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Pharmaceutical Pricing and Reimbursement Information

FRANCE

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Pharma Profile

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Executive summary

BACKGROUND

The French health insurance system was implemented in 1945. It is divided into three main schemes, as shown here.

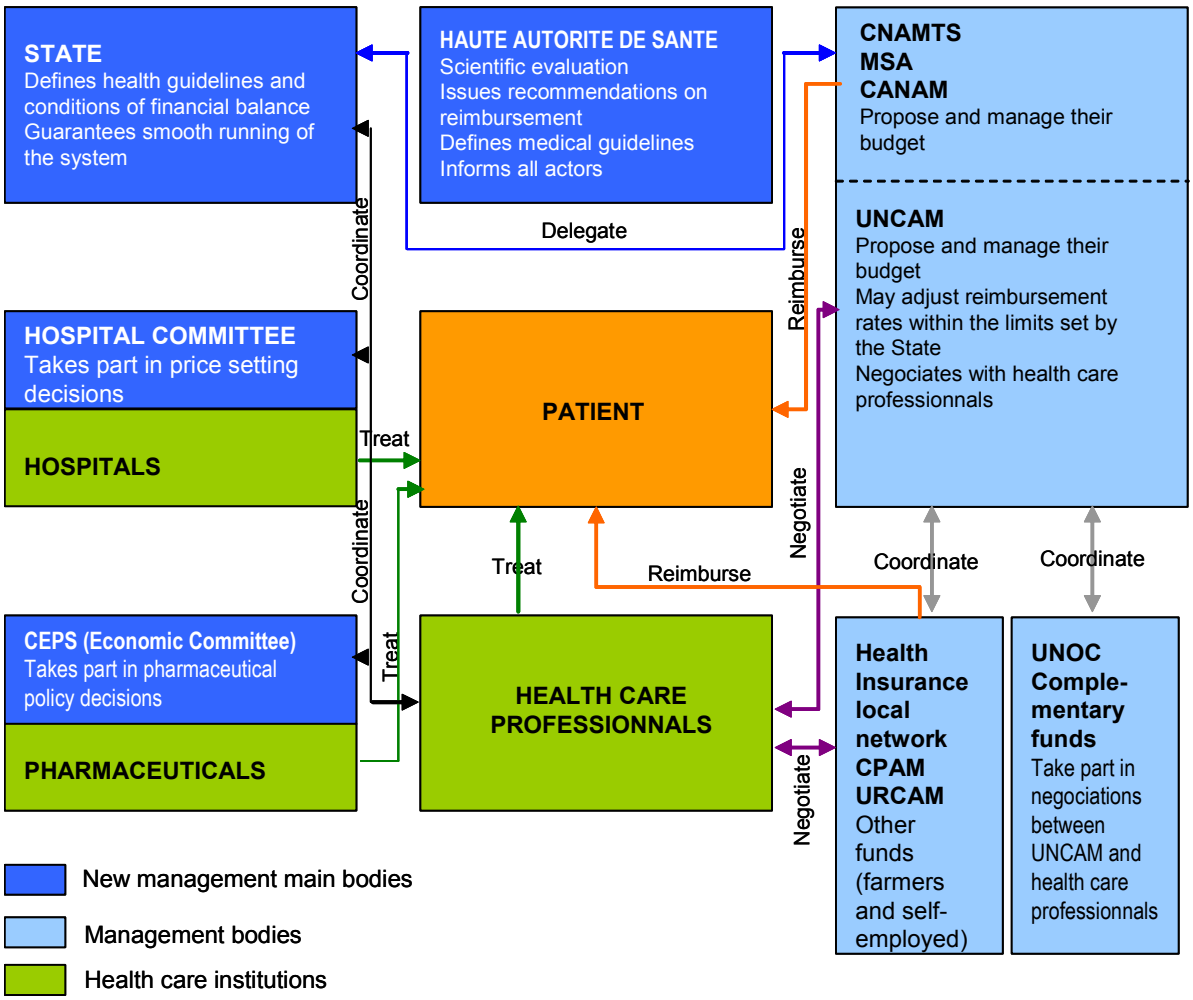
- The general scheme, which covers employees in the industry, business and services sectors, covers 85% of the French population. It is managed by the National Insurance Fund for Salaried Employees (Caisse Nationale d'Assurance Maladie des Travailleurs Salariés, CNAMTS).
- The agricultural scheme, which covers farmers and farm employees, is managed by the Agricultural Mutual Insurance Fund (Mutualité Sociale Agricole, MSA).
- The scheme for self-employed people, which covers craftspeople, retailers and independent professions, is managed by various organisations belonging to the Health Insurance Fund for Independent Professions (Caisse d'Assurance Maladie des Professions Indépendantes, CANAM).

The general health insurance scheme is funded mainly through:

- contributions from wages (49.6%);
- taxes (36.4%);
- state transfers and contributions (6.4%);
- other contributions (7.6%), e.g. from insurance companies in the event of casualties due to car accidents.

In 2004, the total health expenditure (Dépenses totales de santé, THE) was 10.5% of gross domestic product (Produit intérieur brut, GDP), of which 78.4% was public expenditure and 21.6% was private expenditure.

Figure 0.1: France - Main actors in the health care system



Key to abbreviations:

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
MSA	Mutualité Sociale Agricole	Agricultural Mutual Health Insurance Fund Health (for farmers and farm employees)
CANAM	Caisse d'Assurance Maladie des Professions Indépendantes	Health Insurance Fund for Independent Professions
UNCAM	Union Nationale des Caisses d'Assurance Maladie	National Union of Complementary Health Insurance Funds (= CNAMTS + MSA + CANAM)
CPAM	Caisse Primaire d'Assurance Maladie	Local level of CNAMTS
URCAM	Union Régionale des Caisses d'Assurance Maladie	Regional Union of Complementary Health Insurance Funds (equivalent of UNCAM at regional level)
UNOC	Union Nationale des Organismes d'assurance maladie Complémentaires	National Union of Complementary Health Insurance Funds ("Mutuelles")

Figure 0.1 refers to the whole health care system (including pharmaceuticals). The Economic Committee for Health Care Products (Comité Economique des Produits de Santé, CEPS) only deals with pharmaceuticals and medical devices. Hospital Committees draw up a limited list of pharmaceuticals for use in their hospital (chosen from among a special list of pharmaceuticals approved for hospital use) (cf. 2.1.3.4).

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.

Patients must register with a referring doctor (generally a general practitioner (Médecin Généraliste, GP)) who acts as a gatekeeper for specialist care. If they fail to do so, they may be reimbursed at a lower level. Out-patient doctors are remunerated on a fee-for-service basis. Hospitals are remunerated through a combination of annual fixed budgets and fee-for-service payments.

PHARMACEUTICAL SYSTEM

Key actors of the pharmaceutical system are listed here.

- The French Agency for the Medical Safety of Health Products (Agence Française de Sécurité Sanitaire des Produits de Santé, AFSSAPS), through a Market Authorisation Commission, is responsible for granting market authorisation. The Agency for the Medical Safety of Health Products (AFSSAPS) is also in charge of classification, vigilance and advertisement.
- The High Authority for Health (Haute Autorité de Santé, HAS), through the Transparency Commission (Commission de la Transparence), is in charge of assessing medical service and improvement of medical service provided. The High Authority for Health (HAS) gives technical advice on including pharmaceuticals on the positive list of reimbursable pharmaceuticals and issues recommendations.
- The Economic Committee for Health Care Products (CEPS) is in charge of cost-efficacy assessment and price-volume negotiations. The Economic Committee for Health Care Products (CEPS) sets reference prices (Tarif Forfaitaire de Responsabilité, TFR) and the prices of reimbursable pharmaceuticals, as well as the prices of some hospital products.
- The National Union of Complementary Health Insurance Funds (Union Nationale des Organismes d'assurance maladie Complémentaires, UNCAM) sets the reimbursement rates for reimbursable pharmaceuticals.

