115, IRDES 2006)

[23] AFIPA: http://www.afipa.org/afipa/pdf/10084_les-chiffres-du-marche-09.VL.pdf

[24] At pharmacy retail price (PRP) level, including value-added tax (VAT), the Association of the European Self-Medication Industry (AEGSP) estimated self-medication to be at € 1.99 billion in 2009.

[25] http://www.ameli.fr/accueil-de-la-ccam/index.php

There is an out-of-pocket payment of € 1.- per visit for patients over 18 years old and not under Universal Health Insurance Coverage (CMU) nor State Medical Aid (AME) (cf. Section 3.2.2.1).

Moreover, since 2005 in France, people consulting specialists directly without having consulted a GP first get a lower level of reimbursement (cf. section 1.4.2).

1.3.4 In-patient care

Since 1996 the parliament has been voting on a yearly 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 several subtargets:

- health care in private practice (cf. Section 1.4.2):
    - 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 hospitals split between:
    - payed under the activity-based system “T2A”;
    - other expenses;

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 medicines sector.

The budget is then divided between regions by the Ministry of Health, and the regional health agency (ARS), allocate individual budgets to each hospital in the framework of regional resource allocation (see section 1.2). At regional level the ARS bring together the health services of the state and the health insurance funds and are responsible for

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

Hospital expenses accounted for 41% (€ 89 billion in 2008) of the total health care expenditure.

[26] http://www.ameli.fr/professionnels-de-sante/medecins/votre-convention/tarifs/tarifs-conventionnels-des-medecins-generalistes/tarifs-des-medecins-generalistes-en-metropole.php

Health expenditures (€ 217.4 billion) accounted for 11% of the GDP in 2008 (cf. table 1.2).

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 concerns both the private and public sectors. In the beginning it only applied 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 ARS 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 in in-patient care

The basic rule is that hospital treatment costs are reimbursable through the social security system at a rate of 80%. Still full coverage (100%) applies to 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 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.

1.4 Access to health care

1.4.1 Health care professions

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

Health professionals	2000	2005	2006	2007	2008	2009
Total no. of doctors[1]	194,000	205,864	207,277	208,191	208,249	209,143
- of which GPs	94,746	100,646	101,267	101,549	101,380	101,667
- of which work in the out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- of which work in the in-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of pharmacists[2]	n.a.	n.a.	n.a.	n.a.	n.a.	73,332
- of which work in community pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	54,254
- of which work in hospital pharmacies	n.a.	n.a.	n.a.	n.a.	n.a.	5,450

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

[1] Number of professionally active physicians which include practising physicians and other physicians for whom their medical education is a prerequisite for the execution of the job. Reference period: 31st December. Coverage: Data refer to metropolitan France and D.O.M. (overseas departments). Data refer to active physicians, either self-employed ("libéraux") or/ and salaried. Self-employed physicians are physicians registered in the "ADELI Registry" and working full-time or part-time in private practice or private surgery, in a clinic or laboratory. Salaried physicians are physicians registered in the "ADELI Registery", practising only full-time in hospital activities and in the field of health care, preventive medicine, control, teaching, research or administration. All public and private hospitals and clinics are covered. Stomatologists are included in the number of physicians. Dentists are not included.

[2] Number of professionally active pharmacists. Coverage: Data refer to metropolitan France and D.O.M. (overseas departements).

Source: Eco-Santé France 2010[27] (from ADELI) for doctors, CNOP[28] for pharmacists

[27] http://www.ecosante.fr/index2.php?base=FRAN&langh=FRA&langs=FRA&sessionid=

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

1.4.2 Out-patient care

Ambulatory care is largely developed in France and offers a wide variety of services.

The organisation of ambulatory care in France is largely determined by the principles of the self-employed physician charter of 1927: free choice of GP by the patient, absolute respect of professional secrecy, the right to charge fees for each treated patient, direct payment by the insured party, freedom in therapeutic and medicine prescription, and choice of practice area. The Prefered Doctor scheme and healthcare pathway reform were introduced in 2004 and is a strongly incentive for insured individuals to register with a GP of their choice. This reform introduced a hierarchical system of accessibility to care in France. [29]

The self-employed, which include both general practitioners and specialists, represent the majority of healthcare professionals. In 2010, 67% of general practitioners (GPs) are self-employed, 11% are salaried in the private sector and 22% in the public sector.[30]

Along with self-employed health professionnals other ambulatory care services and structures coexist. Occasionally very old, these structures are generally organised on a territorial basis, either at municipal level such as home nursing services and a number of community health centres, or at departmental level such as Maternal and Infant Protection (PMI*) units and the departmental fire and emergency services. These structures can be organised at hospital level such as the Hospital at Home service (HAH), specialist hospital consultations and hospital emergency services, or they can depend on specific institutions such as school doctors, the French National Health Insurance agencies' medical centres, occupational medicine or organisations such as "SOS Doctors".[31] The share of GPs working in group with other health professionnals went up from 43% in 1998 to 54% in 2009. About 75% of GPs group practice are composed of GPs and/or specialists only with an average of 2 to 3 physicians.[32]

Health care professionals can be self-employed (that is, independent professionals engaged in private practice) or employed by institutions. However, it is common for specialists to have mixed activities, so their total remuneration is likely to be a composite sum. Most self-employed professionals work within the terms of an agreement with the health insurance fund. Self-employed health professionals provide the vast majority of out-patient service. Please refer to section 1.3.3 for further details on remuneration.

The principal unions of doctors are:

- for generalists, the French Federation of General Practitioners (Fédération française des médecins généralistes, MG FRANCE), the Confederation of French Medical Unions (Confédération des Syndicats Médicaux Français, CSMF), the Federation of Doctors in

[29] IRDES 2009, http://www.irdes.fr/EspaceAnglais/Publications/IrdesPublications/QES141.pdf

[30] Hubert 2010, http://www.elysee.fr/president/root/bank_objects/rapport_definitif_.pdf

[31] IRDES 2009, http://www.irdes.fr/EspaceAnglais/Publications/IrdesPublications/QES141.pdf

[32] Hubert 2010, http://www.elysee.fr/president/root/bank_objects/rapport_definitif_.pdf

France (Fédération des Médecins de France, FMF) and the Union of Self-employed Doctors (Syndicat des Médecins Libéraux, SML);

- and for specialists, the Confederation of French Medical Unions (CSMF). They are represented in some committees, e.g. the group that enters into discussions with the Economic Committee for Health Care Products (CEPS) on generics.

The principal unions of doctors, Union of Self-employed Doctors (SML), the Confederation of French Medical Unions (CSMF) and ALLIANCE, signed agreements with health insurance funds, National Union of Health Insurance Funds (UNCAM), in 2005. This agreement was the first of its kind for general practitioners (GPs) and specialists. In return for higher tariffs, doctors accept a new organisation of the system with the introduction of a sort of "**gatekeeper**" role, being the "médecin traitant", as the standard way to consult. S/he can refer the patient to a specialist as the "médecin correspondant". Since then, patients must register with a referring doctor (generally a general practitioner - Médecin Généraliste, GP; but could also be a specialist) who acts as a **gatekeeper** for specialist care. If they fail to do so, they may be reimbursed at a lower level (reimbursement rate decreased by 40%).

This agreement promotes guidelines for rational use of medicines in the activities of doctors and determines targets on the use of medicines and on savings in some therapeutic areas, including antibiotics, statins, proton pump inhibitors (PPI) and generics. This includes good practices and cost-effective prescribing. There are no direct penalties (cf. section 3.3.4.1 for further details).

1.4.3 In-patient care

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[33]. 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).

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

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[34].

Classification of hospitals

There are **five specific categories of public hospitals** (954 in 2008), 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;
- 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[35]:

[34] 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- pa tients and the specialised accommodation services required by in-patients. Hospitals may also provide out- pa tient 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 produc tion 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 neither be considered as "hospital" of the purpose of this PHIS Pharma Profile nor of the PHIS Hospital Pharma Report..

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

- 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).

In 2005 public hospitals accounted for about three quarters of the overall number of hospital beds[36], 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), cf also Table 1.4.

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.

[36] 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.

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[37].

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

In-patient care	2000	2005	2006	2007	2008	2009
No. of hospitals[1]	n.a.	2,854	2,813	2,772	2,716	n.a.
Classified according to ownership						
– thereof public hospitals	n.a.	987	977	972	954	n.a.
– thereof private owned hospitals	n.a.	1,867	1,836	1,800	1,762	n.a.
– thereof not-for-profit privately owned hospitals	*n.a.*	*n.a.*	*n.a.*	*n.a.*	*n.a.*	*n.a.*
– thereof for-profit private hospitals	*n.a.*	*n.a.*	*n.a.*	*n.a.*	*n.a.*	*n.a.*
Classified according to subtypes[2]						
– thereof general hospitals	n.a.	1,681	1,646	1,618	1,577	n.a.
No. of acute care beds	246,817	224,030	224,168	222,194	n.a.	220,167
– thereof in the public sector	*n.a.*	*149,565*	*148,767*	*148,518*	*n.a.*	*146,574*
– thereof private owned hospitals	*n.a.*	*74,465*	*75,401*	*73,676*	*n.a.*	*73,593*
– thereof in not-for-profit privately owned hospitals	*n.a.*	*19,800*	*n.a.*	*n.a.*	*n.a.*	*18,382*
– thereof in for-profit private hospitals	*n.a.*	*54,665*	*n.a.*	*n.a.*	*n.a.*	*55,211*
Average length of stay (acute care) in days	5.6	5.4	5.3	5.3	5.2	n.a.
No. of hospital pharmacies	n.a.	n.a.	n.a.	2,639	n.a.	2,594

No. = number

1 excludes overseas departments if not stated otherwise

2 according to the OECD definition and its subtypes

Source: OECD Health Data 2010 for average length of stay, and acute care beds in 2000. DREES SAE[38] http://www.insee.fr/fr/themes/tableau.asp?reg_id=0&ref_id=nattef06116; otherwise, Hospital pharmacies: CNOP[39]

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 alterna-

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

38 http://www.sae-diffusion.sante.gouv.fr

39 http://www.ordre.pharmacien.fr/fr/bleu/index3.htm

tives to usual hospitalisation. On the other hand, beds in long-term care institutions have increased in recent years, in response to the needs of a growing number of dependent elderly people[40].

[40] 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 repre sented, in 2002, 17.5% of total beds, compared to 10% in 1987. See DREES “Données sur la situation sani taire et sociale en France en 2005”, Annexe A au Projet de la loi de financement de la Sécurité Sociale pour 2005.

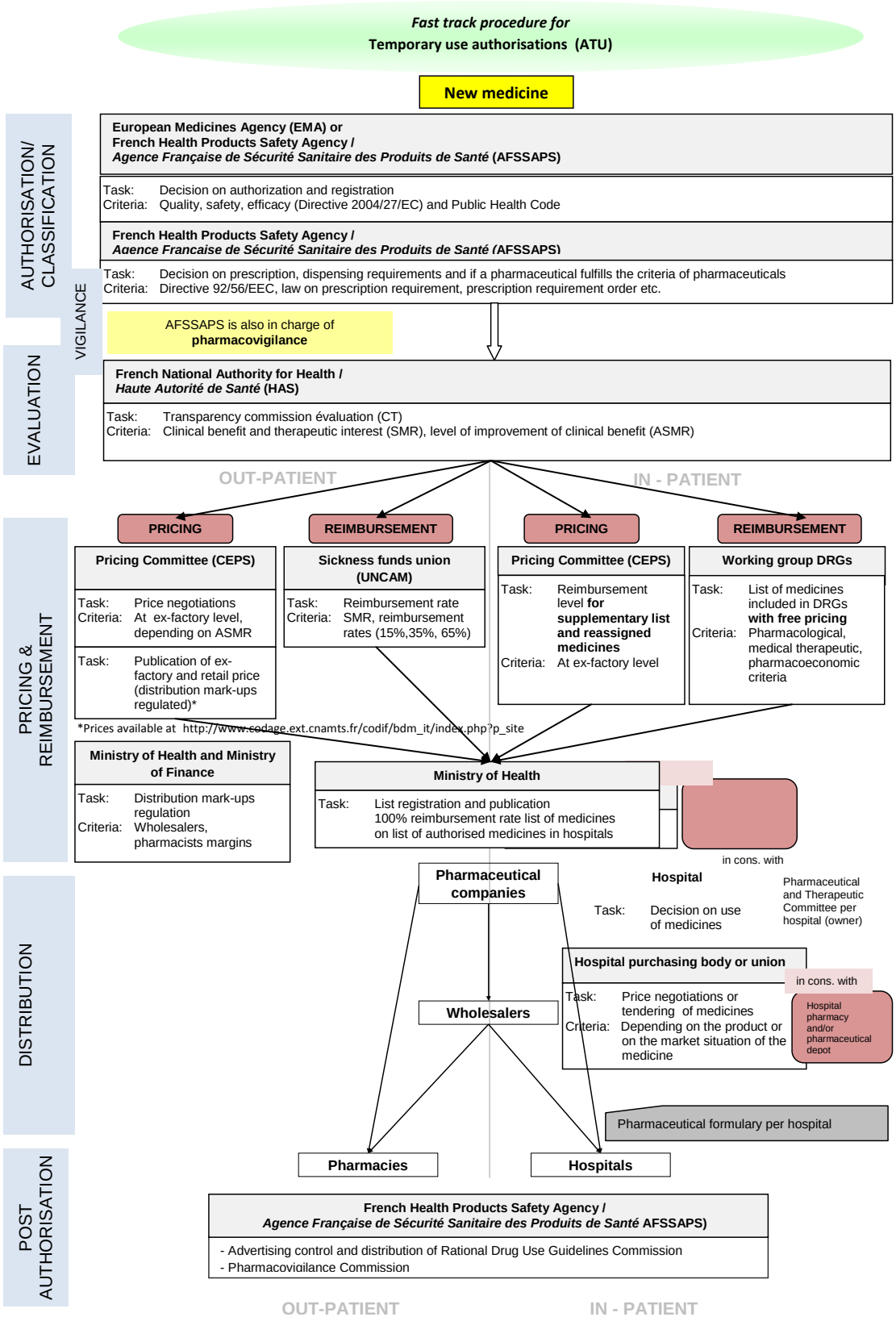
2 Pharmaceutical system

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

2.1 Organisation

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

Figure 2.1: France – Flowchart of the pharmaceutical system, 2011



Source: CNAMTS

2.2 Regulatory framework

The main players in the French pharmaceutical system are the state bodies at national level (Ministry of Health and Social Security (Ministère du Travail, de l'Emploi et de la Santé) and Ministry of Economy, Finance, and Employment (Ministère de l'Economie des Finances et de l'Emploi, MINEFE), which drive policy in this sector, with assistance from the Medicines Agency and the Economic Committee for Health Care Products (CEPS), along with a partial role for health insurance funds. The Parliament votes every year on the Finance Law of the Social Security System (Loi de financement de la sécurité sociale, LFSS); before this vote each year the Court of Accounts produces a report on the application of the Finance Law, policy and legislation. In this Law the National Target for Health Insurance Expenditure (Objectif National des Dépenses d'Assurance Maladie, ONDAM) for the year to come has been voted for since 1996. Within the ONDAM, the budget for medicines is split between two subtargets on out-patient health care and in-patient health care. The ONDAM subtargets for out-patient health care include (for other subtargets refer to section 1.3.4):

- 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;

During the course of the year an independent committee called “Comité d’alerte” analyses the development of the expenditure: if the trend shows that the defined target risks to be exceeded it must inform/state this and the health insurance funds have one month to propose measures to the Government. In 2007, for the first time new measures to control the expenditures were taken under the committee supervision “Comité d’alerte” (prices cut).

2.2.1 Policy and legislation

In the pharmaceutical sector many laws and decrees are in act, driven by European legislation. They are summarised into two laws (called “Codes”): the Public Health Code (Code de la Santé Publique, CSP[41]) and the Social Security Code (Code de la Sécurité Sociale, CSS[42]).

The regressive statutory mark-up schemes for wholesalers and pharmacists are detailed in a decree published in the country’s official bulletin[43].

41 http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665&dateTexte=20080606

42 http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006073189&dateTexte=20080606

43 http://www.legifrance.gouv.fr/affichTexte.do?dateTexte=&cidTexte=JORFTEXT000018213915&fastPos=1&fastReqId=935011621&oldAction=rechExpTexteJorf

2.2.2 Authorities

The **French Health Products Safety Agency** (Agence Française de Sécurité Sanitaire des Produits de Santé, AFSSAPS) was created by law on 1 July 1998. It has been effective since 9 March 1999 under the authority of the Ministry of Health. Approximately 900 people are employed and nearly 2,000 experts participate in commissions or working groups. The normal way to obtain **market authorisation** is under the European Commission (Commission Européenne, EC) Directive 2004/27. The usual time frame for this process is 210 days. A simplified procedure exists for generics by proving the bioequivalence of the medicine with the original product. There do not seem to be problems raised by industry with delays in obtaining market authorisation; the period of 210 days seems to be enough.

Before market authorisation is granted, it is possible to put medicines on the market with a fast track procedure called a temporary use authorisation (Autorisation temporaire d'utilisation, ATU). Two kinds exist: one for a number of patients of the same type called "ATU de cohorte". For this procedure it is necessary to conduct the usual studies and obtain a market authorisation. The other type is an agreement, called "ATU nominative", established on an individual patient basis.

If necessary, a patient can obtain a specific authorisation to import the product if it is not available in France. The Director of the French Health Products Safety Agency (AFSSAPS) implements the health policy on medicines and vigilance over medicines. Over 70% of the budget of the French Health Products Safety Agency (AFSSAPS) comes from taxes and fees paid by the industry. Health insurance funds are represented in the Board of Directors by one member, but are not represented in the Market Authorisation Commission.

From 1945 to 1986 the **prices** of all products (not only health and medicines) were under administrative control. Since then, prices have been deregulated, but in the case of a few economic activities, e.g. where there is a monopoly, prices are controlled. In the pharmaceutical sector only reimbursable medicines are controlled, whereas in non-reimbursable sectors there is free pricing, e.g. in hospitals and for over-the-counter (OTC) products (Médicament en vente libre).

Pricing decisions are carried out by the **Economic Committee for Health Care Products** (CEPS) for reimbursable products for out-patients, since 2005 for a list of costly medicines outside the fee-for-service payment system of hospitals and for products sold by hospitals to out-patients. Different institutions are represented: the Ministry of Social Affairs (Ministère des Affaires Sociales, MAS), Ministry of Health, Ministry of Economy, Finance and Employment (MINEFE), health insurance funds, complementary insurance and private insurance, the Directorate of Hospitals in the Ministry of Social Affairs (MAS), and the Ministry of Research.

The Economic Committee for Health Care Products (CEPS) and the Association of Pharmaceutical Industry (Les Entreprises du Médicament, LEEM) negotiate a price agreement for reimbursable medicines in accordance with art. L 162-16-4 of the Social Security Code (CSS) or, if this is not possible, the Economic Committee for Health Care Products (CEPS) can set a price alone. This is carried out in accordance with the European Union (Union Européenne, EU) Transparency Directive. The Economic Committee for Health Care Products (CEPS) also conducts the economic regulation in the sector according to the advice received every year by the ministers concerned. The Economic Committee for Health Care Products (CEPS) is now involved in price setting for

medicines sold by hospitals to out-patients, as well as in tariff setting for costly products paid for directly by health insurance funds for in-patients in hospitals. The Economic Committee for Health Care Products (CEPS) is also involved in the regulation of medical visits by sales representatives of the pharmaceutical industry.

Decisions on reimbursement status are made by the Minister of Health and Social Affairs after receiving technical advice from a scientific committee, the Transparency Commission (Commission de la Transparence) which is a department of the French National Authority for Health (HAS), a new body created by the Law of 13 August 2004.

The organisation for steering the health insurance system involves reinforced responsibilities, implemented through the steps described here.

A reorganised National Insurance Fund for Salaried Employees (CNAMTS) Council.

a) Marked by the return of the employers' representatives of the French Business Confederation (Mouvement des Entreprises Françaises, MEDEF) and the General Confederation of Small and Medium-sized Enterprises (Confédération Générale des Petites et Moyennes Entreprises, CGPME), and open to representatives of mutual insurance companies (cf. Section 1.3.2) and other institutions in the health insurance sector, the Council consists of six members representing the Union Nationale des Professions Libérales (French National Union of Independent Professions), the Fédération Nationale des Travailleurs Handicapés (French National Union of Disabled Workers), the Union Nationale des Associations Familiales (French National Union of Family Associations), the Collectif inter-associatif sur la santé (Inter-Associative Health Group), the Union Nationale des Syndicats Autonomes (French National Union of Independent Trade Unions) and the Fonds de Financement de la CMUC (Fund for the Complementary Universal Health Insurance Coverage (CMUC), a means-tested, public supplementary insurance programme).

b) Set up to define the risk management policy guidelines and to clarify the modalities for implementing the health care policy and organisation of the health care system.

The creation of a French National Authority for Health (HAS):

a) as a body defining the scope of reimbursable treatments.

b) to conduct periodic evaluations of medical services and to draw up recommendations for good medical practices.

c) to conduct pharmaco- economic evaluations as of 2008.

d) to certify health web sites, computer-assisted prescription softwares (2007)

A better representation of the health insurance system within the Economic Committee for Health Care Products (CEPS), which:

a) sets the prices of medicines;

b) establishes the "Tarif forfaitaire de Responsabilité" (fixed amount on the basis of which Health Insurance Funds reimburse some groups of generic medicines).

Different bodies are concerned with medicines or similar products, e.g. the French Agency for the Medical Safety of Food Products (Agence Française de la Sécurité Sanitaire des Produits Alimentaires, AFSSA), the French Agency for Environmental Health and Safety (Agence Française de la Sécurité Sanitaire Environnementale et de Sécurité au Travail, AFSSET) (with environmental problems and security at work), and the National Institute for Monitoring Public Health (Institut National de la Veille Sanitaire, INVS).

The decision on prescription status for a medicine is made by the Director of the French Health Products Safety Agency (AFSSAPS). It is a health policy decision. Since Decree No. 2004-546 of 15 June 2005 under European Commission (EC) Directive 2001/83/EC on prescription status of medicines, new forms of prescription status have been introduced in France. Now five classes of prescription status exist:

- medicines used in hospital-only settings
- medicines with hospital prescription
- medicines with first hospital prescription
- medicines with prescription reserved for certain specialists
- medicines requiring a special monitoring during treatment.

The health insurance funds manages the rate of reimbursement for each medicine and can modify the set/determined rates for regulation, if this is necessary, with certain limits (cf. section 3.2.2.3). They also sign a general agreement with doctors' unions on the application of guidelines to increase economic efficiency in prescription and to promote prescription of generics (cf. section 3.3.4.1). They sign agreements with pharmacists to promote generic substitution (cf. section 3.3.2), participate in active risk management with public health objectives, and also seek more effective regulation, e.g. on antibiotics consumption.

In mid-2003 the national health insurance fund (National Insurance Fund for Salaried Employees (CNAMTS) introduced health insurance representatives (Délégués d'Assurance Maladie, DAM, cf section 2.4.4).

Table 2.1: France – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2011

Fields	**Legal basis**	**Scope (in-patient, out-patient sector)**	**Authorities in English (local name, local abbreviation)**	**Activity / responsibility in the pharmaceutical system**	**Actors and interest associations in English (local name, local abbreviation)**
Market authorisation	Public health code Social security code	In- and out-patient sectors	French Health Products Safety Agency (Agence française de sécurité sanitaire des produits de santé, AFSSAPS)	In charge of market authorisation, classification, vigilance, advertisement	Pharmaceutical companies Interest associations: LEEM – pharmaceutical industry association, – GEMME: generics industry association
Evaluation	Independent body	In- and out-patient sectors	French National Authority for Health (Haute Autorité de Santé, HAS)	Technical advice for including a medicine on the positive list; recommenda-tions, pharmaco-economic evaluations	

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Pricing / Purchasing	Pricing : CSS and CSP codes Procurement for in-patient: - EU Directive No. 2004/17 and 2002/18 - Local implementation depends on the status of the hospital: • Public : 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 re-lated to pro-curement contracts for which the decree no. 2006-975 of 1 August 2006 mentioned above is not applicable.	In- and out-patient sectors	Ministry of Health and Social Affairs (Ministère de la Santé et des Affaires Sociales) Ministry of Economy, Finance and Employment (Ministère de l'Economie des Finances et de l'Emploi, MINEFE) Economic Committee for Health Care Products (Comité économique des produits de santé, CEPS)	Setting of prices for pharmaceuticals in out-patient and in-patient (medicines outside the DRG system) sectors	Pharmaceutical companies Interest associations: LEEM – pharmaceutical industry association, – GEMME: generics industry association
Reimbursement	CSS code	In- and out-patient sectors	National Union of Health Insurance Funds (Union nationale des caisses d'assurance maladie, UNCAM)	Setting of reimbursement levels	
Promotion	CSP code	In- and out-patient sector	French Health Products Safety Agency (Agence française de sécurité sanitaire des produits de santé, AFSSAPS)	Committee in charge of medicines pharmaceuticals advertising control and recommenda-tions on proper use	

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Distribution	Interministerial decree	Out-patient sector	Ministry of Social Affairs Ministry of Health Ministry of Economy, Finance and Employment	Margin mark-up	For wholesalers and pharmacists
Vigilance		In- and out-patient sector	French Health Products Safety Agency (Agence française de sécurité sanitaire des produits de santé, AFSSAPS)		

Source: CNAMTS

2.3 Statistics

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

2.3.1 Availability of medicines

2.3.1.1 Market authorisation

Table 2.2: France – Number of medicines 2000, 2005–2009

Medicines (at end of year)	2000	2005	2006	2007	2008	2009	Method of counting
Authorised	11,470	14,990	14,391	15,341	15,350	16,070	Counting different pharmaceutical forms, dosages and pack sizes, but not including homeopathic products
On the market	6,640	8,650	9,448	9,714	9,700	10,750	
POM	4,000	5,000	5,900	6,300	6,230	7,480	
Reimbursable	n.a.	6,100	6,610	6,981	6,870	8,070	
Generics	n.a.	n.a.	n.a.	3,710	4,210	4,894	
Parallel traded	n.s.	n.s.	n.s.	9	14	37	
Hospital-only	n.a.	n.a.	n.a.	n.a.	~2,700	~2,750	

POM = prescription-only medicines, n.a. = not available, n.s. = not significant

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

In 2009 a total of 16,070 medicines were registered in France (counting different pharmaceutical forms, dosages and pack sizes, but not including homeopathic products). All data presented are estimated based on many different partial sources. The French Health Products Safety Agency (AFSSAPS) is responsible for the different classifications of prescription-only medicines (POM) (Médicament à prescription obligatoire) and over-the-counter (OTC) medicines or non-prescription products (cf. section 2.2.2.).

The increase of authorised medicines between 2000 and 2009 is mainly due to new market authorisation of generics. However, the generics were not all marketed.

The increase in reimbursable medicines was more moderate than for the total of authorised medicines which is due to some de-listing.

Generic substitution has been allowed in France since 11 June 1999 (Art. L5125-23 of the Public Health Code (CSP) (for further information on generic promotion (cf. section 3.3.2). The French Health Products Safety Agency (AFSSAPS) monitors the positive list of generic products and establishes groups which contain the original product and its generics. Within each group, substitution by a pharmacist is possible. Several substances which have never been proctected by a licence are nonetheless not included in a group by the French Health Products Safety Agency (AFSSAPS), even though the law permits the creation of a group for these products, e.g. paracetamol or aspirin.

At the moment parallel imports are not very significant in France. This market is quite limited with 52[44] authorisations for 28 medicines in France in 2010.

2.3.1.2 Access to medicines

Table 2.3: France – Number of new molecular entities, 2000-2009

New molecular entities	2000 – 2009	2004 – 2009
Number of new molecular entities	217	123

Source: Le Moniteur des Pharmaciens

In 2009, the average time period between first submission for registration on reimbursement list, i.e. after marketing authorisation, and publication on the reimbursable list is 66 days for generics and 256 for non-generics (see also Table 2.4).[45] No information is available for average time period between reimbursement publication and actual market availability to patients.

Table 2.4: France – Average time of first applications for registration on the reimbursable medicines lists, 2009

Type of product	Accepted	Abandoned, withdrawn or rejected	All
Generics	65	124	66
Non-generics	213	579	256
All	89	468	106

Unit = number of days

Source: CEPS 2009, table 17

Table 2.5: France – Average time of first applications for registration on the reimbursable medicines lists by process stages, 2009

Product type	Transpa-rency commission	Examinati-on	Negotiation	Agreement	Publication or closure	Total
Generics	0	19	1	17	29	66
Non-generics	86	28	41	33	68	256
All	n.appl.	21	9	20	37	106

n.appl. = not applicable, unit = number of days

Source: CEPS 2009, table 18

[44] http://www.afssaps.fr/var/afssaps_site/storage/original/application/fad3fcba65de4f6102a5cdf81374f02f.pdf

2.3.2 Prescriptions

Table 2.6: France – Annual prescriptions 2000, 2005–2009

Prescriptions	2000	2005	2006	2007	2008	2009
No. of prescriptions (in volume in Mio.)	n.a.	2,671	2,491	2,572	2,487	2,540
Prescriptions in value (in Mio. Euro)	n.a.	25,247	25,378	26,412	26,763	27,209

n.a. = not available

Prescription in volume = number of items dispensed and reimbursed.
Prescription in value = public expenditure of dispensed medicines that were reimbursed

Data are estimated from reimbursement general scheme data .

Source: CNAMTS MEDICAM[46]

2.3.3 Sales

Table 2.7: France – Pharmaceutical sales 2000, 2005 –2009

Sales	2000	2005	2006	2007	2008	2009
Sales at ex-factory price level (Million of Euro)	n.a.	22,470	22,686	23,690	24,400	25,090
– Sales in out-patient sector	n.a.	17,970	18,095	18,790	18,945	19,363
– Sales at hospitals	n.a.	4,500	4,591	4,900	5,450	5,726
Sales of parallel traded medicines	n.app.	0	0	0	0.7	4.8

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

Source: CEPS activity reports for 2007, 2008 and 2009[47]

Self-medication, defined as medicines bought without a medical prescription, represented 6.5% of the pharmaceutical sales in France in 2009 (14% in volume), accounting for € 1.9 billion[48, 49].

[45] CEPS 2009, table 17

[46] http://www.ameli.fr/l-assurance-maladie/statistiques-et-publications/donnees-statistiques/medic-am-generic-am-biolam-lpp-am/medic-am-2004-2009.php

[47] http://www.sante.gouv.fr/les-activites-du-ceps.html

[48] AFIPA: http://www.afipa.org/afipa/pdf/10084_les-chiffres-du-marche-09.VL.pdf

[49] At pharmacy retail price (PRP) level, including value-added tax (VAT), the Association of the European Self-Medication Industry (AEGSP) estimated self-medication to be at € 1.99 billion in 2009.

2.3.4 Consumption

Table 2.8: France – Annual pharmaceutical consumption 2000, 2005–2009

Consumption (billion)	2000	2005	2006	2007	2008	2009
Total pharmaceutical consumption						
In packs	n.a.	n.a.	n.a.	n.a.	2.9	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the in-patient sector						
In packs	n.a.	n.a.	n.a.	n.a.	0.4	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the out-patient sector						
In packs (CEPS 2009)	n.a.	2.82	2.66	2.56	2.53	2.61
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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

Source: CEPS 2009, Leem from GERS

Data on consumption in DDD is only available for specific pharmaceutical classes, e.g:

- At ATC -2 level [50]: annual report on sales on medicines to pharmacies and hospital in France on a ten year period. Latest available report: *Analyse des ventes de médicaments aux officines et aux hôpitaux en France données 1998-2008*, Afssaps, June 2010.
- Antibiotics [51]: *La consommation d'antibiotiques: situation en France au regard des autres pays européens,* November 2006, CNAMTS, Points de repère N.6.

Data on consumption in volumes of prescribed medicines by therapeutic classes is also available:

- Expenditures of reimbursed medicines dispensed by community pharmacies in 2009: *Médicaments remboursables délivrés en officine: principales évolutions en 2009*. December 2010, CNAMTS, Points de repère N.34[52]
- Consumption in volumes (packs, standard unit) and expenditures (excluding distribution margin and VAT) for 8 main out-patient therapeutic classes including antibiotics, diabetics, proton pomp inhibitors, statins
    - *Comparaisons européennes sur huit classes de médicaments*, December 2007, CNAMTS, Points de repère N.12[53]

[50] http://www.afssaps.fr/var/afssaps_site/storage/original/application/3b13d02741902933e1f930db3d882603.pdf

[51] http://www.ameli.fr/fileadmin/user_upload/documents/Points_de_repere_n__6.pdf

[52] http://www.ameli.fr/fileadmin/user_upload/documents/Points_de_repere_n__34.pdf

[53] http://www.ameli.fr/fileadmin/user_upload/documents/Points_de_repere_n__12.pdf

- *Consommation et dépenses de médicaments en France et en Europe: évolutions 2006 – 2009*, CNAMTS, Point d'information 10 mars 2011[54].

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. This publication publishes figures only for the first fifty most sold medicines on ATC level 2[55].

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[56].

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 medicines through a global survey in French hospitals. In each hospital, information on prices and quantities are collected for each medicine.

2.3.5 Generics

Generics are defined in the Public Health Code (Code de la Santé Publique, CSP) Art. L601-6[57].

The French Health Products Safety Agency (AFSSAPS) is responsible for the list of generics called 'le repertoire[58]'. The list is organised by groups of medicines defined by the original product and its generics. A generic group is defined for all molecules of the same Anatomic Therapeutic Chemical (ATC) classification level 5, with the same dosage and the same packaging and it is composed of the original product which patent expired and its generics.