There are 339 pharmaceutical companies based in France. The French market is the fourth largest market in the world with a market share of 5.4%. The leading pharmaceutical manufacturer is Sanofi-Aventis with a market share of 16%, followed by Pfizer, GlaxoSmithKline, AstraZeneca and Bristol Myers Squibb. France's pharmaceutical turnover is the highest in Europe (€ 40,585 Mio. in 2005).

In 2005 there were 11 wholesalers with 189 outlets. The total number of pharmacies included:

- 22,669 private pharmacies
- 1,120 public pharmacies
- 1,551 hospital pharmacies dispensing pharmaceuticals to out-patients
- + 122 dispensing doctors.

Drugstores are not allowed to dispense pharmaceuticals.

In 2004 the total pharmaceutical expenditure (Dépenses totales de medicaments, TPE) was € 30,279 Mio. A total of 69% of the total pharmaceutical expenditure (TPE) was public expenditure and 31% was private expenditure (2005 data).

PRICING

Prices for reimbursable pharmaceuticals 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 Finance and Industry (Ministère des Finances et de l'Industrie, MINEFI), compulsory Health Insurance Funds and complementary Health Insurance Funds.

Pricing policies in France include:

- statutory pricing for reimbursable products and some hospital-only innovative pharmaceuticals;
- price negotiation between the Economic Committee for Health Care Products (CEPS) and pharmaceutical manufacturers, along with a 4-year agreement known as "accord cadre";
- free pricing for non-reimbursable pharmaceuticals and most pharmaceuticals approved for hospital use and for over-the-counter (OTC) pharmaceuticals (Médicament en vente libre).

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

Only pharmaceuticals 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 pharmaceuticals (Level of improvement of clinical benefit ("Amélioration du service médical rendu", ASMR) levels I to III) must be consistent with the prices of similar pharmaceuticals 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 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 pharmaceuticals with Level of improvement of clinical benefit (ASMR) ≥ III must not be lower than the cheaper 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.

Table 0.1: France - Wholesale mark-up scheme for reimbursable pharmaceuticals 2006

Ex-factory price in € (excluding value-added tax (VAT))	Maximum mark up as a % of Ex-factory price	Wholesale price in € (excluding VAT)
0.00-22.90 example 22.90	10.3	25.26
22.91-150.00 example 150.00	6.0	159.98
>150.00 example 200.00	2.0	210.98

Table 0.2: France - Pharmacy mark-up scheme for reimbursable pharmaceuticals 2006

Ex-factory price in € (excluding value-added tax (VAT))	Maximum mark up as a % of ex-factory price (€ +0.53 per pack excluding VAT)	Public price in € excluding VAT
0.00-22.90 example 22.90	26.1	31.77
22.91-150.00 example 150.00	10.0	179.20
>150.00 example 200.00	6.0	233.20

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

The standard value-added tax (Taxe sur la Valeur Ajoutée, VAT) rate in France is 19.6% on most products and services. The value-added tax (VAT) rate is 2.1% on reimbursable pharmaceuticals and 5.5% on non-reimbursable pharmaceuticals.

Pharmaceutical companies must commit themselves to submitting prices similar to those granted in Germany, Spain, Italy and the United Kingdom. In the event of a price change in one or more of the above-mentioned countries, they also commit themselves to adjusting their prices so that they remain consistent with the new prices in those countries. If actual sales are above the sales forecasts planned for the first four years after launching a product (these forecasts must be included in the price application dossier), the company must reimburse the State for the extra costs borne by Health Insurance Funds.

REIMBURSEMENT

- The National Union of Complementary Health Insurance Funds (UNCAM) is in charge of setting the reimbursement rate after assessment of medical service and improvement of medical service by the Transparency Commission and cost-efficacy assessment and pricing by the Economic Committee for Health Care Products (CEPS).

- The pricing procedure only applies to reimbursable pharmaceuticals. Pharmaceuticals must have been granted a price prior to reimbursement.

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

- The National Union of Complementary 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 4.1).

Table 0.3: France - reimbursement categories and rates

Reimbursement category	Reimbursement rate (%)	Characteristic of category
Pharmaceuticals for severe chronic diseases e.g. cancer	100	Special list approved by Minister of Health
Pharmaceuticals for serious diseases	65	Normal rate determined by UNCAM
Pharmaceuticals for moderately serious diseases	35	Rate determined by UNCAM
Pharmaceuticals pending delisting	15	New temporary rate for veinotonics determined by UNCAM

UNCAM = National Union of Complementary Health Insurance Funds

There is no reference price system in France, except for a list of 153 generic groups. The list was first introduced on 27 August 2003. The reference price (TFR) is generally equal to the generic price. The list and reference prices (TFR) are the responsibility of the Economic Committee for Health Care Products (CEPS). A new generics group is included in the reference price list each time a poor rate of substitution is observed for this group.

There is no flat prescription fee. Co-payments comprise the difference between the retail price (100%) and the rate of reimbursement.

Most pharmaceuticals dispensed in hospitals to in-patients are included in the daily rate, i.e. in the hospital's budget. However, for some highly innovative pharmaceuticals with regulated prices, hospitals can claim reimbursement from the Health Insurance Funds on a 100% basis, in addition to the daily rate. For pharmaceuticals dispensed to out-patients, hospitals claim reimbursement directly from the Health Insurance Funds, including a margin, but this is gradually changing to a system with a fee-for-service payment per dispensation.

According to the Law of 14 August 2004, the National Union of Complementary Health Insurance Funds (UNCAM) can increase or reduce the rate of reimbursement by 5% against the current rate, if the annual budget for health expenditure (Dépenses de santé, HE) voted by Parliament is not met.

RATIONAL USE OF PHARMACEUTICALS

Some treatment guidelines have been produced by the High Authority for Health (HAS). There is no national formulary.

Advertisement of pharmaceuticals is strictly regulated, as shown here.

- Advertisement of prescription-only medicine(s) (Médicament à prescription obligatoire, POM) is allowed in medical reviews only.
- Advertisement of over-the-counter (OTC) pharmaceuticals is allowed in all media intended for the general public (press, television (TV), etc.).

Recent campaigns have been run by Health Insurance Funds to heighten both doctors' and patients' awareness of rational use of antibiotics, tranquillizers, sleeping pills and statins that are over-prescribed in France compared to other European countries.

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.

Generic substitution is allowed on a voluntary basis. It is promoted through a financial incentive to pharmacists (higher margin) and through television (TV) advertising campaigns intended for consumers.

Individual consumption data are available but they are currently not monitored.

CURRENT CHALLENGES AND FUTURE DEVELOPMENTS

Although the pharmaceutical expenditure (Dépenses de medicaments, PE) of the compulsory health insurance schemes increased by 5% from 2004 to 2005, it should decrease significantly in 2006, partly due to price reductions initiated in 2005 and partly due to the 2006 pharmaceutical plan. The measures initiated in 2006 (generic policy, de-listing and cuts in the reimbursement rate of some pharmaceuticals, price cuts in brand name pharmaceuticals, etc.) should lead to more than € 1 billion savings in 2007.