In 2004, three measures affected the growth of the **generics market**:

1. Art. 19 of the Finance Law of the Social Security System (LFSS) for 2004 provides that market authorisation for a generic medicine can be delivered before the expiry of the intellectual property rights attached to the reference specialty.
2. Art. 30 of the Law of 13 August 2004 modifies the definition of a generic under European legislation. This article specifies that "the various salts, esters, isomers, isomer mixtures,

54 http://www.ameli.fr/fileadmin/user_upload/documents/DP_Consommation_medicaments_en_Europe_vdef_01.pdf

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

56 http://www.sante.gouv.fr/ceps/3ceps.htm

57 http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=8EA7A901AA7D305DDE1162F194F55E11.tpdjo10v_2?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006693765&dateTexte=20080722&categorieLien=cid

58 http://afssaps.sante.fr/htm/5/generiq/indgen.htm

complexes or derivatives from the same active principal are considered to be the same active principal, unless they present significantly different properties in term of safety and efficacy".

3. Decree of 18 February 2005 introduced Art. R. 5121-41-1 of the Public Health Code (CSP). Minor changes in market authorisation are considered to be the same as the original authorisation.

In 2009, the market share of generics on the substitution list was 71.2% in terms of pack numbers and 62.2% in terms of sales total excluding VAT. These figures were 70.8% and 57.2% respectively in 2008 (CEPS 2009[59]).

In 2009, the generics included on the substitution list accounted for sales worth € 2.7 billion, a 31.5% increase on the figure for the generics included on the list in 2008.

Table 2.9: France – Development of the generic shares 2005–2009

Generic share	Volume in packs		Value in ex-factory price excluding VAT	
	2005	2009	2005	2009
Shares in % of total market (in-patient/ out-patient)	n.a.	n.a.	n.a.	n.a.
Shares in % of total out-patient market	15%	24%	8%	14%
Shares in % of out-patient reimbursement market	15%	24%	8%	14%
Shares in % of out-patient off-patent market	52%	71%	34%	62%
Shares in % of the in-patient market	n.a.	n.a.	n.a.	n.a.

n.a.= not available

Source: Share in total out-patient market and off-patent market from CEPS activity 2006 and 200960, share in out-patient reimbursement market from CNAMTS

[59] http://www.sante.gouv.fr/IMG/pdf/rapport_d_activites_du_CEPS_en_2009_Vanglais.pdf

[60] http://www.sante.gouv.fr/les-activites-du-ceps.html

2.3.6 Top 10 medicines

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

Position	Top active ingredients used in the out-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the out-patient sector, ranked with regard to expenditure	
1	N02BE01	PARACETAMOL	1	B01AC04	CLOPIDOGREL
2	N02AC54	DEXTROPROPOXYPHENE + PARACETAMOL	2	N02BE01	PARACETAMOL
3	J01CA04	AMOXICILLINE	3	C10AA05	ATORVASTATINE
4	H03AA01	LEVOTHYROXINE SODIQUE	4	R03AK06	SALMETEROL + FLUTICASONE
5	M01AE01	IBUPROFENE	5	A02BC05	ESOMEPRAZOLE
6	N02AX02	TRAMADOL	6	A02BC01	OMEPRAZOLE
7	N02BA01	ACETYLSALICYLIQUE ACIDE	7	C10AA07	ROSUVASTATINE
8	A10B02	METFORMINE	8	L04AB01	ETANERCEPT
9	A03AX12	PHLOROGLUCINOL	9	A02BC02	PANTOPRAZOLE
10	N02AA59	CODEINE IN ASSOCIATION	10	R03AK07	FORMOTEROL + BUDESONIDE

Source: MEDICAM CNAMTS[61]

[61] http://www.ameli.fr/l-assurance-maladie/statistiques-et-publications/donnees-statistiques/medic-am-generic-am-biolam-lpp-am/medic-am-2004-2009.php

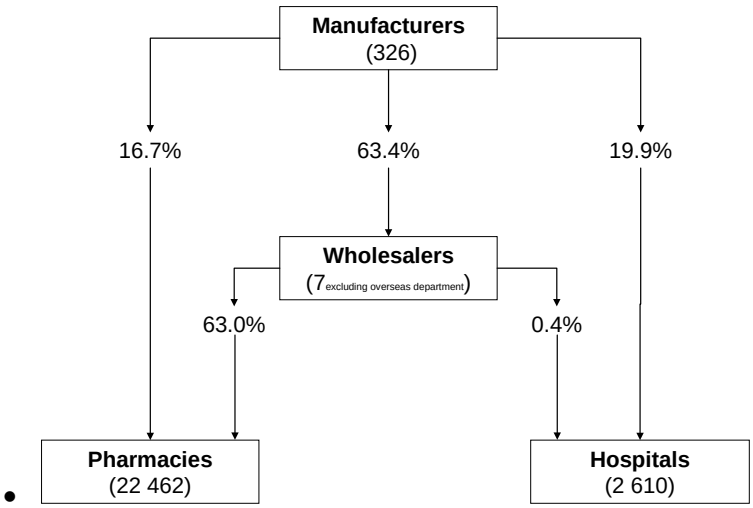
Table 2.11: France – Top 10 active ingredients in value and volume in the in-patient sector, 2009

Position	Top active ingredients used in the in-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the in-patient sector, ranked with regard to expenditure	
1	N02BE01	PARACETAMOL	1	L01XC07	BEVACIZUMAB
2	N02AC54	DEXTROPROPOXYPHENE + PARACETAMOL	2	L01XC03	TRASTUZUMAB
3	A02BC05	ESOMEPRAZOLE	3	L01XC02	RITUXIMAB
4	A06AD15	MACROGOL	4	L04AB02	INFLIXIMAB
5	A12BA01	POTASSIUM	5	L01CD02	DOCETAXEL
6	C03CA01	FUROSEMIDE	6	J06BA02	HUMAN IMMUNOGLOBULINE
7	A03AX12	PHLOROGLUCINOL	7	B02BD02	COAGULATION FACTORV VIII
8	B01AB05	HEPARINE	8	L01BA04	PEMETREXED
9	B05XA03	ELECTROLYTE SOLUTION	9	L01XC06	CETUXIMAB
10	B01AC08	ASPIRINE	10	J07BB02	INFLUENZA VACCINE H1N1

Source: Afssaps

2.4 Market players

Figure 2.2: France - Pharmaceutical distribution channels in % of turnover at ex-factory price (excluding overseas territories), 2009



Source: CSRP[62]

[62] http://www.csrp.fr/opencms/sites/fr/repartition/circuit.html

In the pharmaceutical distribution channels, the 326 manufacturers sell in 2009 (cf. Figure 2.2., or 324 according to Eco-Santé source, cf. table 2.12):

- 16.7% of the total amount directly to 22,462 pharmacies;
- 63.4% to 7 wholesalers, of which 63.0% are sold to pharmacists and 0.4% to hospitals;
- 19.9% to hospitals.

2.4.1 Industry

There are **324 pharmaceutical companies** based in France. They are all members of the Association of Pharmaceutical Industry (LEEM). This number includes 12 companies specialised in generics, members of the trade association Generic Producers Association (Association des Fabricants de Génériques, GEMME). Manufacturers specialised in non-reimbursable products are members of the French Association of Self-medication Industry (Association Française de l'Industrie Pharmaceutique pour une Automédication responsable, AFIPA). The French market is the fourth largest market in the world, with a market share of 5.9% in 2009 (LEEM from IMS Health).

The **industry's total sales** were € 50,013 Mio. in 2009: domestic sales accounting for € 21,000 Mio. and exports € 23,105 Mio. (source: LEEM). Domestic sales are broken down into € 19,538 Mio. of reimbursable products and € 1,912 Mio. of non-reimbursable products, which corresponds to a pharmacy out-patient market of € 21,450 Mio. in total. Hospital sales amount to € 5,458 Mio..

The **industry employed** 84,300 people in 1995 and 108,407 in 2009. Research employees re-present 14% of the total workforce. France's turnover in pharmaceutical industry is the second highest in Europe behind Germany. The French industry is not so concentrated. The first five groups represent 28.6% of the total turnover and the first 10 represent 44.6%. The biggest manufacturer is Sanofi-Aventis with a market share of 13%.

In the generics business in 2010, the biggest company is Mylan, the second is BIOGARAN (Servier Group) and the third is Teva (Novartis Group).[63]

Parallel imports of medicines are not significant in France with 52 market authorisations for 28 pharmaceuticals in 2010 (cf. section 2.3.1.1.). The administrative procedure is simplified, without any scientific study.

By advertising new medicines categorised according to illness, the industry puts considerable pressure on health insurance funds.

One part of the industry makes the choice to enter into "nested" markets with only specialists to visit, or hospitals.

[63] http://www.wk-pharma.fr/produits/html/laboratoire-generiqueur/8,8.4/8.4/classement-annuaire-generiqueur.html

The industry struggles against health insurance funds in the generics market by introducing "me-too" products at the end of the patent for the original product, and by engaging in direct sales to pharmacists, with rebates/discounts (cf. section 3.1.4).

The industry is developping a new communicating approach to consumers by introducing discussion groups with patients, for instance to groups of patients concerned by rare diseases.

The pharmaceutical industry has a representative without voting rights in the Transparency Commission of HAS and is not represented in the Economic Committee for Health Care Products (CEPS).

The Association of Pharmaceutical Industry (LEEM) negotiates various agreements with the Economic Committee for Health Care Products (CEPS), e.g. a general agreement called an "accord cadre" regarding processes and means of regulation for out-patient and in-patient sectors. The current agreement "out-patient-in-patient" agreement (*Accord ville-hôpital*)[64] covers the period from 25 September 2008 until 31 December 2012. 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 expenditure of very expensive medicines for hospital use excluded the hospital budget and reassigned medicines (*rétrocession*).

Since 1994, in order to contribute to an improvement in the long term on the economic environment, the State has been working on initiating a convention (i.e. agreement) policy with the pharmaceutical industry.

Art. L 162-17.4 of the Social Security Code (CSS) creates the legal basis and support for this policy and has led to the "accord cadre" of the 13 June 1993 which was just renewed, to be in effect until 2009 and modified by amendments No. 1 and No. 2 of the 29 January 2007. These amendments confirm the method of pricing, the regulation via conventions, and contain 10 amendments.

The key issues of the general agreement (accord cadre) are listed here.

- It ensures the exchange of information and the monitoring of expenditure on reimbursable medicines.
- It formalises the general measures for speeding up procedures and in particular for innovative medicines (price notification, "dépôt de prix").
- A whole chapter within the agreement is dedicated to the improvement of efficiency within pharmaceutical spending. It explains the framework of the agreements with the firms and defines those agreements (L 162-17-4 & L 158-10 from the Social Security Code (CSS), as well as setting out the annual financial regulation and in particular the quantitative end

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

of year discounts. Those discounts are made up of pharmacotherapeutic aggregate discouts and discounts on the turnover.

Amendment No. 2 has mainly modified the procedure of price notification (“dépôt de prix”). This procedure contributes to saving time: the Economic Committee for Health Care Products (CEPS), within the commitments submitted by the firm, has 15 days to oppose the price submitted, stating reasons as justification, or to accept it. The price has to be consistent with the price in Germany, Spain, Italy and the United Kingdom.

All products with a Level of improvement of clinical benefit (Amélioration du service médical rendu, ASMR, i.e. a rating on the level of improvement in the clinical benefit), I III (i.e. medicines with a comparably high clinical benefit level) can benefit from this fast-track price notification procedure. Furthermore, products with the Level of improvement of clinical benefit (ASMR) IV can benefit from this procedure under certain conditions: there has to be a comparable medicine and the daily cost of treatment corresponding to the price submitted must be, at the most, equal to the comparator. The medicine is not intended to replace a generic.

The European price guarantee is maintained during the course of five years (an extension of one year is possible for paediatric medicines).

Post-approval studies can be requested and whether or not the deadline has been respected will be examined.

The Economic Committee for Health Care Products (CEPS) will organise the manufacturers’ information when a generics manufacturer asks for the registration of a generic medicine.

For paediatric medicines a price guarantee to an equivalent level of the daily cost of treatment for an adult must be obtained.

The Economic Committee for Health Care Products (CEPS) decides on the level of financial penalty in the event of an advertising ban.

An agreement, “Charte de la visite médicale”, signed between industry representatives (the Association of Pharmaceutical Industry (LEEM) and Economic Committee for Health Care Products (CEPS) on marketing methods used by sales representatives to inform doctors. Under this agreement, by proposal of the Ministry it is possible to choose some therapeutic classes for which the number of contacts between sales representatives and doctors to be reduced. In addition, there will be national procedures to qualify medical representatives.

Table 2.12: France – Key data on the pharmaceutical industry 2000, 2005–2010

Pharmaceutical industry	2000	2005	2006	2007	2008	2009	2010
Total number of companies[2]	302	339	337	335	326	324	n.a.
– research-oriented	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– generic producers	n.a.	n.a.	n.a.	12	12	12	n.a.
Biotech	n.a.	n.a.	233	n.a.	177	250	n.a.
Number of persons employed[1]	95,300	101,500	103,530	103,633	102,928	108,407	n.a.

n.a. = not available

1 counted per head: number of companies with at least one medicine for human use, from LEEM

Source: Eco-Santé France 201065, biotech number of companies from LEEM[66]

2.4.2 Wholesalers

There are 7 wholesalers (excluding overseas departments) with 4 leading ones:

- OCP (Celesio group): approximately 35.5% market share with 44 outlets;
- Alliance Santé: approximately 26.5% market share with 55 outlets;
- CERP: approximately 27% market share with 62 outlets;
- Phoenix Pharma: around 8.5% of market share and 22 outlets.

These wholesalers employ 12,784 people all over the country. Their role is critical in the distribution of medicines (up to 3 deliveries a day, within a very short time). Altogether they store over 20,000 different packs.

Their activity is strictly controlled and under four legal obligations (art. R5124-59 of the Public Health Code (CSP), “public service obligation”, PSO):

- deliver medicines to all pharmacies within their registered area of activity
- store at least 90% of existing medicines
- keep a permanent stock equivalent to two weeks’ sales
- be able to supply any medicine to any pharmacist in the area within 24 hours.

In addition to the distribution of medicines, they also provide various services, e.g.:

- information on medicines (vocational training);
- assistance in pharmacy management and merchandising;

65 http://www.ecosante.fr/index2.php?base=FRAN&langh=FRA&langs=FRA&sessionid=

66 data for 2008 : http://www.leem.org/leem-image/leem/document/1453.pdf
data for 2009 : http://www.leem.org/leem-image/leem/document/1480.pdf

- legal information updates (laws, decrees, press reviews), and in particular, the French Health Products Safety Agency (AFSSAPS) alerts on faulty batches through web sites.

The wholesalers' trade association is called the Wholesalers Association (Chambre Syndicale de la Répartition Pharmaceutique, CSRP). They are not represented in the Economic Committee for Health Care Products (CEPS).

Wholesalers participate in the containment of health expenditure (HE) through a yearly contribution (between 1.9% and 2.25% of sales) to social security. The contribution in 2008 was € 273 Mio (source: CSRP).

Table 2.13: France – Key data on pharmaceutical wholesale 2000, 2005–2010

Wholesalers	2000	2005	2006	2007	2008	2009	2010
Total number of wholesale compa-	n.a.	11	11	n.a.	n.a.	7	n.a.
Total number of outlets	n.a.	189	190	n.a.	n.a.	195	n.a.

n.a. = not available

Source: CSRP

2.4.3 Retailers

By law, medicines in France are mostly sold through pharmacies which have de facto the monopoly. Drugstores and supermarkets are not allowed to sell medicines and neither are Internet pharmacies.

Two other channels of distribution are possible, as described here.

- In some locations, a few doctors can sell medicines (cf. section 2.4.3.2)
- Hospitals are also allowed to sell some medicines to out-patients from a special positive list, called reassigned medicines (cf. Section 4.2 for detailed definition). These are treatments for severe conditions e.g. cancer, AIDS and hepatitis, for which the treatment has been initiated in hospital. The number of medicines in this category tends to decrease as more and more become available from community pharmacies each month (cf. section 2.4.3.3).

2.4.3.1 Community pharmacies

A pharmacist must be the owner of the pharmacy s/he runs and s/he must be a PharmD and a member of the Pharmacist professional board (Conseil National de l'Ordre, CNOP), and a French or European Union (EU) citizen. Pharmacists are allowed to own only one pharmacy, but since 1990 (Law 90-1258 of 31 December 1990) they have been allowed to have shares in other pharmacies.

The establishment of a new pharmacy is subject to a licence granted by the Préfet (local authority representing the State) after approval by the Pharmaceutical Association (CNOP) (art. L5125-1, -13, -14 and -15 of the Public Health Code (CSP). The authorisation is granted provided that the pharmacy fulfilled statutory demographic prerequisites as defined in the Public Health Code (CSP) (Art. L 5125-3, Art. L 5125-4). The rules as of 22 December 2007 are as follows:

- per 2,500 inhabitants for the first pharmacy;
- per 3,500 inhabitants for any additional pharmacy.

As of 22 December 2007 until 2010, no new pharmacy can be created, transfers being promoted instead. Transfers are authorised all over France during this period.