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List of abbreviations

AESGP	Association of the European Self-Medication Industry	
AFIPA	French Association of Self-medication Industry	Association Française de l'Industrie Pharmaceutique pour une Automédication responsable
AFSSET	French Agency for Environmental Health and Safety	Agence Française de la Sécurité Sanitaire Environnementale et de Sécurité au Travail
AFSSA	French Agency for the Medical Safety of Food Products	Agence Française de la Sécurité Sanitaire des Produits Alimentaires
AFSSAPS	French Agency for the Medical Safety of Health Products	Agence Française de Sécurité Sanitaire des Produits de Santé
ALD	Long-Term Illness	Affection de longue durée
AME	State Medical Aid	Aide Médicale d'Etat
APR	Federation of Rural Pharmacies	Association des Pharmacies Rurales
ASMR	Level of improvement of clinical benefit	Amélioration du service médical rendu
ATC	Anatomic Therapeutic Chemical classification	Classification Anatomique, Thérapeutique, Chimique
ATU	Temporary Utilisation Authorisation	Autorisation temporaire d'utilisation
CANAM	Health Insurance Fund for Independent Professions	Caisse d'Assurance Maladie des Professions Indépendantes
CCP	Complementary Protect Certificate	Certificat Complémentaire de Protection
CEPS	Economic Committee for Health Care Products	Comité Economique des Produits de Santé
CGPME	General Confederation of Small and Medium-sized Enterprises	Confédération Générale des petites et moyennes entreprises
CMU	Universal Health Insurance Coverage	Couverture Maladie Universelle
CMUC	Complementary Universal Insurance Health Coverage	Couverture Maladie Universelle Complémentaire
CNAF	National Fund For Family Allowances	Caisse Nationale d'Allocations Familiales
CMTS	National Insurance Fund for Salaried Employees	Caisse Nationale d'Assurance Maladie des Travailleurs Salariés

CNAVTS	National Old-Age Insurance Fund for Salaried Employees	Caisse Nationale d'Assurance Veillesse des Travailleurs Salariés
CNOP	Conseil National de l'Ordre	Pharmaceutical Association
CPAM	Local level of CNAMTS	Caisse Primaire d'Assurance Maladie
COG	Management and Objectives Agreement	Contrat d'Objectif et de Gestion
CPG	Pluriannual Management Contracts	Contrat pluri-annuel de gestion
CPI	Intellectual Property Code	Code de la Propriété Intellectuelle
CRDS	Tax for reimbursement of social debt	Contribution pour le remboursement de la dette sociale
CSG	General Social Contribution	Contribution Sociale Généralisée
CSMF	Confederation of French Medical Unions	Confédération des Syndicats Médicaux Français
CSP	Public Health Code	Code de la Santé Publique
CSRP	Wholesalers Association	Chambre Syndicale des Répartiteurs Pharmaceutiques.
CSS	Social Security Code	Code de la Sécurité Sociale
DAM	Sickness Insurance Representatives	Délégué de l'Assurance Maladie
DG SANCO	Health and Consumer protection Directorate General	Direction Générale Santé et Protection du Consommateur
EC	European Commission	Commission Européenne
EMEA	European Agency for the Evaluation of Medicinal Products	Agence Européenne du médicament
EU	European Union	Union Européenne
FIT	Prescription Guide	Fiche d'Information Thérapeutique
FMF	Federation of Doctors in France	Fédération des Médecins de France
FSPF	Federation of Pharmacists in France	Fédération des Syndicats Pharmaceutiques de France
GEMME	Generic Producers Association	Association des Fabricants de Génériques
GDP	Gross Domestic Product	Produit intérieur brut
GGE	General Government Expenditure	Dépenses de l'Etat

GP	General Practitioner	Médecin Généraliste
HAS	High Authority of Health	Haute Autorité de Santé
HCAAM	High Committee for the Future of Social Security	Haut Conseil pour l'Avenir de l'Assurance Maladie
HE	Health Expenditure	Dépenses de santé
HiT	Health Systems in Transition	Systèmes de santé en transition
HOM	Hospital-Only Medicine	Médicament de la réserve hospitalière
INN	International Nonproprietary Name	Dénomination Commune Internationale
INPI	National Institute for Industrial Property	Institut National de la Propriété Industrielle
INVS	National Institute for Monitoring Public Health	Institut National de la Veille Sanitaire
LEEM	Association of Pharmaceutical Industry	Les Entreprises du Médicament
LFSS	Finance Law of the Social Security System	Loi de financement de la sécurité sociale
MAS	Ministry of Social Affairs	Ministère des Affaires Sociales
MEDEF	French Business Confederation	Mouvement des Entreprises Françaises
MG FRANCE	French Federation of General Practitioners	Fédération française des médecins généralistes
Mio.	Million	Million
MINEFI	Ministry of Finance and Industry	Ministère des Finances et de l'Industrie
MSA	Agricultural Mutual Insurance Fund (for farmers and farm employees)	Mutualité Sociale Agricole
NCU	National Currency Unit	Monnaie nationale
ÖBIG	Austrian Health Institute	Institut de santé Autrichien
OECD	Organisation for Economic Co-operation and Development	Organisation de coopération et de développement économiques
ONDAM	National Target for Health Insurance Expenditure	Objectif National des Dépenses d'Assurance Maladie
OPP	Out-of-Pocket Payment	Reste à charge ou ticket modérateur

OTC	Over-The-Counter pharmaceuticals	Médicament en vente libre
PE	Pharmaceutical Expenditure	Dépenses de médicaments
POM	Prescription-Only Medicines	Médicament à prescription obligatoire
PPI	Proton Pump Inhibitor(s)	
PPP	Pharmacy Purchasing Price	Prix d'achat des médicaments par les pharmaciens
PPRI	Pharmaceutical Pricing and Reimbursement Information project	
PRP	Pharmacy Retail Price	Prix à la consommation ou prix public
R&D	Research and Development	
ROR	Rubeola-Mumps-Roseola	Rougeole-Oreillons-Rubéole
RSI	National Insurance Fund for Self-employed Workers	Régime Social des Indépendants
SD	Self-Dispensing (Doctors)	
SEL	Incorporated Company(ies)	Société(s) d'Exercice Libéral
SHI	Social Health Insurance	Assurance sociale
SML	Union of Self-Employed Doctors	Syndicat des Médecins Libéraux
SMR	Clinical benefit	Service médical rendu
SPC	Summary of Product Characteristics	
TFR	Reference price	Tarif Forfaitaire de Responsabilité
THE	Total Health Expenditure	Dépenses totales de santé
TPE	Total Pharmaceutical Expenditure	Dépenses totales de médicaments
TV	Television	Télévision
UNCAM	National Union of Social Health Insurance Funds	Union Nationale des Caisses d'Assurance Maladie
UNOCAM	Body of complementary insurance and mutual funds	Union Nationale des Organismes Complémentaires d'Assurance Maladie

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31-month project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission (EC) and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organization (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by:

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other;
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”;
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information;
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU); and
- disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries’ pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from the competent authorities, medicines agencies, social insurance institutions, research institutes) and edited by experts coordinating the PPRI project.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI web site at http://ppri.oebig.at. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available on the PPRI web site.

1 Background

Chapter 1 aims to provide an overview on the country, in particular on the health care system. As the focus on the PPRI Pharma Profiles is on pharmaceutical pricing and reimbursement, the authors of this Profile did not write a full chapter, as they did for the following ones, but opted for the presentation of some key figures on the health care system, presented in two tables and accompanied by a brief description of the health care 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).
- Old-age branch: French National Old-Age Insurance Fund for 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 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 available 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 "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, is managed by the Agricultural Mutual Insurance Fund (Mutualité Sociale Agricole, MSA).
- The scheme for non-salaried and non-farming, self-employed workers, 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 Complementary Health Insurance Funds (Union Nationale des Caisses d'Assurance Maladie, UNCAM), which is a new body bringing together the three 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 tariffs.
- Extended powers for the National Insurance Fund for Salaried Employees (CNAMTS) Managing Director, who:
  - is also the Managing Director of the National Union of Complementary Health Insurance Funds (UNCAM) and carries out National Union of Complementary 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 High Authority for Health (Haute Autorité de Santé, HAS):
  - as the body created to define the scope of reimbursable treatments;
  - which conducts periodic evaluations of medical services and draws up recommendations for good medical practices.
- 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 pharmaceuticals;
  - establishes the "Tarif forfaitaire de responsabilité" (fixed amount on the basis of which Health Insurance Funds reimburse some groups of generic pharmaceuticals).

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.

Table 1.1: France - Key figures on the health care system 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005	Source
Total mid-year population (Mio.)	57,844	59,012	59,393	59,777	60,154	60,521 e	60,873 e	INSEE Bilan démographique 2005
Life expectancy at birth, total	77.9	79.0	79.2	79.4	79.4	80.3	n.a.	OECD Health Data 2006, June 2006
Life expectancy at birth, females	81.8	82.7	82.9	83.0	82.9	83.8 e	83.8 e	INSEE Bilan démographique 2005
Life expectancy at birth, males	73.9	75.3	75.5	75.8	75.9	76.7 e	76.8 e	
GDP in billion €	1,195	1,441	1,497	1,549	1,595	1,659	1,710	
GGE in Mio. €	282,028	320,358	330,322	349,954	355,764	376,816	388,104	
THE in Mio. €	112,473	132,326	139,372	155,035	165,419	173,878	n.a.	OECD Health Data 2006, June 2006
Public HE in Mio. €	85,843	100,319	105,810	121,048	129,570	136,262	n.a.	OECD Health Data 2006, June 2006
Private HE in Mio. €	26,630	32,007	33,562	33,986	35,849	37,616	n.a.	OECD Health Data 2006, June 2006

Variable	1995	2000	2001	2002	2003	2004	2005	Source
Total no. of hospitals	n.a.	n.a.	n.a.	3,022	2,987	2,933	2,891[,e]	INSEE
No. of acute care beds	266,141	240,817	235,833	234,756	230,727	226,803	n.a.	OECD Health Data 2006, June 2006
Total no. of doctors	113,546	113,994	114,242	114,227	113,866	114,160	n.a.	Eco-Santé 2006, June 2006
No. of visits to GPs per patient per year	5.2	5.7	5.8	5.9	6.0	5.9	n.a.	Eco-Santé 2006, June 2006

GDP = gross domestic product, GGE = general government expenditure, GP = general practitioner, e = estimation, n.a. = not available, THE = total health expenditure, HE = health expenditure, data do not include French Overseas Departments

Out-patient doctors are remunerated on a fee-for-service basis. Hospitals are remunerated partly through ex-ante annual fixed budgets (approximately 75%) and partly on a fee-for-service basis (approximately 25%), which is being gradually implemented and is expected to account for 50% of hospital remuneration in 2007.

Public pharmaceutical expenditure (Dépenses de medicaments, PE) (social security and state or local funds) accounted for 69% of out-patient pharmaceutical expenditure (PE) in 2005. The remaining 31% from private expenditure included 18.4% of expenses for private health insurance and 12.7% out-of-pocket payments (Reste à charge ou ticket modérateur, OPP) (including cost-sharing and self-medication) by households.

Private health insurance in France corresponds to complementary health insurance which patients subscribe to on a (usually) voluntary basis. A total of 94% of the population is covered by complementary health insurance, including 8% covered by the free Complementary Universal Health Insurance Coverage (CMUC), provided for people with low incomes (cf. 2.2).

Table 1.2: France - Diseases with highest morbidity and the leading causes of mortality 2002-2003

No.	Top 5 diseases with highest morbidity (1 = most common)	ICD-10 code	No.	Top 5 leading causes of mortality (1 = most common)	ICD-10 code
1	Diseases of the digestive system	K00-K93	1	Diseases of the circulatory system (I00-I99)	I00-I99
2	Diseases of the eye and adnexa	H00-H59	2	Neoplasms (C00-D48)	C00-D48
3	Endocrine, nutritional and metabolic diseases	E00-E90	3	Malignant neoplasms (C00-C97)	C00-C97
4	Diseases of the circulatory system (I00-I99)	I00-I99	4	Other heart diseases (I30-I33,I39-I52)	I30-I33,I39-I52
5	Diseases of the musculoskeletal system and connective tissue	M00-M99	5	Ischaemic heart diseases (I20-I25)	I20-I25
Source: DREES Données sur la situation sanitaire et sociale en France, 2005 from ESPS (IRDES) Declared morbidity in 2002			Source: EUROSTAT		
Year: 2002			Year: 2003		

2 Pharmaceutical system

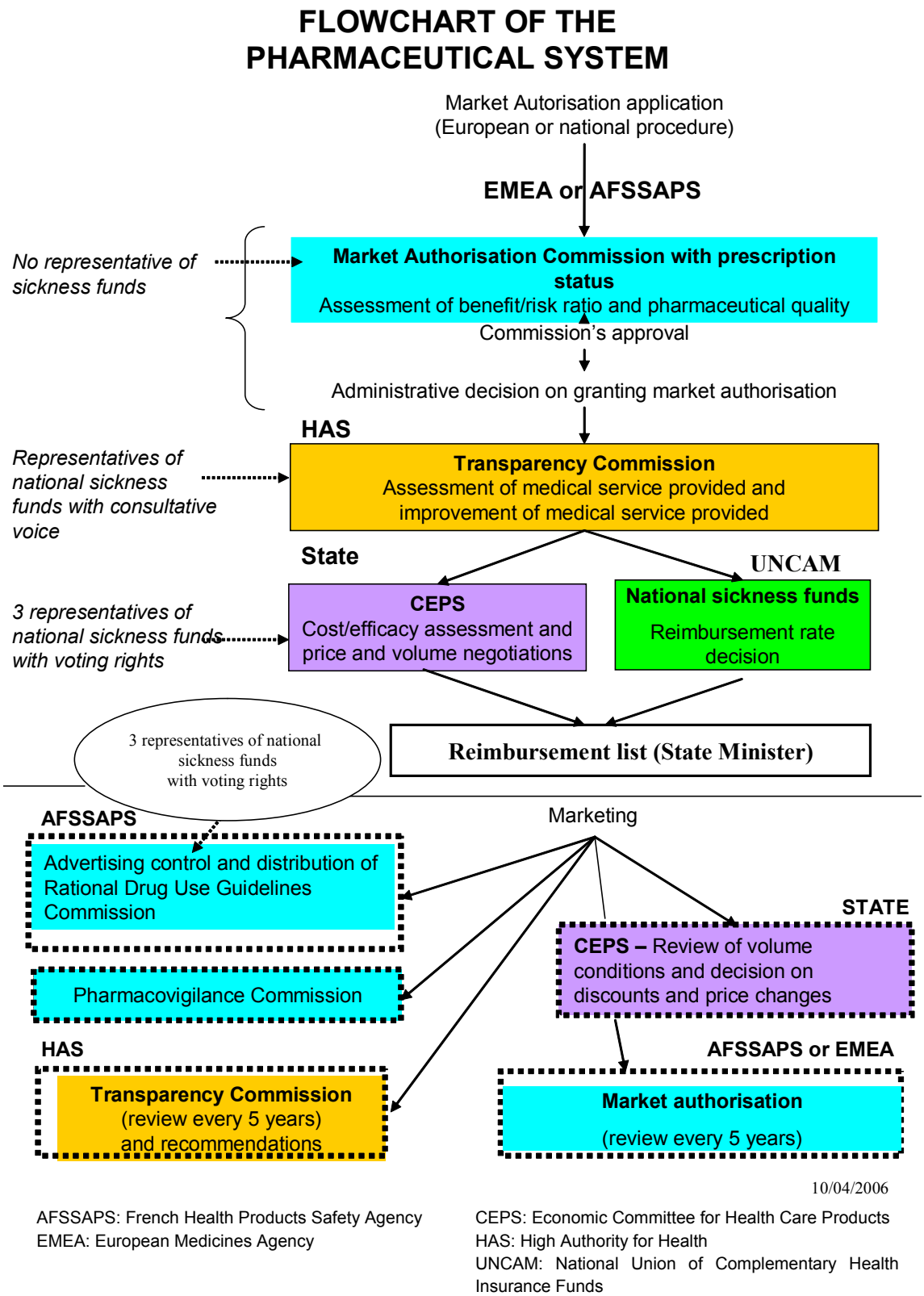
2.1 Organisation

In the following section the authors describe the regulatory framework of the French pharmaceutical system (legal basis, main authorities and their tasks), as well as the French pharmaceutical market (key data and players).