However, there is no particular incentive or obligation for pharmacists to establish pharmacies in rural areas. In remote places, where a pharmacy would not be financially viable, access to medicines is ensured by dispensing doctors (around 120, cf. section 2.4.3.2.). The total number of private community pharmacies as of 2009 was 22,511 (cf. Table 2.13), i.e. about one pharmacy per 2,700 inhabitants.

Ownership of pharmacies is only allowed by pharmacists. Branch pharmacies are not permitted, but pharmacies can be run as incorporated companies, known as Sociétés d'Exercice Libéral (SEL)[67] so a pharmacist can invest in a share of another pharmacy.

Opening hours, number of pharmacists employed, availability of medicines by wholesalers and advertising are also regulated.

Pharmacists can purchase medicines directly from the manufacturer, especially products with a high turnover. Discounts granted to pharmacists by wholesalers or the pharmaceutical industry are regulated (for further information see section 3.1.4).

The majority of pharmacies are privately owned but there are a few "mutuelles" (i.e. complementary health insurance)-owned pharmacies. Pharmacy chains are not allowed but pharmacies are allowed to belong to groups of pharmacies (there are approximately 40 of them) with common interests (in purchasing, merchandising, advertising, etc.). In France, four types of pharmacies exist, as detailed here.

- Private pharmacies, owned by a pharmacist, represent the majority of pharmacies. There have been fewer than approximately 23,000 since the year 2000.
- Pharmacies that are part of the mining social insurance scheme which only miners from this scheme can access. By law, miners can go to private or "mutual" pharmacies but don't do so in practice since they would have to pay in advance for their medicines. They are owned by the mining health insurance fund so pharmacists are managers and employees.

[67] company formed by self-employed practitioners

- Few “Mutual” pharmacies are accessible to all patients covered by a complementary mutual health insurance association (cf. section 1.3.2). They are owned by the union of mutuals “La Mutualité Française”, which means that pharmacists are managers and employees.
- Hospital pharmacies for out-patients also exist (for specific medicines, cf. section 2.4.3.3.).

Pharmacists may belong to a trade association, as listed here.

- Federation of Pharmacists in France (Fédération des Syndicats Pharmaceutiques de France, FSPF).
- National Union of Pharmacists of France (Union Nationale des Pharmacies de France, UNPF).
- Union of Pharmacists (Union des Syndicats de Pharmaciens d’Officine, USPO).
- Federation of Rural Pharmacies (Association des Pharmacies Rurales, APR).

The trade associations are represented in negotiations with the health insurance authorities. They are also involved in the licensing process with the local authorities and pharmaceutical associations.

Pharmacists’ remuneration is a combination of profit margin and a flat fee per pack dispensed of € 0.53 (cf. Table 3.5).

For further details cf. section 3.1.5.2.

Table 2.14: France – Retailers of medicines 2000, 2005–2010

Retailers	2000	2005	2006	2007	2008	2009	2010
No. of community pharmacies[1]	22,698	22,610	22,561	22,514	22,590	22,511	n.a.
– *Thereof: No. of private pharmacies*[2]	22,698	22,610	22,561	22,514	22,590	22,511	n.a.
– *Thereof: No. of public pharmacies*	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of hospital pharmacies for out-patients3	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of dispensing doctors	n.a.	~120	~120	~120	~120	~120	n.a.
No. of other POM disp., *please specify*	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
Total no. of POM dispensaries	22,698	22,730	22,681	22,634	22,710	22,631	n.a.
No. of internet pharmacies	0	0	0	0	0	0	0
No. of OTC disp., like drugstores	0	0	0	0	0	0	0

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

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

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

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

3 all hospital pharmacies may dispense medicines, but only from a specific list of medicines

Source: Eco-Santé France 2010[68] ; CNOP[69] for number of private pharmacies

2.4.3.2 Dispensing doctors

In some remote areas authorised doctors can dispense medicines. This is the case on some small islands, in some mountain valleys and some rural areas. The total number of dispensing doctors is 120.

Midwives and physiotherapists are allowed to prescribe a limited number of medicines but not to dispense them.

2.4.3.3 Hospital pharmacies

Hospital pharmacies (pharmacies à usage intérieures, PUI) dispense medicines to in-patients as well as to out-patients. Although all hospitals dispense medicines to in-patients, only a number of them dispense medicines to out-patients. It is each hospital's decision. Only public hospitals are allowed to dispense medicines to out-patients; private hospitals are not.

68 http://www.ecosante.fr/index2.php?base=FRAN&langh=FRA&langs=FRA&sessionid=

69 http://www.ordre.pharmacien.fr/fr/bleu/index3.htm

Hospital pharmacies are allowed to dispense medicines from a special list for out-patients (please refer to section 4.2.1).

There are two positive lists at hospital level:

1. a list of hospital medicines for the hospital sector (*liste des medicaments agréés aux collectivites*) which includes all medicines that are allowed for use at hospital (so it includes out-patient medicines). In 2008, about 2,700 medicines in 2008 were listed (estimate from Theriaque database).

2. A hospital-only medicines list (Médicament de la réserve hospitalière, HOM) for in-patient stay only. Those medicines can not be delivered to out-patients

The number of medicines dispensed by hospital to out-patients tends to decrease as more and more become available from community pharmacies. In fact, hospitals choose to work with a limited list of medicines.

In France there is a specific list of reassigned medicines (retrocession) delivered by hospital pharmacies to out-patients (including medicines not available in out-patient pharmacies). 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 pharmaceutical companies. It takes into account the risks associated with using the products and makes it easier to control stocks (see section 4.2.1).

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.

2.4.3.4 Other POM dispensaries

Not applicable.

2.4.3.5 Other retailers

By law, medicines in France are mostly sold through pharmacies which have de facto the monopoly. Drugstores and supermarkets are not allowed to sell medicines and nor are Internet pharmacies.

Internet pharmacies are not allowed in France. Medicines can only be purchased from non-French web sites. It is legal for consumers to purchase over-the-counter (OTC) medicines from foreign Internet pharmacies. However, the Pharmaceutical Association (CNOP) is currently looking into this problem and trying to work out how to legalise this business.

2.4.4 Promotion

Advertising of medicines is regulated by law (Art. L 5122-1 to L 5122-16 and Art. R.5122-1 to R. 5122-47 of the Public Health Code (CSP), in line with the European Commission (EC) Directive 2001/83/EC. Control of this legislation is carried out by the French Health Products Safety Agency' (AFSSAPS) body, "Committee in charge of medicines advertising control and recommendations on proper use".

Direct advertising of over-the-counter (OTC) medicines to patients is allowed by law (Art L. 5122-6 of the Public Health Code (CSP) as is advertising of vaccines or products reducing tobacco dependence. Advertising is prohibited for medicines available on medical prescription only, for reimbursed products and also for products with advertising restrictions set out in the market authorisation. It is based on a system of prior vetting. When a non-prescription reimbursable product is de-listed, it is possible to advertise up to six months before de-listing, if an agreement is made between the Economic Committee for Health Care Products (CEPS) and the company, to preserve the financial interests of the health insurance fund during this period (Art. D 5172-7-1 of the Public Health Code (CSP).

Advertising of a medicine to people qualified to prescribe or supply is allowed. The French Health Products Safety Agency (AFSSAPS) must be notified of each advertisement during the eight days following the launch of the campaign. If a product has prescribing restrictions, advertising is only possible to people authorised to prescribe, including hospital pharmacists.

Advertising on the Internet of medicines is allowed but according to general advertising regulation, i.e. it is prohibited for medicines available on medical prescription only, for reimbursed products and also for products with advertising restrictions set out in the market authorisation. The French Health Products Safety Agency (AFSSAPS) and the pharmaceutical industry have signed a "charter of good conduct" on this. No sanctions exist.

Various measures are implemented in order to restrict or control the promotional spending of manufacturers:

- there are taxes on promotional expenditure; for 2005 the amount was € 227 million
- if an advertisement is forbidden, after transparency procedures, the Economic Committee for Health Care Products (CEPS) can charge the company a penalty of a maximum of 10% of the sales of the product concerned;
- a Charter on medical sales representatives has been signed between the Economic Committee for Health Care Products (CEPS) and the Association of Pharmaceutical Industry (LEEM) (Art. L 167-17-8 of the Social Security Code (CSS); The number of sales representatives was about 23,000 in 2005[70].
- in a global agreement between the Economic Committee for Health Care Products (CEPS) and the pharmaceutical industry it was decided to reduce the amount of contact

[70] http://www.has-sante.fr/portail/upload/docs/application/pdf/certification_of_sales_representatives_calls.pdf

between each company and doctors in various medical fields, e.g., statins, proton pump inhibitors (PPI), antibiotics (macrolides and fluoroquilonones), triptans and antiasthma combined;

- samples must be claimed by doctors, as under the agreement between the Economic Committee for Health Care Products (CEPS) and the industry, sales representatives are not allowed to carry samples – doctors request them directly from the company.

Health insurance funds manage the means of informing patients on rational use of medicines (e.g. the famous “Antibiotics are not automatic” campaign on the uses of antibiotics), on prevention (through the preventive fund campaign on flu vaccines), on promoting vaccinations for rubeola-mumps-roseola (rougeole-oreillons-rubéole, ROR) and on iatrogenic for elderly people.

There is no regulation on information to patients in the in-patient sector.

Since mid-2003, the national health insurance fund (National Insurance Fund for Salaried Employees (CNAMTS) implemented **sickness insurance representatives (DAM)** to visit doctors and pharmacists, in out-patient and in-patient sectors, and explain the setup of the health insurance fund’s risk management arrangements.

The objectives are to inform the health professionals on:

- the conventions signed with the health insurance fund;
- her/his activities;
- the insurance fund’s objectives and orientation of risk management.

The representatives conduct face-to-face visits with health professionals, who are mostly prescribing physicians, but also with pharmacists (e.g. on generic substitution) and dentists. A sample of professionals are targeted on specific themes e.g. antibiotics, generic substitution, breast cancer screening, prevention, overprescribing or unmet goals according to the conventions (i.e. conventions of the doctors with the health insurance fund). The duration of the visits is approximately 30 minutes with a target of 350,000 visits in 2008, so a health insurance representative (DAM) visits a general practitioner (Médecin Généraliste, GP) approximately three times per year. The workforce was approximately 950 in 2008 (700 in 2006). They are managed by a regional manager acting as the link between the National Insurance Fund for Salaried Employees (CNAMTS) and the health insurance representative (DAM). Health insurance representatives (DAM) are professionals with medical training specific to campaigns. Since 2007, they are certified by a Qualified Professional Certificate of the Social Security. Training accounted for approximately 25 days per health insurance representative (DAM) in 2006. Visit preparation consists of approximately one training day per campaign, including evaluation of the preparedness of the health insurance representative (DAM). They are provided with guidelines and specific documents to give to the professional, including a report on her/his activity. Impact evaluation has been conducted, for instance, a positive significant impact on prescription of antibiotics.

The National health insurance fund also conducts risk management through its Health Insurance Medical Control Service at local level. Each local health insurance fund (CPAM, Caisse Primaire d'Assurance Maladie) has its own Health Insurance Medical Control Service department, made up of advisory practitioners - doctors, chemists, dentists - and administrative staff. This service helps and controls social insured and healthcare professionals[71]. The service:

- Advises social policyholders and healthcare professionals on medico-social regulations and on the correct use of treatment.
- Provides assistance to policyholders and healthcare professionals to improve the management of long-term diseases.
- Analyses and manages patients' applications for benefits and the activity of healthcare professionals and establishments.
- Manages the successful implementation of regulations and medical practices.
- Leads studies.

In this framework, the National Health Insurance Fund (CNAMTS) targets 62,000 visits of advisory practitioners 'médecins conseils' to health professionals in 2008.

2.5 Funding

This section provides an overview of the funding of medicines.

[71] http://www.ameli.fr/l-assurance-maladie/connaitre-l-assurance-maladie/getting-informed-about-health-insurance/health-insurance-network/health-insurance-medical-control-service.php

2.5.1 Pharmaceutical expenditure

Table 2.15: France – Total pharmaceutical expenditure 2000, 2005–2009

Pharmaceutical expenditure	2000	2005	2006	2007	2008	2009
TPE in million Euro[1]	n.a.	22,470	22,686	23,690	24,395	25,091
– thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
PE in the out-patient sector pharmaceuticals only and excluded expenditure of other medical non-durables [2]	23,631	31,466	32,421	33,886	34,902	n.a.
– thereof public	15,735	21,726	22,011	23,083	23,044	n.a
– thereof private	7,896	9,740	10,410	10,803	11,857	n.a
PE in the out-patient sector[1]	n.a	17,970	18,095	18,790	18,945	19,365
– thereof public	n.a	n.a	n.a	n.a	n.a	n.a
– thereof private	n.a	n.a	n.a	n.a	n.a	n.a
PE in the in-patient sector[1]	n.a.	n.a.	4,800	4,900	5,450	5,726
• thereof public	n.a	n.a	n.a	n.a	n.a	n.a
• thereof private	n.a	n.a	n.a	n.a	n.a	n.a

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

[1] at ex-factory prices from national sources: CEPS (see sources detail hereafter)

[2] as defined by the OECD as out-patient expenditure of medicines and other medical non-durables. In this table we refer to expenditure of pharmaceuticals only and excluded expenditure of other medical non-durables.

Source: OECD Health Data 2010 for out-patient PE, shares of PE in the in-patient sector from CEPS activity reports 2008 and 2009 [72]

The French pharmaceutical expenditure (PE) in out-patient sector accounted for € 34,902 Mio. in 2008.

2.5.2 Sources of funds

Public pharmaceutical expenditure (PE) (social security and state or local funds) accounted for 66% of the out-patient pharmaceutical expenditure (PE, i.e. expenditure on medicines and other medical non-durables?) in 2009. The remaining 34% from private expenditure included 17% of expenses for private health insurance and 17% of out-of-pocket payments (OPP) (including cost-sharing and self-medication, cf.3.2.4.2) of households.[73]

Private health insurance in France corresponds to complementary health insurance which patients subscribe to on a (usually) voluntary basis. In 2008, a total of 94% of the population

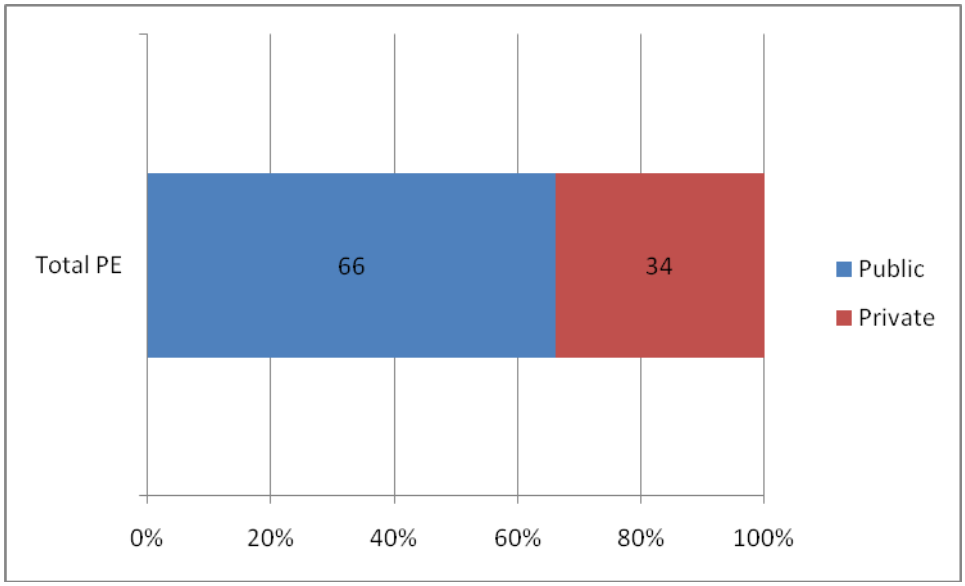
[72] http://www.sante.gouv.fr/ceps/3ceps.htm

[73] National health accounts 2009 (CNS 2009)

is covered by complementary health insurance, including 6% covered by the free Complementary Universal Health Insurance Coverage (CMUC), provided for people with low incomes[74]. In 2009, 4.186 million people[75] were registered under the CMUC coverage system, among which 36%[76] belong to the universal health coverage (CMU). Please refer to section 1.3.2 for further details on funding of the healthcare system.

Self-medication, defined as medicines bought without a medical prescription, represented 6.5% of the pharmaceutical sales in France in 2009 (14% in volume), accounting for € 1.9 billion[77]. At pharmacy retail price (PRP) level, including value-added tax (VAT), the Association of the European Self-Medication Industry (AEGSP) estimated self-medication to be at € 1.99 billion in 2009.

Figure 2.3: France – Share of public and private pharmaceutical expenditure, 2009



PE = pharmaceutical expenditure

Source: National health accounts 2009 (CNS 2009)

[74] IRDES, ESPS survey: http://irdes.fr/EspaceEnseignement/ChiffresGraphiques/CouvertureComplementaire/DonneesGnles.html

[75] Fonds CMUC 4th report : http://www.cmu.fr/userdocs/RAPPORT%20EVALUATION%204.pdf

[76] CNAMTS[76]

[77] AFIPA: http://www.afipa.org/afipa/pdf/10084_les-chiffres-du-marche-09.VL.pdf

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

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

3.1 Pricing in the out-patient sector

3.1.1 Organisation of pricing

After having obtained **market authorisation**, the manufacturer can decide on which market to place the medicine. A key distinction is on the hospital market for in-patients and the market for out-patients who buy medicines in pharmacies (cf. Table 2.14). For the hospital market pricing is free.

For the out-patient market, the manufacturer can choose to enter the non-reimbursable market or the reimbursable market. If s/he chooses the non-reimbursable market, pricing is totally free and s/he can sell the product the day after having obtained the market authorisation. If s/he chooses the reimbursable market, the price is regulated and the process for getting granted reimbursement status is regulated.

The **Pricing Committee** (Economic Committee for Health Care Products, CEPS) is in charge of pricing reimbursable medicines only. There is free pricing for non-reimbursable medicines. The Economic Committee for Health Care Products (CEPS) needs the advice of the Transparency Commission for setting the price. This advice contains a Level of clinical benefit ("Service medical rendu", SMR), which may be considered as major, moderate, weak or insufficient, and a Level of improvement of clinical benefit (ASMR) against the comparable products existing in the market, from ASMR 1 to ASMR 5 (cf. section 3.2.1).

As a rule, the Economic Committee for Health Care Products (CEPS) finds an agreement with the manufacturer on the price in line with the technical level of relative improvement provided by the product in comparison with other products available in the same therapeutic area. Very seldom, there is no agreement with the manufacturers. In such cases the product is not entered into the positive list. It is always possible for manufacturers to decide to reopen the discussion on a new basis.

The members of the Committee (that holds a weekly meeting) with voting rights are:

- President (Independent expert – s/he must try to find a consensus between members);
- Vice President (Independent expert);
- one representative of the Ministry of Social Affairs (MAS);
- one representative of the Ministry of Health;
- one representative of the Ministry of Industry;

- one representative of the Ministry of Finance;
- two representatives of the health insurance fund for salaried people;
- one representative for other health insurance funds;
- one representative for complementary insurance and private insurance;
- two members without voting rights – one representative of the Directorate of Hospitals in the Ministry of Social Affairs (MAS) and one representative of the Ministry of Research.

For a reimbursable product, the company submits a report simultaneously to the French National Authority for Health (HAS) for technical advice from the Transparency Commission, to the Economic Committee for Health Care Products (CEPS) for pricing, and to the National Union of Health Insurance Funds (UNCAM) for the reimbursement rate.

The time frame for inclusion on the positive list and decisions on pricing and the level of reimbursement complies with the timing of the Transparency Directive (180 days). At the end of the process, the Ministry of Social Affairs' (MAS) decision regarding the inclusion of the product on the positive list, the price granted by Economic Committee for Health Care Products (CEPS) and the reimbursement rate granted by the National Union of Health Insurance Funds (UNCAM) are all published in the same issue of the country's official bulletin.

3.1.2 Pricing policies

Table 3.1: France – Ways of pricing of medicines at manufacturer level, 2011

Pricing policies	(Non) prescription market		(Non) reimbursement market		Specific groups of medicine		
	POM	OTC	Reimbursable	Non-reimbursable	Generics	Parallel traded	
Free pricing	Yes for non reimbursable	Yes	No	Yes	Non-reimbursable		
Statutory pricing					Yes according agreement with manufacturers		
Price negotiations	Yes for reimbursable	No	Yes, including price/volume agreements and risk-sharing	No		Yes	
Tendering							
Others – specify							

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

Source: CNAMTS

France was one of the first countries to show real transparency on prices for more than 20 years, with a public database that every patient can consult. This service is now on the Internet websites of health insurance funds.[78]

The pricing system for parallel traded medicines has been the same as for other medicines in France since the integration of the relevant European legislation by Decree No. 2004-83 of 23 January 2004. Only 37 products (2009) are approved.

3.1.2.1 Statutory pricing

Statutory pricing applies to generics.

The ex-factory price of a generic is based on the ex-factory price of the original product. The multiplier was 0.55 from 2006 onwards (cf. 3.1.2.5).

3.1.2.2 Negotiations

The negotiations are carried out in compliance with a procedure described in a general agreement between the industry and the Economic Committee for Health Care Products (CEPS) ("accord cadre"), the duration of which is four years. This concerns all reimbursable medicines, at ex-factory price level.

The Economic Committee for Health Care Products (CEPS) finds an agreement with the manufacturer on the price in line with the technical level of relative improvement provided by the product in comparison with other products available in the same therapeutic area. Very seldom, there is no agreement with the manufacturers. In such cases the product is not entered into the positive list. It is always possible for manufacturers to decide to reopen the discussion on a new basis.

These agreements can lead to price/volume or risk-sharing agreements (see section 3.1.3.5).

Since 2004, medicines for out-patients only available from hospital pharmacies (list or reas-signed medicines, see section 4.2.1) have been controlled. At ex-factory level, the margin is controlled as well. The price is negotiated between the Economic Committee for Health Care Products (CEPS) and the manufacturer. If an agreement cannot be reached, the price can be set by the Economic Committee for Health Care Products (CEPS).

3.1.2.3 Free pricing

Non-reimbursable medicines in the out-patient sector have benefited from free pricing at all levels since 1986, according to an edict that cancels the general price control in France. This is the same for medicines purchased by hospitals.

[78] For more information: http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI

Before 2008, over-the-counter (OTC) medicines did not exist in France since no medicines were on free access including non-reimbursable medicines. Since 1 July 2008, the government approved the self-sevice in pharmacy of a specific list of non-reimbursable pharmaceuticals in pharmacies. The list[79] of 217 medicines was published by the Ministry of Health.

OTC as non-reimbursable medicines are freely priced. The wholesalers' and pharmacists' margins are also free. Over-the-counter (OTC) medicines are not reimbursed, but in certain therapeutic classes they are in direct competition with reimbursable products.

3.1.2.4 Tendering

Not applicable.

3.1.2.5 Generics

When the patent of an original product expires and this product is registered on the generic group list ("le repertoire") by Afssaps, then its ex-factory price price is decreased by -15%.

The price of generics is calculated as 45% of the ex-factory price of the original product before being decreased by 15%. The pharmacy retail price (PRP) is the sum of the ex-factory price plus the wholesale mark-up plus the pharmacist's mark-up, pharmacist's mark-up of a generic calculated on the ex-factory price of the original product (except for medicines under the reference price system, called TFR, cf. section 3.2.3, see also section on mark-ups for details 3.1.5).

After a 18 months period, the ex-factory prices are again reviewed if the penetration rate exceeds or equals 60%:

- -12,5% for the original product
- -7% for the generics.

If the substitution target of 60% is not achieved, the generic group, defined as the original product and its generics, is eligible to reference price system "TFR".

3.1.3 Pricing procedures

The pricing procedure in France is a mixture of internal price referencing, external price referencing, volume agreements and few cost-sharing ones.

[79] http://www.sante-jeunesse-sports.gouv.fr/IMG/pdf/Listes_des_medicaments_PMF_par_specialites.pdf

Table 3.2: France – Pricing procedures, 2011

Pricing procedure	In use: yes / no	Price type[1]	Scope[2]
External price referencing	Yes	Manufacturer	Part of reimbursable medicines: those with the highest level of improvement of medical service (reference countries are United Kingdom, Germany, Italy, Spain)
Internal price referencing	Yes	Manufacturer	Reimbursable medicine The comparison with the prices of other products is systematically performed for all reimbursable medicines
Cost-plus pricing	No	-	-
Indirect profit control	No	-	-
Risk/cost sharing	Yes	Manufacturer	-
Price/volume agreements	Yes	Manufacturer	-

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

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

Source: CNAMTS

3.1.3.1 External price referencing

In French law, the process of external price referencing is described in Art. L-162-17-6 of the Social Security Code (CSS). In the "accord cadre" 2003-2006, Art. 4 describes the procedure for setting the pricing process for innovative products. For these products, the principle is that the price is fixed within 14 days after receiving the advice of the Transparency Commission.

A prerequisite is that the pharmaceutical company has signed an agreement, a "convention" of four years' duration with the Economic Committee for Health Care Products (CEPS) under Art. L 162-17-4 of the Social Security Code (CSS).[80]

For this to be applicable to a product, the procedure requires that:

- the product has a Level of improvement of clinical benefit (ASMR) I, II or III for the major indication; or
- the product has a Level of improvement of clinical benefit (ASMR) IV in specific cases for some level of daily cost of comparable products and if the product will not replace an existing product with generics (cf. section 5.1).

The company must apply for a price similar to the price accepted by the company in Germany, Spain, Italy and the United Kingdom (the information on these prices is provided directly by the company). The company also agrees that all price changes in these other countries will be reflected by a price change in France, and signs an agreement on the

[80] http://www.leem.org and http://www.leem.org/htm/themes/accueil.asp?id_rubrique=65

volume of the sales. If that agreement is not respected, the company must pay a claw-back payment (cf. section 3.1.3.5). As a symbol of "goodwill", the company may sign additional agreements with the Economic Committee for Health Care Products (CEPS), e.g. agreeing that it will recommend the posology that is proposed in the summary of product characteristics (SPC) and also pragmatic studies on the use of the product in "real life".

3.1.3.2 Internal price referencing

Comparisons in prices are systematically carried out for all reimbursable medicines with the indications mentioned by the Transparency Commission in the advice given on the medicine. Generally, comparisons are made using daily cost of treatment, or sometimes using the cost of a "cure" (i.e. the cost of the therapies when used at the recommended dose level for the recommended duration). Comparisons are made primarily on ex-factory prices and for each strength and each pack size.

3.1.3.3 Cost-plus pricing

Not applicable.

3.1.3.4 (Indirect) profit control

Not applicable.

3.1.3.5 Price/volume and risk-sharing agreements

In France, the pricing committee (CEPS) conducts **price-volume agreements or contracts based on posologies or treatment durations**. Price/volume agreements mainly concern medicines with a need "*to ensure that the quantities of its sales remain consistent with its medically established target patient group*" [81]. They apply to medicines for which the "*ASMR rating is only applicable to some of its indications or to a small patient group or where, regardless of any financial considerations, public health requirements dictate that a drug should only be used for a limited number of indications for which it is absolutely essential, as is often the case for antibiotics, for example.*"[81,82]

Regarding **risk-sharing agreements**, the CEPS states in its activity report for 2009 that it may agree on a conditional price upon further very strict conditions for medicines for which evaluation "*would not warrant the price requested*". The conditions are stated as follows:

1. *"the anticipated but unproven benefit must be such that it could not reasonably have been proven during the clinical trials carried out prior to marketing authorisation, and for example that the benefit can only be proven in real-life practice"*

[81] CEPS 2009 : http://www.sante.gouv.fr/IMG/pdf/rapport_d_activites_du_CEPS_en_2009_Vanglais.pdf

[82] Please refer to the CEPS 2009 report section 1.4.2. Volume clauses for further details on price reductions implementation

2. *"if this benefit exists, it must represent a clear advantage and must be preferable in public health terms. In the third place, a study must be devised which at the end of the fixed-term trial period will definitively prove whether or not the benefit exists and if so, whether it is significant enough"*

3. *"the company marketing the medicine must enter into an agreement whereby it undertakes among other things to bear the financial costs in the event of failure of the medicine."*

3.1.4 Discounts / rebates

Discounts and rebates of the pharmacy purchasing prices (Prix d'achat des médicaments par les pharmaciens, PPP) are negotiated between the supplier (wholesaler) and the pharmacist and are regulated.

For **reimbursable** medicines the maximum level of rebates/discounts granted to pharmacists is fixed by regulations. The two latest regulations can be found in Art. L 138-9 of the Social Security Code (CSS): Pharmacists are not allowed to receive more than 2.5% discount for reimbursable products, with one exception for reimbursable generics as described hereafter.

For **reimbursable generics**, the regulation differs whether the medicines are supplied through a wholesaler or directly from the manufacturer to the pharmacist as follows:

- For generics supplied by a wholesaler, the discount/rebate rate should be lower than 10.74%. In fact, this maximum limit was not well respected and the legislation was changed in 2008 (see below).
- For generics directly supplied by the manufacturer to the pharmacist, the Ministerial Order of 29 December 2005 limited the discounts/rebates given. They could not exceed 20% in 2006, and 15% in 2007 of the ex-factory price. If the advantages exceed this level the pharmacist must reduce the consumer price. These discounts are not allowed since 2008 anymore according to the Law (see below for details).
- Since 2008, according to the "Chatel" Law number 2008-3 of 3 January 2008[83]:
  - the maximum discount/rebate for reimbursable generics is 17% of the ex-factory price whether or not it is directly supplied to the pharmacist.
  - the pharmacist can also benefit from the wholesale margin.

As of 2008, for **reimbursable non-generics** from a generic group under the reference price "TFR" (cf. 3.2.3), the maximum discount/rebate is 17% of the reference price of the group (according to the "Chatel" Law number 2008-3 of 3 January 2008[84]).

[83] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000017785995&dateTexte=

[84] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000017785995&dateTexte=

For **non-reimbursable** medicines, the level of discount/rebate is not regulated (for information on claw-backs cf. section 3.3.3).

3.1.5 Mark-ups and taxes

Table 3.3: France – Regulation of wholesale and pharmacy mark-ups, 2011

	Wholesale mark-up			Pharmacy mark-up		
	Regulation	**Content**	**Scope**	**Regulation**	**Content**	**Scope**
France	Yes	Regressive mark-ups	Reimbursed medicines	Yes	Regressive mark-ups	Reimbursable medicines

Source: CNAMTS

The margin system is different for reimbursable and non-reimbursable products as well as for out-patients and in-patients buying medicines from a hospital pharmacy.

For non-reimbursable products, prices and margins are freely established. In March 2008 an agreement was signed between industry and pharmacists for good practices on pricing for products just delisted from reimbursable positive list.

For reimbursable products, margins are controlled for wholesalers and pharmacists. For out-patient and reimbursable medicines a regressive mark-up scheme is now in place.

The ex-factory price, excluding value-added tax (VAT), and the pharmacy retail price (PRP), including value-added tax (VAT) (including wholesalers' and pharmacists' margins), are published in the country's official bulletin. From 2 January 1990 a regressive mark-up scheme was in place for pharmacies and wholesalers. This regulation changed on 28 April 1999 with the introduction of a fixed fee per pack for pharmacists, and on 12 February 2004 it changed again to three levels, officially published on 21 February 2004.

For hospital medicines dispensed to out-patients in hospital pharmacies a fixed fee is applied. The legal basis defining the rules for wholesalers' and pharmacists' margins for reimbursable medicines has been the same Ministerial Order for many years. Before 1990 this was worked out based on a proportion of the ex-factory price.

3.1.5.1 Wholesale remuneration

Wholesale margins are regulated for reimbursable medicines. These are remunerated through a regressive mark-up scheme, regulated by means of a Ministerial Order signed by the Ministry of Health and the Ministry of Finance. The latest amendment was on 6 March 2008 (official bulletin[85]).

[85] http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=FA28450B18DDBC5C2AE9F580B01DCFFD.tpdjo08v_3?cidTexte=JORFTEXT000018213915&dateTexte=&oldAction=rechJO

Table 3.4: France – Wholesale mark-up scheme for reimbursable medicines, 2011

Part of the ex-factory price in € (excluding value-added tax (VAT)	Maximum mark-up as a % of ex-factory price
0.00-22.90	9.93
22.91-150.00	6.0
150.00-400	2.0
> 400	0

Source: CNAMTS, Decree of 4 August 1987, current version, modified by decree of 6 March 2008.

Examples for wholesale price in € (excluding VAT):

- price = € 22.90 : wholesale price =€ 25.17
- price = € 150 : wholesale price = € 159.90
- price = € 400 : wholesale price = € 414.90
- price = € 1,000 : wholesale price = € 1,014.90

3.1.5.2 Pharmacy remuneration

Pharmacists' unions indicated an average margin on reimbursable medicines of 24% in 2001 and 21.5% in 2010[86]. If the rate goes down, the total amount continues to increase with the growth of the turnover.

For generics, there is a special calculation of pharmacy remuneration that provides the same amount of money as remuneration for pharmacists as there is for delivering the original product (cf. section 3.3.2.2).

A flat fee of € 0.53 (due only for reimbursable medicines) is included in the price. This amount is also refunded by the health insurance funds, and by complementary health insurance. It is different from the out-of-pocket fee per pack of € 0.50 (cf. 3.2.4.2).

The pharmacist remuneration also includes discounts/rebates from the supply chain as described in section 3.1.4.

[86] Source : Le Moniteur des Pharmacies

Table 3.5: France – Pharmacy mark-up scheme for reimbursable medicines, 2011

Part of the ex-factory price in € (excluding value-added tax (VAT))	Maximum mark-up in % of ex-factory price
0.00-22.90	26.1
22.91-150.00	10.0
> 150.00	6.0

Source: CNAMTS

Examples of public price in € excluding VAT (i.e. including wholesale margin and fee per pack for pharmacist margin) :

- Price= € 22.90 : public price= € 31.68
- Price= € 150 : public price=179.12
- Price= € 400 : public price=449.12

For **generics**, there is a special calculation of pharmacy remuneration that provides the same amount of money as remuneration for pharmacists as there is for delivering the original product (cf. section 3.4.2).