Figure 2.1 depicts only the flowchart for reimbursable pharmaceuticals, from market authorisation to the inscription of reimbursable pharmaceuticals into the positive list. At this stage a pharmaceutical bought in a pharmacy on a prescription by a doctor can be reimbursed by the sickness funds.

The figures show the positions of the different institutions and their roles in the product life cycle. It is worth noting that after market authorisation a manufacturer can choose to be present only in the hospital sector or only in the non-reimbursable sector.

Figure 2.1: France - Flowchart of the pharmaceutical system for reimbursable pharmaceuticals 2006



Source: CNAMTS

2.1.1 Regulatory framework

The main players in the French pharmaceutical system are the state bodies at national level (Ministry of Health and Social Security, Minister of Finance and Industry (Ministère des Finances et de l'Industrie, MINEFI)), 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 sickness 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) is voted for. During the course of the year an independent committee called "Comité d'alerte" analyses the evolution of the expenditure: if the trend shows that the defined target risk is to be overlapped it must declare this and the sickness funds have one month to propose measures to the Government.

2.1.1.1 Policy and legislation

In the pharmaceutical sector many laws and decrees are in operation, driven by European legislation. They are summarised into two laws (called "Codes"): the Public Health Code (Code de la Santé Publique, CSP) and the Social Security Code (Code de la Sécurité Sociale, CSS). They can be accessed via the web sites listed here:

- http://www.legifrance.gouv.fr/WAspad/RechercheSimpleCode;jsessionid=F1WV4FW6S9zxkvzzmH7hW3LKFWih20TyBQr210bRG17KLTJhGzKE!366235823!iwsspad1.legifrance.tours.ort.fr!10038!-1!814546890!iwsspad2.legifrance.tours.ort.fr!10038!-1?commun=CSANPU&code= ;
- http://www.legifrance.gouv.fr/WAspad/RechercheSimpleCode;jsessionid=F1WV4FW6S9zxkvzzmH7hW3LKFWih20TyBQr210bRG17KLTJhGzKE!366235823!iwsspad1.legifrance.tours.ort.fr!10038!-1!814546890!iwsspad2.legifrance.tours.ort.fr!10038!-1?commun=CSECSO&code= .

The regressive statutory mark-up schemes for wholesalers and pharmacists are detailed in a decree published in the country's official bulletin[1].

2.1.1.2 Authorities

The French Agency for the Medical Safety of Health Products (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 amount of time for this process is 210 days.

[1] http://www.legifrance.gouv.fr/WAspad/RechercheSimpleTexte?fs_natu=&fs_num=&fs_nor=&fs_jour=&fs_mois=&fs_annee=&fs_pubjour=&fs_pubmois=&fs_pubannee=&fs_rech=TIT&fs_mot=prix+et+marges+m%E9dicaments+remboursables&checkMot=&checkMotTit=checked&checkMotTitTex=#

A simplified procedure exists for generics by proving the bioequivalence of the pharmaceutical with the original product.

Before market authorisation is granted, it is possible to put pharmaceuticals on the market with a fast track procedure called a temporary utilisation 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 normal studies and obtain a market authorisation. The other type is an agreement of sorts, 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. There do not seem to be industry problems with delays in obtaining market authorisation; the period of 210 days seems to be enough.

The Director of the Agency for the Medical Safety of Health Products (AFSSAPS) implements the sanitary policy on pharmaceuticals and vigilance over pharmaceuticals. Over 70% of the budget of the Agency for the Medical Safety of Health Products (AFSSAPS) comes from taxes and fees paid by the industry. Sickness 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 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 pharmaceuticals are controlled, whereas in other non-reimbursable sectors there is free pricing, e.g. in hospitals and for over-the-counter (OTC) products (Médicament en vente libre).

Pricing activities are carried out by the Economic Committee for Health Care Products (CEPS) for reimbursable products for out-patients, and since 2005 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 Finance and Industry (MINEFI), sickness funds, complementary insurance and private insurance, the Directorate of Hospitals in the Ministry of Social Affairs (MAS), and the Ministry of Research.

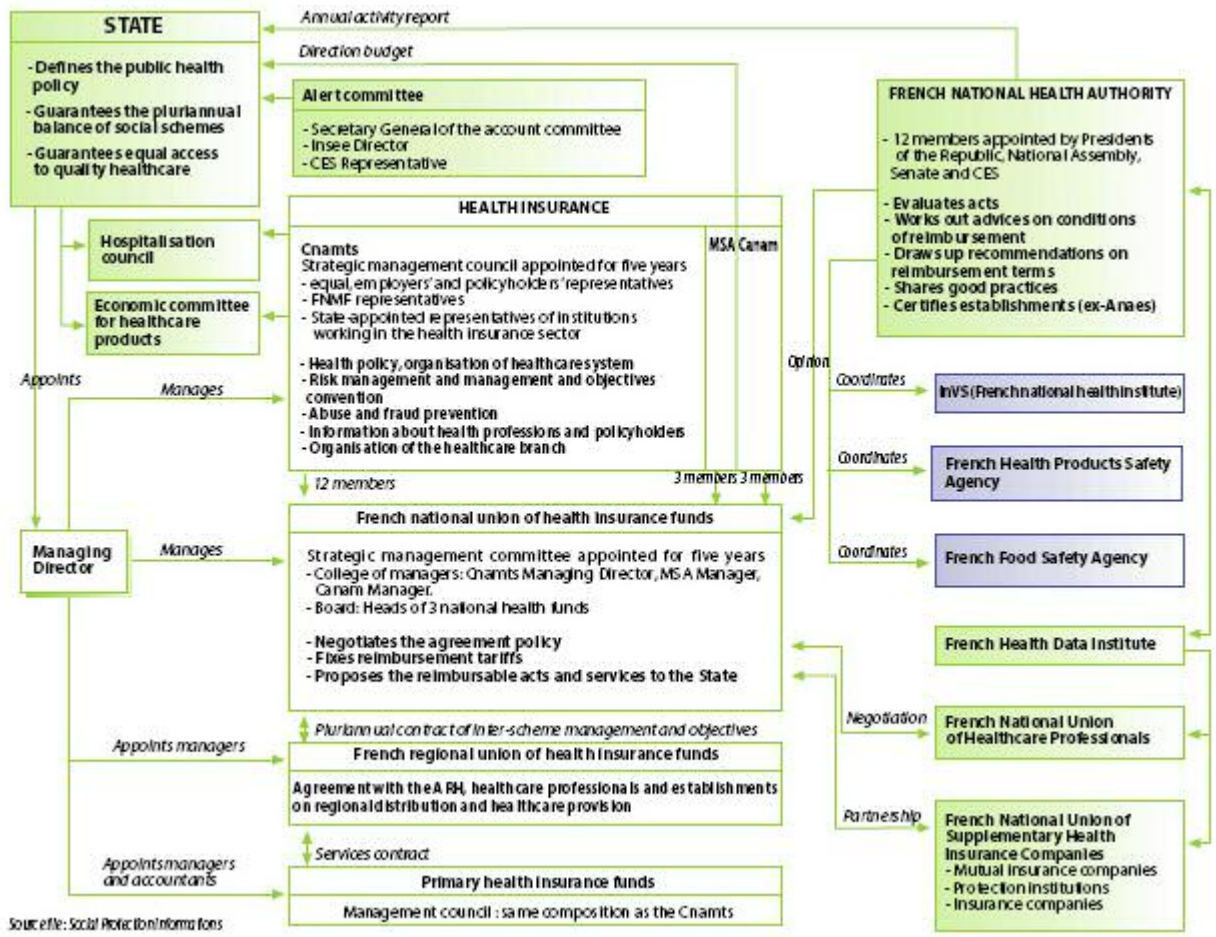
The Economic Committee for Health Care Products (CEPS) and the Association of Pharmaceutical Industry (Les Entreprises du Médicament, LEEM) negotiate a price agreement for reimbursable pharmaceuticals in accordance with art. L 162-16-4 of the Social Security Code (CSS) or, if this is not possible, the 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 pharmaceuticals sold by hospitals to out-patients, as well as in tariff setting for costly products paid for directly by sickness 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 (Commis-

sion de la Transparence) which is a department of the High Authority for Health (HAS), a new body created by the Law of 13 August 2004.

The new management of the health insurance system resulting from the 13 August 2004 reform is depicted in Figure 2.2.

Figure 2.2: France – Health insurance organisation 2006



Source: CNAMTS

The new 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. 1. Background) 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 Tra-

vailleurs 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 High Authority for Health (HAS):

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

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

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

  a) sets the prices of pharmaceuticals;

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

Different bodies are concerned with pharmaceuticals 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 pharmaceutical is made by the Director of the Agency for the Medical Safety of Health Products (AFSSAPS). It is a sanitary decision. Since Decree No. 2004-546 of 15 June 2005 under European Commission (EC) Directive 2001/83/EC on prescription status of pharmaceuticals, new forms of prescription status have been introduced in France. Now five classes of prescription status exist:

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

The sickness funds now manage the rate of reimbursement for each pharmaceutical and can modify the common rates for regulation, if this is necessary with certain limits (cf. 4.2.2). 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. 5). They sign agreements with pharmacists to promote generic substitution (cf. 5.5.1), participate in active risk management with sanitary missions, and also seek more effective regulation, e.g. on antibiotics consumption.

In mid-2003 the national sickness fund (National Insurance Fund for Salaried Employees (CNAMTS)) implemented sickness insurance representatives ("Délégués d'Assurance Maladie", DAM), which were further developed according to the 2004 reform of the health care system. The objectives are to inform the health professionals on:

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

They conduct face-to-face visits with 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 sickness fund). The duration of the visits is approximately 30 minutes with a target of 150,000 visits per year, so a sickness insurance representative (DAM) visits a general practitioner (Médecin Généraliste, GP) approximately three times per year. The workforce was approximately 700 in 2006 and is expected to double by 2009. They are managed by a regional manager acting as the link between the National Insurance Fund for Salaried Employees (CNAMTS) and the sickness insurance representative (DAM). Sickness 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 sickness insurance representative (DAM) in 2006. Visit preparation consists of approximately one training day per campaign, including evaluation of the preparedness of the sickness insurance representative (DAM). They are provided with guidelines and specific documents to give to the professional, including a report on her/his activity.

Table 2.1: France - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Ministère des Affaires Sociales (MAS) Ministère de la Santé Ministère des Finances (MINEFI)	Ministry of Social Affairs Ministry of Health Ministry of Finance and Industry	Regulatory body	Overall planning and legislative authority In charge of the reimbursement legislation/decisions
Agence française de sécurité sanitaire des produits de santé (AFSSAPS)	Agency for the Medical Safety of Health Products	Medicines agency (subordinate to the Ministry of Health)	In charge of market authorisation, classification, vigilance, advertisement
Haute Autorité de Santé (HAS)	High Authority for Health	Independent body	Technical advice for including a pharmaceutical on the positive list; recommendations
Comité économique des produits de santé (CEPS)	Economic Committee for Health Care Products	Joint committee of ministers and sickness funds	In charge of setting the reference prices (TFR) and prices of the reimbursable pharmaceuticals and some products in hospitals
Union nationale des caisses d'assurance maladie (UNCAM)	National Union of Complementary Health Insurance Funds	Third-party payers (Head of sickness funds)	In charge of setting the (%) level for the reimbursement of pharmaceuticals

Source: CNAMTS

2.1.2 Pharmaceutical market

2.1.2.1 Availability of pharmaceuticals

On 1 January 2005 a total of 14,990 pharmaceuticals 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 Agency for the Medical Safety of Health Products (AFSSAPS) is responsible for the different classifications of prescription-only medicines (POM) (Médicament à prescription obligatoire) and over-the-counter (OTC) pharmaceuticals or non-prescription products.

Table 2.2: France - Number of pharmaceuticals 1995, 2000-2005

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005
Authorised	5,970	11,470	12,140	12,780	13,340	14,110	14,990
On the market	3,010	6,640	7,060	7,500	7,910	8,280	8,650
POM	n.a.	4,000	4,000	4,200	4,600	4,800	5,000
Reimbursable	n.a.	5,100	5,100	5,200	5,500	5,700	6,100
Generics	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Parallel traded	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = prescription-only medicine(s), n.a. = not available

Source: CNAMTS, AFSSAPS

The increase of authorised pharmaceuticals between 2000 and 2005 is mainly due to new market authorisation of generics. However, the generics were not all marketed.

For reimbursable pharmaceuticals, the moderate increase is due to some de-listing.

2.1.2.2 Market data

The increase in the market is due mainly to the arrival of new products that are more costly than previously. The increase of the price per pack has a structural effect: an old cheap product is replaced by a new expensive one. In the hospital sector the increase is due to the arrival of very costly new products, e.g. those used in oncology.

Table 2.3: France - Market data 1995, 2000-2005

Pharmaceutical industry in Mio. €	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescriptions by volume	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of annual prescriptions by value	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical sales							
Sales at ex-factory price level	11,472	14,635	15,626	16,311	17,320	18,360	19,438
Sales at wholesale price level	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales at PRP level	18,454	23,631	25,502	26,928	28,555	30,071	31,143
Sales in hospitals at ex-factory price level	1,877	2,628	3,049	3,600	4,000	4,400	4,400
Sales of generics at ex-factory price level, reimbursable market only	n.a.	1,844	2,172	2,316	2,286	2,699	3,304
Sales of parallel traded pharmaceuticals	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.a.
Exports and imports at ex-factory price level							
Total pharmaceutical exports	4,029	9,621	12,861	14,467	14,529	15,340	16,747
Total pharmaceutical imports	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	10,589

n.a.= not available, n.app. = not applicable, PRP = pharmacy retail price

Source: LEEM from GERS (ex-factory price level excluding value-added tax (VAT)), *National health accounts 2005 -DREES (excluding hospital sales and including value-added tax (VAT))

The exports increased significantly thanks to the development of manufacturing activities. Many companies choose France for production. Since 1995, France is the most important exporting country in Europe for pharmaceuticals.

In terms of value, the generics market reached 17% of the reimbursable market in 2005, compared to 12.6% in 2000, but in terms of volume, generics accounted for 18.4% in 2000 and 25% in 2005.