3.1.5.3 Remuneration of other dispensaries

The fees paid to hospitals for handling the distribution of products authorised to be sold to out-patients have been regulated since October 2006: a total of € 28 per line of delivery (a line of prescription can include, e.g., the delivery of three identical packs, with the fee always being € 28). This fee is included in the price paid by the patient and the total amount is reimbursed on the same basis as for all reimbursable medicines, by the Social Health Insurance (Assurance sociale, SHI) or Complementary Health Insurance Funds.

The remuneration for the few dispensing doctors is the same as for the community pharmacists.

3.1.5.4 Taxes

3.1.5.4.1 Value-added tax

The standard value-added tax (VAT) rate is 19.6% on most products and services in France, but the value-added tax (VAT) rate is 2.1% on reimbursable medicines and 5.5% on non-reimbursable medicines.

3.1.5.4.2 Other taxes

Fees for registration of market authorisation range from € 674 to € 25,400, and for parallel import authorisation from € 674 to € 9,150. The annual tax on medicines or on parallel import medicines ranges from € 250 to € 17,000. These taxes are paid to the French Health Products Safety Agency (AFSSAPS) by manufacturers or importers. An annual contribution (under Art. L 245-2 of the Social Security Code (CSS) on pharmaceutical manufacturers for

promotional activities and also under Art. L245-6 of the Social Security Code (CSS) is funded from the manufacturers' medicines turnover.

3.2 Reimbursement in the out-patient sector

This section describes the scope of the reimbursement system, the regulatory framework and the main authorities in the out-patient sector as of 2011.

3.2.1 Organisation

The National Union of Health Insurance Funds (UNCAM) is in charge of setting the reimbursement rate. This procedure happens after:

- assessment of medical service (SMR) and improvement of medical service (ASMR) by the Transparency Commission (see below)
- and the Economic Committee for Health Care Products (CEPS) having concluded the pricing procedure.

There is a positive list of reimbursable medicines which is determined by the Ministry of Health after receiving technical advice from the Transparency Commission. Only medicines that provide an improvement of medical service or savings in the cost of treatment are eligible for reimbursement.

The National Union of Health Insurance Funds (UNCAM) has been in charge of defining the reimbursement categories since 13 August 2004 (Art. L322-2 and L182-2 of the Social Security Code (CSS). There are three reimbursement categories (cf. Table 3.6 in section 3.2.2.3.). The reimbursement rate is based on the HAS recommendation regarding SMR and the seriousness of the disease.

The composition of the Transparency Commission is defined in Art. R. 163-15 of the Social Security Code (CSS): 20 members with voting rights appointed by decision of the French National Authority for Health (HAS), consisting of one president (scientific), two vice-presidents, 17 members (scientific) and 6 substitute members.

In addition, there are eight members with consultative voice:

- four members of agencies or state representatives: director of social security department, director of heath department, director of hospital department, director of French Health Products Safety Agency (AFSSAPS);
- four other members (three representatives of Health Insurance Funds, one for each main fund, and one representative of the pharmaceutical industry).

The duties of the Transparency Commission are defined in Art. R.163-2 to R.163-21, L.161-37, L161-39 and L.161-41 of the Social Security Code (CSS). The procedures are defined in Art. R.163-18 of Social Security Code (CSS).

The Transparency Commission gives two kinds of appraisal for each new product or reappraisal, as detailed here.

- The level of actual clinical benefit (Service medical rendu, SMR) for each indication: medical value (severity of the disease, clinical effectiveness), interest for public health, target population. This level determines the rate of reimbursement. The SMR may be considered as major, moderate, weak or insufficient (cf. section 3.2.2.3). The normal rate is 65%. For products for the treatment of diseases without special gravity and homeopathic products the rate is 30% by law (Art. R322-1 of Social Security Code (CSS).
- The level of improvement of clinical benefit (amelioration du service medical rendu, ASMR) or added value of a medicine within an indication. This level is determined in relation to relevant comparators, in particular the most recent product, the best-seller and the cheapest product. There is a four-level improvement of clinical benefit (ASMR) scale:
    - major (ASMR I): new therapeutic area, reduction of mortality;
    - important (ASMR II): important improvement in therapeutic efficacy and/or with important reduction of side-effects;
    - moderate (ASMR III): modest improvement in therapeutic efficacy and/or with reduction of side-effects;
    - minor (ASMR IV): very minor improvement;
    - No improvement (ASMR V).

Comparisons are made with the products of the same Anatomic Therapeutic Chemical (Classification Anatomique, Thérapeutique, Chimique, ATC) classification code and also with products with the same therapeutic indications.

The Level of improvement of clinical benefit (ASMR) is directly linked with the price negotiation between the Economic Committee for Health Care Products (CEPS) and the pharmaceutical company. If there is no improvement in clinical benefit (ASMR), the medicine must be cheaper than therapeutic equivalents in order to be included in the positive list of reimbursable medicines.

A special procedure is possible under the third paragraph of Art. R 163-2 of the Social Security Code (CSS), called “médicament d’exception”. In this case the prescription must be made with a special formulary and under control of the Health Insurance Funds’ managing doctors. A prescription guide (“Fiche d’Information Thérapeutique”, FIT) must be published at the same time as inclusion in the positive list and the price. The prescription guide (FIT) contains information on posology and duration of treatment, and also possible restrictions on prescribing or dispensing mentioned in the market authorisation. Currently only 35 products are on this list. They represent € 750 Mio. at ex-factory price level. The main therapeutic areas are erythropoietin, interferon beta, specific antirheumatic agents and growth hormones.

Since the introduction of the Law of 13 August 2004 the rate of reimbursement for each product has been determined by the National Union of Health Insurance Funds (UNCAM) (Art. L322-2 and L182-2 of the Social Security Code (CSS).

The Minister of Health can decide that for some irreplaceable and costly products (e.g. treatments for cancer and HIV, as well as growth hormones), co-payment must be removed. This positive list is managed by the Ministry of Health under Art. R 322-2 of the Social Security Code (CSS).

3.2.2 Reimbursement schemes

The health insurance system is divided into three main schemes, as listed here.

- The general scheme, which covers employees in the industry, business and services sectors, covers 85% of the French population. It is managed by the National Insurance Fund for Salaried Employees (CNAMTS).
- The agricultural scheme, which covers farmers and farm employees (about 7% of the population covered), is managed by the Agricultural Mutual Insurance Fund (Mutualité Sociale Agricole, MSA).
- The scheme for non-salaried and non-farming, self-employed workers (about 5% of the popluation covered), which covers craftspeople, retailers and independent professions, is managed by various organisations belonging to the National Insurance Fund for Self-employed Workers (Régime Social des Indépendants, RSI).

The system also includes a number of other special schemes (sailors, miners, railway employees, Paris public transport employees, employees from the Electricity and Gas Board, etc.).

3.2.2.1 Eligibility schemes

The French reimbursement scheme is **both product and patient specific (both disease and social criteria)**.

Product specific criteria

There is a positive list for the out-patient sector. Under Art. L 5126-4 of the Public Health Code (CSP) the Minister of Health can decide to authorise hospitals to dispense a list of products to out-patients. In this case the rate of co-payment is fixed by the National Union of Health Insurance Funds (UNCAM).[87]

Some products are dispensed by hospitals to out-patients without full market authorisation. They are regulated by Art. L 5121-12 and Art. R 5121-68 of the Public Health Code (CSP), with temporary utilisation authorisation (ATU) (cf. section 2.3.1.1.) “nominative” for one

[87] http://www.ameli.fr/professionnels-de-sante/medecins/exercer-au-quotidien/nomenclatures-et-codage/medicaments/medicaments-a-code-ucd.php

patient or “cohorte” for a group of patients. No co-payment is required. This special authorisation is – like other authorisations - granted by the French Health Products Safety Agency (AFSSAPS). E.g., in 2004, 24,000 nominative temporary utilisation authorisations (ATU) were granted. At present nine products have been granted a temporary utilisation authorisation “ATU de cohorte”[88].

Patient specific criteria

For certain groups of patients, pharmaceutical expenses related to an “Affection de longue durée or ALD” (Long-term illness) are fully reimbursed under Art. L 322-3 and L.324-1 of the Social Security Code (CSS) (Law of 13 August 2004) and Art. D 322-1, as described hereafter.

1. For patients with long-term illnesses from a specific list

Health insurance funds pay 100% of the pharmaceutical expenses related to a list of 30 chronic and costly diseases[89]. Some diseases which are not in the list of 30 diseases are also free of charge, when they constitute a progressive or disabling disorder, with a previous treatment period of longer than six months and are costly (e.g. degenerative macula), along with multiple diseases of more than six months’ duration.

Exemption from co-payment is only valid for treatment of long-term illness(es) (Affection de longue durée, ALD), whereas for other diseases normal reimbursement applies.

A special prescription form is needed with two zones (“ordonnancier bi-zone”): one for prescription in relation to long-term illness (ALD) at the top of formulary, and one for other diseases at the bottom.

When a patient suffers from certain conditions and the referring doctor wants her/him to be reimbursed fully for expenses related to those conditions, a special procedure is needed. A special protocol is required for this (“protocole de soins”), written on the basis of coordination between different actors necessary to cure the disease/condition, including a specialist, a nurse, or a “médecin traitant”, who is a kind of “family doctor”, chosen by the patient. This doctor sends the protocol to the medical service of the relevant health insurance fund to obtain an agreement.

The patient must sign the formulary approved by the medical service. In 2008, the long-term illness (ALD) coverage concerned 8,3 million patients (14,6% of the general scheme policy-holders), amounted to 62% of reimbursed expenditure by the health insurance in 2008[90]. Four diseases areas account for about three-quarter of the total number of patients under the

88 http://agmed.sante.gouv.fr/htm/5/atu/indatu.htm

89 list defined in the Social Security Code art. D 322-1

90 Points de repère 27, « Les personnes en affection de longue durée au 31 décembre 2008 » http://www.ameli.fr/fileadmin/user_upload/documents/27_-_ALD_2008.pdf

ALD program: cardiovascular diseases (2,8 million), malignant tumours (1,7 million), diabetes (1,6 million) and psychiatric diseases (0,95 million).

In 2006, it represented a total of € 55.7 billion: € 17.5 billion for heart diseases, € 14 billion for cancers, € 10.2 billion for psychiatric affections and € 9 billion for diabetes.

The continuous growth of expenditure is due to the increase in population, in prevalence (e.g. diabetes, cancers, hepatitis), in life expectancy, and due to the expansion of the criteria for 100% reimbursement (e.g. fasting blood sugar level had gone down from 1.40 gr/l to 1.26 gr/l since the mid-1990s).

On average, patients (including the people in the "long-term illness" (ALD) category, covered at 100% rate) receive treatment funded at the 76% level in 2006.

2. For socially disadvantaged patients (cf. 3.2.4.3)

- Universal Health Insurance Coverage (CMU)
- State Medical Aid

3.2.2.2 Reimbursement lists

There is a positive list of reimbursable medicines (Art. L 162-17 of the Social Security Code (CSS) for the out-patient sector. The list mentions reimbursable therapeutic indications and comes under the responsibility of the Minister of Health after receiving technical advice from the Transparency Commission, a body of the French National Authority for Health (HAS).[91]

The positive list is updated on a day-to-day basis and published in the official bulletin. For the Health Insurance Funds the positive list[92] is updated every week, like a database.

Inclusion of a medicine in the positive list is granted for five years, reassessed at each renewal (every five years). A product can also be reassessed if a major change appears in its profile. The Minister of Health can demand a total or partial reassessment of the positive list under Art. R 163-19 of Social Security Code (CSS).

After review, it is possible to de-list a product, to change the rate of reimbursement, or to modify the indications reimbursed once the actual conditions of use have been verified. The company can argue against the decision, and the case may go to court to challenge the decision once it has been published.

3.2.2.3 Reimbursement categories and reimbursement rates

According to the CSS code the rate is fixed in the law, but now the National Union of Health Insurance Funds (UNCAM) is responsible for ensuring that the National Target for Health

[91] http://www.has-sante.fr/portail/upload/docs/application/pdf/ri_ct_2005_v.04-10-06.pdf

[92] http://www.codage.ext.cnamts.fr/codif/bdm_it/index.php?p_site=AMELI

Insurance Expenditure (ONDAM) is not met, so it has the power to change the rate by +or- five points. E.g. 30% can become 25% or 35%. Please refer to section 3.2.1.

The following tables give an overview of the reimbursement categories and rates.

Table 3.6: France – Reimbursement categories of medicines, 2011

Reimbursement category	Reimbursement rate for		Description
	serious disease	non-serious disease	
Major clinical benefit (SMR)	65%	30%	Normal rate determined by Minister of Health, UNCAM can modify it, +or - 5 points
Moderate clinical benefit (SMR)	30%[1]		Normal rate determined by Minister of Health, UNCAM can modify it, +or - 5 points
Weak clinical benefit (SMR)	15%[93]		Rate determined by Minister of Health, UNCAM can modify it, +or - 5 points
Insufficient clinical benefit (SMR)	Not listed	Not listed	Not listed

SMR = clinical benefit, UNCAM = National Union of Health Insurance Funds

1 Arrêté du 18 mars 2011 relatif à la participation de l'assuré prévue au I de l'article L. 322-2 du code de la sécurité social[94]. Before May 2011 the reimbursement rate was 35%.

Source: Social Security Code (CSS)[95]

France - Exceptions for reimbursement of medicines

Reimbursement category by clinical benefit (SMR)	Reimbursement	Characteristic of category
For severe chronic diseases e.g. cancer	100% rate for treatments related to the disease the patient was registered for in the ALD coverage	Special list approved by Minister of Health

ALD = rate for serious disease, SMR = clinical benefit

Source: CNAMTS

93 since 16 april 2010 according the list of medicines published in the official bulletin. Reimbursement rate of 15% for medicines with weak clinical benefit (SMR) introduced in 2010 according to decree N. 2010-6 on 5 January 2010 regarding the article L. 322-2 of social security code (CSS) and advice of UNCAM according to article R. 322-1 of CSS, published in the official bulletin 17th feb. 2010 (please mention more prominently in the text)

94 http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=65FC88A201C32C8D1ECBB3B506167FBA.tpdjo09v_1?cidTexte=JORFTEXT000023759818&dateTexte=&oldAction=rechJO&categorieLien=id

95 http://legifrance.com/affichCode.do?cidTexte=LEGITEXT000006073189&dateTexte=20080723

France - Average reimbursement rates 1995, 2000, 2005–2009

Real rate of reimbursement for medicines (general scheme only)	1995	2000	2005	2006	2007	2008	2009
Rate	70.6	73.6	75.1	76.2	76.8	75.6[(a)]	75.7[(a)]

Source: LEEM, (a) CEPS 2009 from CNAMTS

3.2.3 Reference price system

France has a reference price system. The clusters are not so broad as for Germany, but for part of the generics sector there is a reference price system (Tarif Forfaitaire de Responsabilité, TFR), i.e. all medicines in a generic group have the same level of reimbursement. The reimbursement limit called “tariff level” is often equal to the generic price and the reimbursement rate is often based on this tariff. If a product under this scheme is more expensive than the “tariff” (reference price), the patient must make up the difference.

A generic group is defined for all molecules of the same Anatomic Therapeutic Chemical (ATC) classification level 5, with the same dosage and the same packaging. The different reference price (TFR) level is modified by the Economic Committee for Health Care Products (CEPS).

The list and the levels of tariffs are managed by the Economic Committee for Health Care Products (CEPS). The current policy of the Economic Committee for Health Care Products (CEPS) is to add a new group in the TFR list and the corresponding reference tariff each time a poor rate of substitution is observed for a generic group. This is combined with the actions of the National Union of Health Insurance Funds (UNCAM) upon generic substitution, through a “convention” (i.e. agreement) with pharmacists.

The first list was implemented on 27 August 2003. In 2010, 194 generic groups with about 95 molecules were under TFR among the 548 generic groups. The TFR market accounted for 17% of the generics market in value.

3.2.4 Private pharmaceutical expenses

Public pharmaceutical expenditure (PE) (social security and state or local funds) accounted for 66% of out-patient pharmaceutical expenditure (PE) in 2009. The remaining 34% from private expenditure included 17% of expenses for private health insurance and 17% out-of-pocket payments (OPP) (including cost-sharing and self-medication, cf. 3.2.4.2) of households (cf. section 2.5.2).

Private health insurance in France corresponds to complementary health insurance patients subscribe to on a (usually) voluntary basis (see section 1.3.2). In 2008, 94% of the population was covered by complementary health insurance, including 6% covered by the free

complementary universal health insurance coverage (CMUC) provided for people with low income. [96]

3.2.4.1 Direct payments

There is free pricing for the over-the-counter (OTC) market, included the wholesaler and pharmacy level. The patient pays the full consumer price.