Table 2.4: France - Top 10 best-selling pharmaceuticals, by active ingredient, 2005

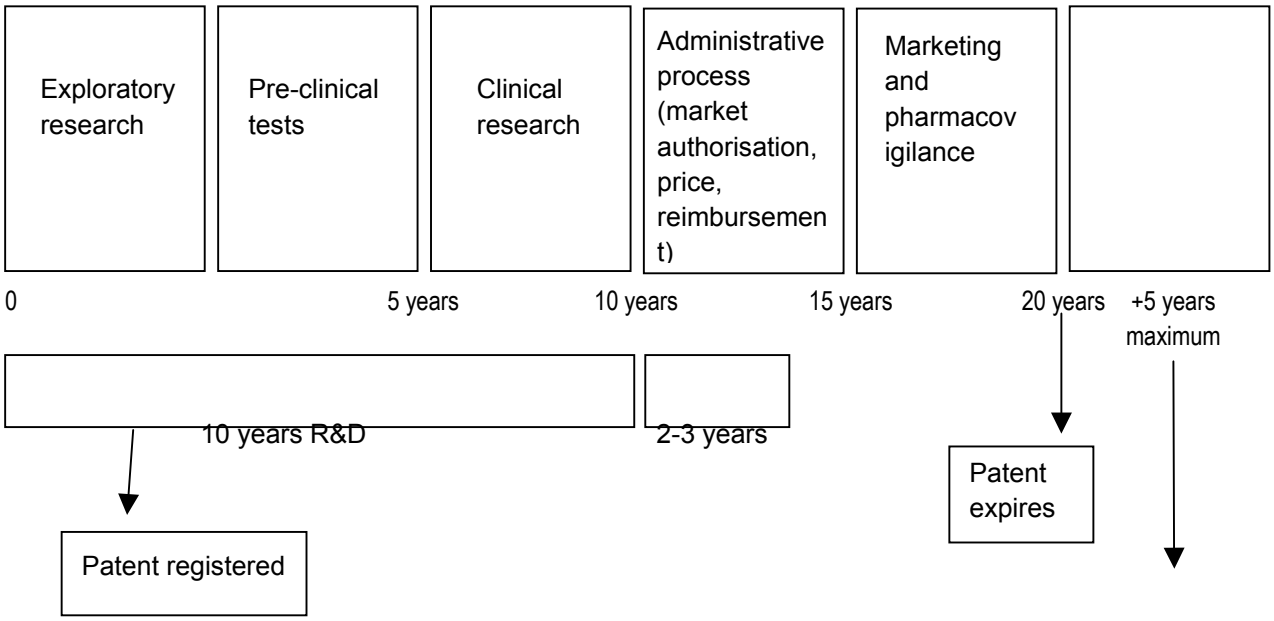
Position	Pharmaceutical, by active ingredient VALUE	Pharmaceutical, by active ingredient VOLUME
1	CLOPIDOGREL	PARACETAMOL
2	ATORVASTATINE	DEXTROPROPOXYPHENE + PARACETAMOL
3	PRAVASTATINE	ACETYLSALICYLIQUE ACIDE
4	OMEPRAZOLE	AMOXICILLINE
5	PARACETAMOL	METFORMINE
6	SALMETEROL	IBUPROFENE
7	SIMVASTATINE	LEVOTHYROXINE SODIQUE
8	LANSOPRAZOLE	DIOSMINE
9	ESOMEPRAZOLE	PHLOROGLUCINOL
10	PANTOPRAZOLE	DEXTROPROPOXYPHENE + PARACETAMOL + CAFEINE

Source : MEDICAM CNAMTS, http://www.ameli.fr

2.1.2.2 Patents and data protection

In France, according to the European Patent Convention, original pharmaceuticals receive market protection for 20 years through the National Institute for Industrial Property (Institut National de la Propriété Industrielle, INPI) and under art. L 613-13 of the Intellectual Property Code (Code de la Propriété Intellectuelle, CPI). An additional period of five years maximum is possible with a Complementary Protection Certificate (Certificat Complémentaire de Protection, CCP). This certificate is attainable up to 15 years after the market authorisation; it is commonly accepted that the effective protection on the market is 15 years.

Table 2.5: France - Patent registration procedure



R&D = Research and development
Source: LEEM

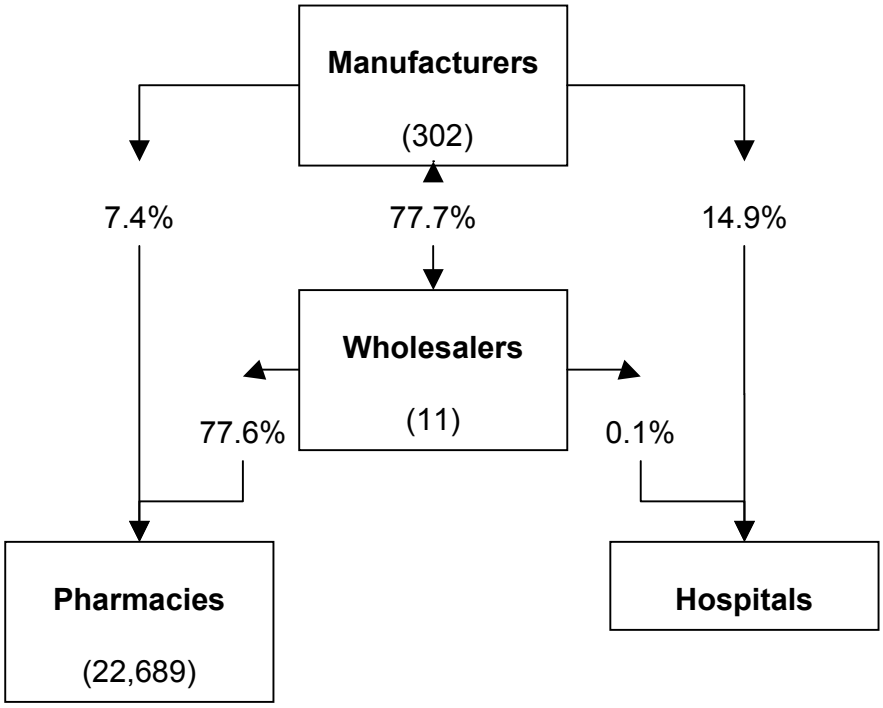
2.1.3 Market players

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

In the pharmaceutical distribution channels, the 302 manufacturers sell:

- 7.4% of the total amount directly to 22,689 pharmacists
- 77.7% to 11 wholesalers, of which 77.6% are sold to pharmacists and 0.1% to hospitals
- 14.9% to hospitals.

Figure 2.3: France - Pharmaceutical distribution channels



Source: CSRP

2.1.3.1 Industry

There are 339 pharmaceutical companies based in France. They are all members of the Association of Pharmaceutical Industry (LEEM). This number includes 12 companies specialising in generics, members of the trade association Generic Producers Association (Association des Fabricants de Génériques, GEMME). Manufacturers specialising 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 5.4%.

The industry's total sales was € 40,585 Mio. in 2005: € 23,838 Mio. was domestic sales and € 16,747 Mio. was exports.

Domestic sales are broken down into € 18,134 Mio. of reimbursable products and € 1,304 Mio. of non-reimbursable products, which corresponds to a pharmacist market of € 19,438 Mio. in total. Hospital sales amount to € 4,400 Mio.

The industry employed 84,300 people in 1995 and 100,000 in 2004. Research employees represent 13% of the total workforce. France's turnover is the highest in Europe. This industry is not so concentrated. The first five groups represent 37.5% of the total turnover and the first 10 represent 55.3%. The biggest manufacturer is Sanofi-Aventis with a market share of 16%, followed by Pfizer, Glaxo Smith Kline, Astra Zeneca and Bristol Myers Squibb.

In the generics business, the biggest company is Merck Generics (Merck AG Group), the second is BIOGARAN (Servier Group) and the third is Sandoz (Novartis Group).

At the moment parallel imports represent very little in France. This part of the industry is just beginning, with fewer than five market authorisations in 2006. The administrative procedure is simplified, without any scientific study. The pharmaceutical industry has a representative without voting rights in the Transparency Commission and is not represented in the Economic Committee for Health Care Products (CEPS). By advertising new pharmaceuticals categorised according to illness, the industry puts considerable pressure on sickness funds. The industry is trying to create a new look by introducing discussion groups with patients or patient groups with orphan (rare) diseases.