3.2.4.2 Out-of-pocket payments

Table 3.7: France – Out-of-pocket payments for medicines, 2011

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	€ 1.-per visit to doctor (GP or specialist) € 0.50 per pharmaceutical pack dispensed	Yearly maximum limit: € 50 (the limit calculation includes fixed co-payments for medical devices and transport Exemptions: • Children under 18 years old • Complementary CMU or AME holders • Pregnant women under maternity coverage (begins at the 6th month of pregnancy)
Percentage payments	For medicines not fully reimbursed by the mandatory health insurance (UNCAM) and if private health insurance or complementary health insurance does not cover it. It depends on reimbursement rate (85%, 70% or 35%)	Exemptions: patient under the Long-term illness coverage system (ALD) which includes a 100% reimbursement but only for medicines related to the disease(s) registered for the ALD coverage
Deductibles	No	-
Reference price system	Yes, see section 3.2.3	No exemptions

ALD = long-term illness / Affection de Longue Durée, AME = Aide Médicale de l'Etat / State Medical Aid, CMU = Couverture Maladie Universelle / Universal Health Insurance Coverage

Source: CNAMTS

3.2.4.2.1 Fixed co-payments

Since 1 January 2005, the patient pays for each consultation or visit to the doctor € 1.- out-of pocket ("participation forfaitaire" ou "forfait"). The maximum annual out-of-pocket payment (OPP) is € 50.- for a consultation or visit with a doctor only.

As of 1 January 2008, the patient also pays a fixed co-payment of € 0.50 for each pack of medicines ("franchises par boite") with an annual ceiling of € 50 and can be reimbursed by

[96] IRDES, ESPS survey : http://irdes.fr/EspaceEnseignement/ChiffresGraphiques/CouvertureComplementaire/DonneesGnles.html

the complementary health insurances (the limit calculation includes fixed co-payments for medical devices and transport). If the complementary health insurances do so they pay more taxes so in practice they prefer not to (exemptions refer to Table 3.7 in 3.2.4.2)

3.2.4.2.2 Percentage co-payments

There is a percentage co-payment for medicines, which have a reimbursement rate of 65% (+/- 5%), 30% (+/- 5%) and 15% (+/- 5%). The difference is mostly reimbursed by complementary health insurances.

3.2.4.2.3 Deductibles

Not applicable.

3.2.4.3 Mechanism for vulnerable groups

Universal Health Insurance Coverage (CMU)

In 2000 January 1st, a Universal Health Insurance Coverage (Couverture Maladie Universelle, CMU) was introduced for low-income people who cannot afford to become a member of a voluntary health insurance (Assurance complémentaire, VHI) scheme (cf. 1.2), according to Law No. 99-641 of 27 July 1999. This is a national unified system to allow people staying in France on a regular basis to access social security even if s/he is not covered by one of the national security systems. If the patient's annual income level is below € 7,083, s/he is exempt from payment. It is also possible for these people to obtain complementary insurance without payment.

This insurance permits access, free of charge, to care from doctors and nurses, as well as paying for medicines, hospital charges and normal charges per day in hospital (if they have the complementary assurance).

State Medical Aid (AME)

A foreigner who is not "in a regular situation" (i.e. without a residence permit) has the right to receive care under the State Medical Aid (Aide Médicale de l'Etat, AME) system. Different administrative conditions are required, e.g. the person must have stayed in France for three months, and have sufficient income and proof of identity. In emergency situations, these obligations do not apply. The patient pays nothing under this scheme.

For patients with long-term illnesses from a specific list

Health insurance funds pay 100% of the pharmaceutical expenses related to a list of 30 chronic and costly diseases[97]. Some diseases which are not in the list of 30 diseases are also free of charge, when they constitute a progressive or disabling disorder, with a previous

[97] list defined in the Social Security Code art. D 322-1

treatment period of longer than six months and are costly (e.g. degenerative macula), along with multiple diseases of more than six months' duration.

Exemption from co-payment is only valid for treatment of long-term illness(es) (Affection de longue durée, ALD), whereas for other diseases normal reimbursement applies (cf. 3.2.2.1).

On average, patients (including the people in the "long-term illness" (ALD) category, covered at 100% rate) receive treatment funded at the 76% level in 2006.

3.3 Volume control in the out-patient sector

3.3.1 Pharmaceutical budgets

In France there are no pharmaceutical budgets being applied for doctors or other health care providers, which means that there are no fixed prescribing budgets in terms of money available to health care professionals. Still, the prescription volume or prescribing habits of general practitioners (GPs) and specialists are monitored by health insurance funds, after consultation with the French National Authority for Health (HAS). Through this, doctors are encouraged to prescribe the most economically viable medicine (generics) from several therapeutically similar alternatives.

Since 2007, doctors have been able to see their prescription profile on the health insurance funds' website.[98]

The health insurance funds are starting to enter into agreements with hospitals. One objective is to change prescribing habits, e.g. by encouraging prescribers in hospitals to start new treatments using medicines that are available in a community pharmacy, preferably generic ones if possible.

3.3.2 Generic policies

3.3.2.1 Generic substitution

Generic **substitution** has been allowed in France since 11 June 1999 (Art. L. 5125-23 of the Public Health Code (CSP). The French Health Products Safety Agency (AFSSAPS) monitors the positive list of generic products and establishes groups which contain the original product and its generics. Within each group, substitution by a pharmacist is possible. Certain substances are not protected by licence but are not included in a group by the French Health Products Safety Agency (AFSSAPS), even though the law permits the creation of a group for these products, e.g. paracetamol or aspirin.

Generic substitution is **voluntary**; it is optional for pharmacists. Parallel imports are included in the generic substitution system. Pharmacies are allowed to substitute a generic for a brand

name medicine (e.g. the original product) but the substitution must be cheaper for the health insurance funds. Both is possible if the doctor has written the prescription with its International Nonproprietary Name (INN) or with its brand name.

Both doctor and patient may oppose generic substitution. Opposition to substitution has no direct consequences for doctors, patients or pharmacists. However, the patient may lose money in one particular instance: if there is a reference price (TFR) for reimbursement for a generic group and the pharmacy retail price (PRP) of the brand name medicine is higher than the reference price (TFR), then the patient must pay for the difference out of her/his own pocket.

There are certain indirect financial incentives in place:

- for doctors – if pharmaceutical expenditure (PE) grows too fast it will not be possible to increase consultation or visit fees;
- for pharmacists – if they don't reach the recommended rate of substitution the Government will implement new reference rates and they will lose money.
- a financial incentive to pharmacists (higher margin);
- an agreement between the UNCAM and the union of pharmacists to increase the rate of substitution;

Pharmacies are not allowed to substitute therapeutically (i.e. dispense a medicine with equal therapeutic benefits (analogous substitution).

Generic substitution is allowed on a voluntary basis. It is promoted through:

- for patients - the non-exemption of initial payment of the patient to the pharmacist (the system of direct payment by the health insurance fund to the pharmacist known as "tiers-payant" and applied in most situations);
- and through television (TV) advertising campaigns intended for consumers.

In 2009, the market share of generics on the current substitution list was 71.2% in terms of pack numbers and 62.2% in terms of sales total excluding VAT. These figures were 70.8% and 57.2% respectively in 2008 (CEPS 2009[99]).

3.3.2.2 INN prescribing

INN prescribing is allowed, but not mandatory.

Physicians are encouraged by agreement (5 June 2002) to write prescriptions by International Non-proprietary Name (INN) by agreement. In the most recent study carried out by the mutual funds it appears that doctors prescribe by International Non-proprietary Name (INN)

[98] http://www.ameli.fr/

[99] http://www.sante.gouv.fr/IMG/pdf/rapport_d_activites_du_CEPS_en_2009_Vanglais.pdf

in the generics market at a rate of 12% (in terms of volume).[100] The rate of generic prescription is growing significantly.

The availability of computer-assisted prescription software (LAP: Logiciels d'Aide à la Prescription) certified by the French National Authority for Health (HAS) should foster generic substitution, particularly through the method of prescription according to International Non-proprietary Name (Dénomination Commune Internationale, INN).

3.3.2.3 Other generic promotion policies

Two types of other incentives exist for promoting the generics:

- If a generics manufacturer requests a price in line with the rate of difference in price of the patented original product (a specific percentage lower), they are sure to obtain this price and the medicine will be placed in the reimbursement list without delay.
- For a pharmacist, there is no difference in delivering a generic or the equivalent brand name product. By law the pharmacist earns the same amount of money in absolute figures when dispensing a generic as when dispensing the original product (cf. section 3.1.5.2).

3.3.3 Claw-backs / Pay back

Art. 31 of the Finance Law of the Social Security System (LFSS) for 1999 introduced the principle of claw-backs (Art. L 138-10 of the Social Security Code (CSS). This mechanism works like a tax.

In principle, all manufacturers of medicines are targeted by the claw-back system. However, if they sign an agreement with the Economic Committee for Health Care Products (CEPS), they are not targeted by the aforementioned taxes and pay a contribution, negotiated with the Economic Committee for Health Care Products (CEPS) under the processes described in the "accord cadre".

By agreement, the Economic Committee for Health Care Products (CEPS) obtains the same amount of money as it would be possible through the application of the law relating to claw-backs. If the turnover increases faster than a predetermined rate, the companies must pay part of this amount back to health insurance fund.

The threshold ("taux K") is 1% in 2010 (LFSS 2010) and was also 1% in 2005, 2006 and 2007.

The claw-back system returns only a part of the excess of the previous turnover sum.

[100] http://www.mutualite.fr/web/frameset.nsf/site2002?OpenFrameSet&Frame=Une&Src=%2Fweb%2Fframeset.nsf%2FMutuelles%2FintroEtu_1%3FOpenDocument%26AutoFramed

3.3.4 Monitoring

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

3.3.4.1 Prescription monitoring

Since the implementation of the Law of 13 August 2004, the French National Authority for Health (HAS) is required to develop guidelines for each of the 30 diseases fully reimbursed by health insurance fund. In 2008 all the guidelines were published. Now HAS begins to publish new guides in collaboration with INCA (French National Cancer Institute) on melanoma skin for example.

These guidelines are reviewed every three years. But during these period list of acts and deliveries are updated once time a year.

The doctors have access to the web database of AFSSAPS or HAS or Health Insurance (AMeli website). To comply better with the convention (ie. agreement with health insurance), they receive also for following conventional action some paper guide like ‘Mes Molécules’. they also receive a professional letter from health insurance to follow the enforcement of the reform.

For special medicines “ Médicaments d’exception”, a guide is published in the official bulletin.

The health insurance funds can monitor patient’s consumption of prescribed and reimbursed medicines by each doctor.

3.3.4.2 Price monitoring

3.3.4.3 Pharmaceutical expenditure monitoring

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 medicines on ATC level 2[101].

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[102].

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

[102] http://www.sante.gouv.fr/ceps/3ceps.htm

3.3.4.4 Consumption monitoring

Each year a special declaration is requested from all pharmaceutical manufacturers. They must declare for each medicine the volume and the financial value of sales in out-patient care and in hospitals (Art. L5121-17 and L. 5121-18 of the Public Health Code (CSP) and Art. L. 162-17-5 of the Social Security Code (CSS).

Each year the national health insurance funds publish reimbursed data for each registered pharmaceutical.

On the website of CNAMTS[103] patients have access to an account with reimbursement details (service "mon compte ameli"). This system allows the prescriber to access the last 12 month reimbursed expenses if the patient agrees so.

High prescribing doctors (compare to other prescribers) can be identified and monitored by health insurances. For instance, health insurance can constrain the doctor's prescriptions to a 'health insurance prior agreement' ("entente préalable"), according to Article 37 of the LFSS 2008. This agreement is the responsibility of the Health Insurance Medical Control Service of the health insurance.

No monitoring of adherence is conducted. The Pharmacist professional board (Conseil National de l'Ordre, CNOP) is launching a national survey on osteoporosis treatments adherence in May 2011 with a target of 4,000 participating pharmacists on a voluntary basis[104]. Results are expected in September 2011. They also conducted a pilot survey on adherence in 2008 for 4 regions[105] with 350 pharmacists on a voluntary basis[106].

3.3.5 Assessment and evaluation

3.3.5.1 Decision-making tools

Pharmacoeconomic studies are not required by law for including a product in the positive list. If a pharmaceutical company produces such a study, it is assessed by the Transparency Commission and the Economic Committee for Health Care Products (CEPS) on an individual basis.

Since 2008, HAS is in charge of conducting pharmaco economic studies according to LFSS 2008. A new commission, the Economic and Public Health Evaluation Commission (CEESP-Commission d'Evaluation Economique et de Santé Publique) was created and pharmaco-economic reevaluations of statins, ACE inhibitors, angiotensin II antogonists and PPI were planned to begin as of second semester of 2008. As a consequence, such reevaluations could be appreciated for inscription on positive list renewal of reimbursed medicines.

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[103] www.ameli.fr

[104] http://www.ordre.pharmacien.fr/fr/vert/index2_1_1.asp?actu_id=1262&struc_id=112

[105] Alsace, Languedoc-Roussillon, Picardie and Poitou-Charentes

[106] Methodology but no results in page 2 : http://www.ordre.pharmacien.fr/fr/pdf/rapport-2008-sections.pdf

This process is ongoing, HAS conducted a public consultation during the first quarter or 2011 on the methodology.

3.3.5.2 Evaluation of measures

3.3.5.3 Reports and results

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 level of improvement of the clinical 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 reimbursement by the National Health Fund (cf. section 3.2.2.3.) and the medicines' prices[107] (cf section 3.1).

3.4 Overview on policy measures in the out-patient sector

Table 3.8: France – Policy measures in the out-patient sector, 2005–2011

Measures	Description	Year
Changes in the pricing policies (e.g. new policies or method-ology and changes, external price referencing; price freezes / cuts, (obligatory) discounts	From 25 September 2008 until 31 December 2012 medicines prices in the out-patient and in-patient sector are regulated by an "out-patient-in-patient" agreement (*Accord ville-hôpital*)[108]. 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 4.2.1).	2008
Changes in the regulation of the mark-ups	Wholesaler mark-up margins review	2008
Changes concerning the VAT rates on medicines	None	
Changes regarding the reimbursement lists and schemes (e.g. de-listings, new reimbursement scheme)	Reimbursement level reviewed to lower level: second wave (first wave in 2003): (35% to 15%) until 31 December 2007 for a list of medicines, removed from reimb. list as of 1 March 2006 for the remaining ones evaluated.	2006
	Reimbursement level reviewed to lower level: third wave	2007
	First biosimilar registration on the positive list Omnitrope with a price decrease from the original product Genotonorm of 20%	2007
	A list of OTC products for self-service in pharmacies	2008

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

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

Measures	Description	Year
	Switch from 35% to 15% new reimbursement rate for a list of products	2010
	Reimbursement rate of 35% change to 30% as of 2 May 2011[109]	2011
Changes regarding a reference price system (e.g. introduction, methodology changes conc. clustering and/or the reference price)	New groups	2005-2012
Changes concerning OPP in the out-patient sector (e.g. introduction of a prescription fee, increase of percentage co-payments)	January: Fixed co-payment of € 1 per visit to the physician	2005
	Before July: Choice of "médecin traitant" (new role of gate-keeper), 40% decrease of reimbursement level otherwise (for visits and medicines)	
	January: Fixed co-payment per package: € 0.50 ("franchise")	2008
Changes in the generics policies (e.g. introduction of	Agreement between pharmacists and UNCAM: this agreement includes substitution target	2006
INN prescribing, generics substitution)	Change of price reduction of generics based on ex-factory price of original product -55% instead of -50%	Sept. 2008
	Change of generic definition: for example a generic as a gellule can be a generic of an original product in tablet[110]	March 2011
Changes concerning monitoring of medicines (e.g. new monitoring tools)		
Changes concerning evaluations and assessments (e.g. price review, reimbursement reviews)	Evaluation agency (HAS) in charge of pharmaco economics studies	2008

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

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

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

Source: CNAMTS

[109] Arrêté du 18 mars 2011 relatif à la participation de l'assuré prévue au I de l'article L. 322-2 du code de la sécurité social.

[110] http://www.legifrance.gouv.fr/jopdf/common/jo_pdf.jsp?numJO=0&dateJO=20110205&numTexte=34&pageDebut=02341&pageFin=02341

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

4.1 Pricing and procurement in the in-patient sector

4.1.1 Pricing

4.1.1.1 Framework

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 2012 medicines prices in the out-patient and in-patient sector are regulated by an "out-patient-in-patient" agreement (*Accord ville-hôpital*)[111]. 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 4.2.1).

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. 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/

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).

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

4.1.1.2 Hospital prices

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

There are no mark-ups because the prices are freely set and medicines are bought at ex-factory price level. Still, hospitals are paid via a fee for the distribution of products authorised to be sold to out-patients: a total of € 28 per line of delivery (a line of prescription can include, e.g., the delivery of three identical packs, with the fee always being € 28, cf. 3.1.5.3)

There are no mandatory discounts granted to (public) hospitals and/or health insurances. Commercial discounts may be freely negotiated between supplier and purchaser.

4.1.2 Purchasing policies

There are currently three main purchasing procedures:

- At standard price, upon invoice (used only marginally).
- Negotiations with the manufacturer.
- Public tendering for benefiting from competition among suppliers, according to forecasted volumes (approximately 60% of hospital purchases). The final decision is not necessarily in favour of the cheaper supplier, but rather in favour of the supplier who is most likely to ensure continuous supply, to avoid shortage.

4.1.2.1 Tendering

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[112] /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*.

[112] DGOS former 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

Some public hospitals in the same geographical area already belong to bulk-buying organisations. This is the same with private hospitals (cf. section 4.1.3).

4.1.2.2 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).

4.1.3 Organisation of procurement

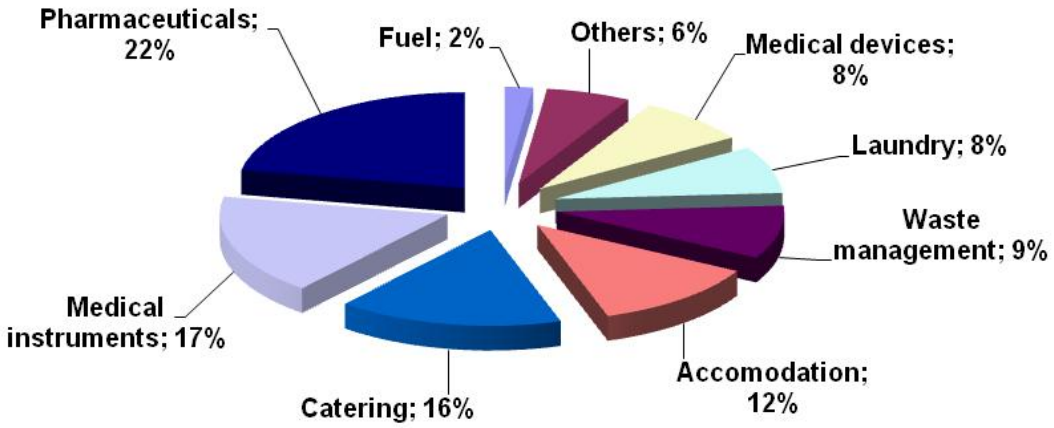
Procurement scope

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

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 4.1: France – Public hospitals expenditure 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)[113]. UNI.H.A. negotiates various products and services from medicines to laundry.

Many other joint/cooperation 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)[114], others related to specialised care centers such 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, chief 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 the hospital pharmaceutical list (cf. section 4.2.2).

Criteria for accepting a tender

Criteria for defining the list of medicines are related first to clinical needs, taking into account the level of improvement of the clinical 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**.

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

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

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, cf section 1.4.3) activities, 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)[115], 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.

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.

4.2 Reimbursement in the in-patient sector

4.2.1 National framework

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 submit-

[115] 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/

ted 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 does not apply 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 three lists of reimbursable medicines, i.e. **positive lists**:

1. one list of reimbursable medicines for out-patient care and for the sales by pharma cies (*liste des medicaments rembursables agrees aux assures sociaux,* see section 3.2.2.2)
2. and a list of hospital medicines for the hospital sector (*liste des medicaments agréés aux collectivites*). It includes about 2,700 medicines in 2008 (estimate from Theriaque database). There also exists a hospital-only medicines list (Médicament de la réserve hospitalière, HOM) which medicines can only be delivered for in-patient stay.

Medicines sub-groups for reimbursement status

About 40% of medicines used in hospitals are **integrated in the performance-based costing** system "*T2A"*. 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 DRG system** has been developed and is reimbursed separately by the health insurance (see below for details). A third group of medicines referred to reassigned, "*rétrocession*", is not included in the DRG system either.

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

In 2008 this list of costly medicines contained about 120 active molecules[116], particularly anticancer medicines, blood products, orphan medicines and some treatments for rheumatoid arthritis. This list is regularly updated, with new entries as innovative and expensive medicines reach the market; in theory medicines 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 2009, these medicines accounted for about € 2.5 billion with a growth rate of 4% compared to 2008 (CEPS activity report 2009).

Table 4.1: France – Share of pharmaceutical expenditure for in-patient supplementary list as share of pharmaceutical expenditure, 2000 and 2005–2009

Expenditure (in million €)	2000	2005	2006	2007	2008	2009
Supplementary list of pharmaceuticals expenditure in hospitals[1]	**n.a**	**n.a**	**1,785**	**2,075**	**2,400**	**2,500**
Share of expenditure for medicines on the supplementary list in HOSPE	n.a	n.a	37%	42%	44%	44%
- thereof HOSPE public	n.a	n.a	1,338	1,575	1,850	n.a.
- thereof HOSPE private	n.a	n.a	0,447	0,500	0,550	n.a.

HOSPE = hospital pharmaceutical expenditure, n.a. = not available

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

Source: CEPS activity report 2008 and 2009[117]

Reassigned medicines are delivered by hospital pharmacies to out-patients for medicines not available from community 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[118] 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 2009, reassigned medicines accounted for about 1.45 billion € with a growth rate of 11% compared to 2008 (CEPS 2009).

[116] 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/

[117] http://www.sante.gouv.fr/ceps/doc/rapport_activite_ceps_2008.pdf, http://www.sante.gouv.fr/ceps/doc/rapport_activite_ceps_2009.pdf

[118] Medicines included in the list of medicines being authorised for use in hospitals ("hospital reserve"?)

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 notification procedure). This notified price may be opposed by CEPS during the following 15 days. In cases of non notification or of opposition by CEPS (the main 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 (ie. hospital) buys a medicine on the reassigned list or supplementary list of medicines 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).

Co-payment

While the basic rule is that hospital treatment costs are reimbursable through the social security system at a rate of 80% (with exception for 100% reimbursement, cf. section 1.4.3.) most medicines used during hospital stay are fully covered.

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 calculate from 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 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[119] in supplementary list of costly medicines (see above), it is possible for hospitals to claim reimbursement to the National Health Fund. 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 of the hospitals is very variable depending on the level of competitiveness in the specific pharmacological class. For some expensive new and innovative products, cost of purchase by the hospital can be above the reimbursement 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.

4.2.2 Hospital pharmaceutical formularies

At hospital level and according to article R.5126-48 of the French Code of Public Health, the Commitee (cf. section 4.2.3) 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.

All 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).

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.

The list in the formulary is drawn up by a the Pharmaceutical and Therapeutic Committee (cf. 4.2.3) from a special list of medicines approved for hospital use (positive list cf 2.4.3.3). Usefulness within the hospital, improvement of medical service provided, as well as economic criteria are all taken into account when deciding whether to include a medicine in the hospital's list.

At minimum a yearly update is recommended.

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

Such HPFs are widely available on paper and electronic format within hospitals.

4.2.3 Pharmaceutical and Therapeutic Committees

The composition and operating mode of Hospital Committees are regulated (Decree No. 2000-1316 of 26/12/2000, Art. 5104-52 to 56).

This committee (*commission du médicament et des dispositifs médicaux stériles,* COMEDIMS) 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.

According to article L.592-2 of the French Public Health Code, chief pharmacists of hospital pharmacies are responsible for purchasing medicines and medical devices. 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. 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*).

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 criterion of choice.

4.3 Volume control in the in-patient sector

4.3.1 Monitoring

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

4.3.1.1 Price monitoring

There is no public source available on negotiated prices by medicines subject to procurement in the framework of hospital expenditures. In each hospital, information on prices and quantities are collected for each medicine.

4.3.1.2 Pharmaceutical expenditure

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[120].

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 medicines through a global survey in French hospitals. In each hospital, information on prices and quantities are collected for each medicine.

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.

4.3.1.3 Consumption monitoring

Monitoring in the in-patient sector

In addition to nationwide statistics on medicines are available at the French National Competent Authority for Safety of Health Products (AFSSAPS)based on manufacturers' tax information for the first fifty most sold medicines only on ATC level 2 (cf. section 3.3.4.3).

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

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).

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 (cf. section 4.2.3).

Pharmacists are responsible for monitoring pharmaceutical consumption.

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

Hospital pharmacies ensure full tracking of their medicines.

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.

4.3.2 Assessment and evaluation

4.3.2.1 Decision-making tools

After marketing authorisation is obtained, if a company apply for reimbursement, the transparency commission of the evaluation agency (HAS) evaluates the medicines. 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 in previous sections).

4.3.2.2 Evaluation of measures

4.3.2.3 Reports and results

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 (please refer to section 3.3.5.3).

4.4 Overview on policy measures in the in-patient sector

Table 4.2: France – Policy measures in the in-patient sector, 2005–2011

Measures	Description	Year
Changes in the pricing framework (e.g. change pricing regulation with relevance for the in-patient sector, change in hospital specific mark-up / VAT which is relevant for the in-patient sector)	From 25 September 2008 until 31 December 2012 medicines prices in the out-patient and in-patient sector are regulated by an "out-patient-in-patient" agreement (*Accord ville-hôpital*)[121]. Before 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 4.2.1).	2008
Changes in procurement (e.g. establishment of new procurement agency, change in relevance of tendering vs. negotiations etc.)	None	
Changes regarding the reimbursement lists (e.g. concerning a national hospital list, the HPF, ...)	None	
Changes in funding (e.g. specific budgets for specific medicines, concerning OPP in the in-patient sector)	Increase of copayment of the day fee	2005 2006 2007 2009 2010
Changes concerning evaluations and assessments	None	

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

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

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

Source: CNAMTS

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

5 Interface management and developments

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

5.1 Interface management

There is a need for interface management and the HPST reform effective in 2010 should help improve it (see section 1.2 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.

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.

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

Table 5.1: France – Measures in the pharmaceutical system, 2010–2011

Measures	Under discussion	Under implementation
General health reforms (e.g. changes in responsibilities and institutions)		The "out-patient-in-patient" agreement (*Accord ville-hôpital*)[122] was renewed until 31 december 2012 HPST reform (see section 1.2)
Pricing policies in general		Price cuts
Mark-ups		
Taxes		
Reimbursement policies		Introduction of a 15% reim-bursement rate in 2010[123] Reimbursement rate of 35% change to 30% as of 2 May 2011[124]
Out-of pocket payments		
Generic policies		Reference pricing: new groups
Reforms targeted at the in-patient sector		
Evaluation & assessment		

Source: CNAMTS

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

[123] since 16 april 2010 according the list of medicines published in the official bulletin. Reimbursement rate of 15% for medicines with weak clinical benefit (SMR) introduced in 2010 according to decree N. 2010-6 on 5 january 2010 regarding the article L. 322-2 of social security code (CSS) and advice of UNCAM according to article R. 322-1 of CSS, published in the official bulletin 17th feb. 2010

[124] Arrêté du 18 mars 2011 relatif à la participation de l'assuré prévue au I de l'article L. 322-2 du code de la sécurité social.

6 Bibliography

Information and statistical data was taken from several sources, quoted in the relevant footnotes and listed under section 6.3 / weblinks.

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6.2 Legislation

In the pharmaceutical sector many laws and decrees are in act, driven by European legislation. They are summarised into two laws (called "Codes"): the Public Health Code (Code de la Santé Publique, CSP[125]) and the Social Security Code (Code de la Sécurité Sociale, CSS[126]).

[125] http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665&dateTexte=20080606

Evaluation : Transparency Commission :

- Definition : Art. R. 163-15 of the Social Security Code (CSS)
- Duties : Art. R.163-2 to R.163-21, L.161-37, L161-39 and L.161-41 of the Social Security Code (CSS).
- Procedures : Art. R.163-18 of Social Security Code (CSS).

The Economic Committee for Health Care Products (CEPS) and the Association of Pharmaceutical Industry (Les Entreprises du Médicament, LEEM) price agreement for reimbursable medicines : art. L 162-16-4 of the Social Security Code (CSS)

External price referencing : Art. L-162-17-6 of the Social Security Code (CSS).

The regressive statutory mark-up schemes for wholesalers and pharmacists are detailed in a decree published in the country's official bulletin[127].

Rebates/discounts granted to pharmacists is fixed by regulations

- Art. L 138-9 of the Social Security Code (CSS)
- The "Chatel" Law number 2008-3 of 3 January 2008[128]

Activity of wholesalers is strictly controlled and under four legal obligations (art. R5124-59 of the Public Health Code (CSP).

Pharmacies regulation:

- Ownership: Law 90-1258 of 31 December 1990
- Establishment: art. L5125-1, -13, -14 and -15 of the Public Health Code (CSP). The authorisation is granted provided that the pharmacy fulfilled statutory demographic prerequisites as defined in the Public Health Code (CSP) (Art. L 5125-3, Art. L 5125-4).

Procurement for in-patient:

- EU Directive No. 2004/17 and 2002/18
- Local implementation depends on the status of the hospital:
    - Public : 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 re-lated to procurement contracts for which the decree no. 2006-975 of 1 August 2006 mentioned above is not applicable

Role National Union of Health Insurance Funds (UNCAM) in reimbursement :Art. L322-2 and L182-2 of the Social Security Code (CSS)

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[126] http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006073189&dateTexte=20080606

[127] http://www.legifrance.gouv.fr/affichTexte.do?dateTexte=&cidTexte=JORFTEXT000018213915&fastPos=1&fastReqId =935011621&oldAction=rechExpTexteJorf

[128] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000017785995&dateTexte=

Positive list : Art. L 162-17 of the Social Security Code (CSS)

Generic

- definition : Public Health Code (Code de la Santé Publique, CSP) Art. L601-6[129].
- Art. 19 of the Finance Law of the Social Security System (LFSS) for 2004 provides that market authorisation for a generic medicine can be delivered before the expiry of the intellectual property rights attached to the reference specialty.
- Art. 30 of the Law of 13 August 2004 modifies the definition of a generic under European legislation. This article specifies that "the various salts, esters, isomers, isomer mixtures, complexes or derivatives from the same active principal are considered to be the same active principal, unless they present significantly different properties in term of safety and efficacy".
- Decree of 18 February 2005 introduced Art. R. 5121-41-1 of the Public Health Code (CSP). Minor changes in market authorisation are considered to be the same as the original authorisation.
- substitution : Art. L5125-23 of the Public Health Code (CSP)

Advertising of medicines : Art. L 5122-1 to L 5122-16 and Art. R.5122-1 to R. 5122-47 of the Public Health Code (CSP), in line with the European Commission (EC) Directive 2001/83/EC.

Promotion by manufacturers : Art. L 167-17-8 of the Social Security Code (CSS)

Annual contribution (under Art. L 245-2 of the Social Security Code (CSS) on pharmaceutical manufacturers for promotional activities and also under Art. L245-6 of the Social Security Code (CSS).

6.3 Web links

Abbreviation	Name	Link
AFIPA	French Association of Self-medication Industry	http://www.afipa.org/
AFSSAPS	French Health Products Safety Agency	http://www.afssaps.fr/?UserSpace=default
CEPS	Economic Committee for Health Care Products	http://www.sante.gouv.fr/comite-economique-des-produits-de-sante-ceps.html
CNAMTS	National Insurance Fund for Salaried Employees	http://www.ameli.fr/

[129] http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=8EA7A901AA7D305DDE1162F194F55E11.tpdjo10v_2?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006693765&dateTexte=20080722&categorieLien=cid

COUR DES COMPTES	Court of Accounts	http://www.ccomptes.fr/fr/CC/Accueil.html
CSMF	Confederation of French Medical Unions	http://www.csmf.org/
DREES	Research Department for Ministry of Social Affairs (MAS)	http://www.sante.gouv.fr/direction-de-la-recherche-des-etudes-de-l-evaluation-et-des-statistiques-drees,5876.html
Fonds CMUC	Fonds CMUC	http://www.cmu.fr/site/cmu.php4?Id=26&style=&col=
FMF	Federation of Doctors in France	http://fmfpro.com/
FSPF	Federation of Pharmacists in France	http://www.fspf.fr/
HCAAM	High Committee for the Future of Social Security	http://www.securite-so-ciale.fr/institutions/hcaam/hcaam.htm
HAS	French National Authority for Health	http://www.has-sante.fr/portail/jcms/j_5/accueil
IRDES	Research Institute for health economy	http://www.irdes.fr/
INSEE	National office for statistics	http://www.insee.fr/fr/home/home_page.asp
LEEM	Association of Pharmaceutical Industry	http://www.leem.org/htm/accueil/accueil.asp
LEGIFRANCE	Government official site for law and regulations	http://www.legifrance.gouv.fr/
LIR	International Research Laboratories	http://www.lir.asso.fr/
MF	Mutualite Française	http://www.mutualite.fr/
MG FRANCE	French Federation of General Practitioners	http://www.mgfrance.org/
MINEFE	Ministry of Economy, Finance and Employment	http://www.minefe.gouv.fr/
MSA	Agricultural Mutual Insurance Fund (for farmers and farm employees)	http://www.msa.fr/
RSI	National Insurance Fund for Self-employed Workers	http://www.le-rsi.fr/
SML	Union of Self-employed Doctors	http://www.lesml.org/
UNPF	National Union of Pharmacists of France	http://www.unpf.org/
USPO	Union of Pharmacists	http://www.uspo.fr/