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

The industry fights against sickness 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. 3.6.1).

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-patients. In March 2004, an “Accord Cadre Hôpital” was also signed between the Association of Pharmaceutical Industry (LEEM) and the Economic Committee for Health Care Products (CEPS) regarding pharmaceuticals sold to hospitals.

Since 1994, in order to contribute to an improvement in the long term on the economic environment, the State has wanted to initiate 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 has just been renewed, to be in effect until 2009 and modified by amendments No. 1 and No. 2 of the 29 January 2007 (cf. 3.1). 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 pharmaceuticals.
- It formalises the general measures for speeding up procedures and in particular for innovative pharmaceuticals (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 of year discounts. Those discounts are made up of pharmacotherapeutic aggregate discouts and discounts on the turnover.

Amendments 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. Furthermore, financial compensation – if the sales forecasts are exceeded – and post-approval studies are planed.

At the time of writing, all products with a Level of improvement of clinical benefit (Amélioration du service médical rendu, ASMR) (a rating on the level of improvement in the clinical benefit, cf. 3.1) of I or II (i.e. pharmaceuticals with a comparably high clinical benefit level) can benefit from this fast-track price notification procedure. Products with a Level of improvement of clinical benefit (ASMR) III are included within the projected limit of € 40 Mio. in the third year of marketing. 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 pharmaceutical and the daily cost of treatment corresponding to the price submitted must be, at the most, equal to the comparator. The pharmaceutical 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 pharmaceuticals).

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 pharmaceutical.

For paediatric pharmaceuticals 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.

A recent agreement, “Charte de la visite médicale”, has been 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 must be reduced. In addition, there will be national procedures to qualify medical representatives.

Table 2.6: France - Key data on the pharmaceutical industry 1995-2005[1]

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	345	302	300	300	300	303	n.a.
- generic producers	n.a.	9	9	11	11	12	12
No. of persons employed[2]	84,300	95,300	96,300	98,100	98,900	100,000	n.a.

[1] as of 1 January, [2] counted per head, n.a= not available

Source: Eco-Santé France 2005

2.1.3.2 Wholesalers

There are three leading wholesalers:

- OCP: approximately 40% market share with 52 outlets
- Alliance Santé: approximately 29.5% market share with 57 outlets
- CERP: approximately 26% market share with 71 outlets.

These wholesalers employ 15,400 people all over the country. Their role is critical in the distribution of pharmaceuticals (up to four deliveries a day, within a very short time). Altogether they store 20,000 different packs. Each outlet delivers pharmaceuticals to an average number of 110 pharmacies, compared to 200 in Germany and in the United Kingdom.

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

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

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

- information on pharmaceuticals (vocational training);
- assistance in pharmacy management and merchandising;
- legal information updates (laws, decrees, press reviews), and in particular, the Agency for the Medical Safety of Health Products (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 1.17% and 2.17% of sales) to social security. The contribution in 2003 was € 305 Mio. for € 15,693 Mio. sales.

Table 2.7: France - Key data on pharmaceutical wholesale 1995-2005[1]

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total no. of wholesale companies	n.a	n.a	n.a	n.a	11	11	11
Total no. of outlets	n.a	n.a	n.a	n.a	188	184	189

[1] as of 1 January, n.a. = not available

Source: CSRP

2.1.3.3 Pharmaceutical outlets / retailers

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

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

- In some locations, a few doctors can sell pharmaceuticals (cf. 2.1.3.3.4).
- Hospitals are also allowed to sell some pharmaceuticals to out-patients from a special positive list. These are treatments for severe conditions e.g. cancer, AIDS and hepatitis, for which the treatment has been initiated in hospital. The number of pharmaceuticals in this category tends to decrease as more and more become available from community pharmacies each month (cf. 2.1.3.4).

2.1.3.3.1 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 Pharmaceutical Association (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 Ordre des Pharmaciens and the representative of the pharmacists associations (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 Pubic Health Code (CSP) (Art. L 5125-3, Art. L 5125-4). The rules are as follows for one pharmacy:

- per 3,000 inhabitants in cities or communes over 30,000 inhabitants;
- per 2,500 inhabitants in cities or communes of less than 30,000 inhabitants;
- per 3,500 inhabitants in French "departments" (counties) with a different health insurance scheme (Bas-Rhin, Haut-Rhin, Moselle and Guyane).

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 pharmaceuticals is ensured by dispensing doctors (122 in total). The total number of private

community pharmacies as of 1 January 2006 was 22,610 (cf. Table 2.8), i.e. one pharmacy per 2,669 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'Exercise Libéral (SEL) so a pharmacist can invest in a share of another pharmacy.

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

Internet pharmacies are not allowed in France. Pharmaceuticals can only be purchased from non-French web sites. It is legal for consumers to purchase over-the-counter (OTC) pharmaceuticals 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.

Pharmacists can purchase pharmaceuticals directly from the manufacturer, especially products with a high turnover. Since February 2004, discounts/rebates granted to pharmacists by wholesalers or the pharmaceutical industry have been regulated and cannot exceed 2.5% on original reimbursable pharmaceuticals and 10.74% on generics.

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 pharmaceuticals. They are owned by the mining sickness fund so pharmacists are managers and employees.
- "Mutual" pharmacies are accessible to all patients covered by a complementary mutual health insurance association (cf. 2.2). 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.

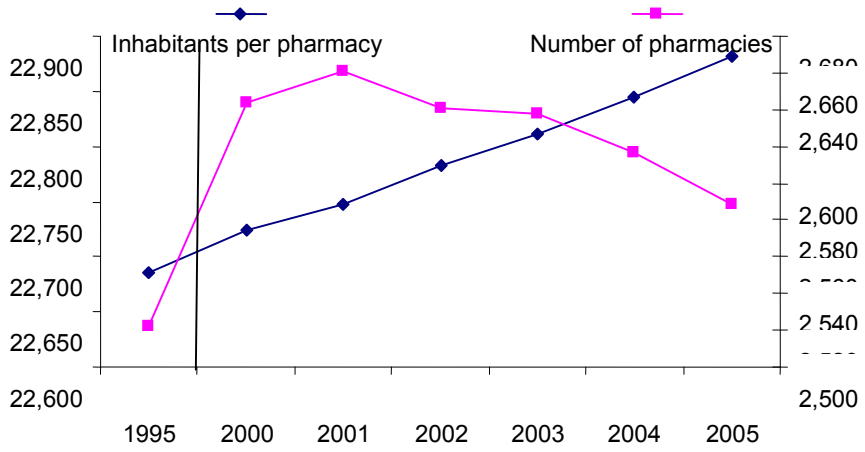
Table 2.8: France - Retailers of pharmaceuticals 1995, 2000-2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
No. of community pharmacies[1]	22,637	22,839	22,868	22,835	22,829	22,794	22,747	n.a.
No. of private pharmacies[1]	22,493	22,698	22,727	22,697	22,691	22,658	22,610	n.a.
No. of pharmacies of the mining scheme[1]	72	68	68	68	68	68	69	n.a.
No. of mutual pharmacies[1]	72	73	73	70	70	68	68	n.a.
No. of public pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of hospital pharmacies for out-patients	n.a.	n.a.	n.a.	1 575	1 569	1 561	1 551	n.a.
No. of other POM dispensaries: SD doctors	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	122	n.app.
Total no. of POM dispensaries	22,637	22,839	22,868	22,835	22,829	22,794	24,420	n.a.
No. of Internet pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of OTC dispensaries, e.g. drugstores: _____	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.

OTC = over-the-counter (pharmaceuticals), POM = prescription-only medicine(s), n.app. = not applicable, NA= not available, POM dispensaries = including SD doctors and hospital pharmacies for out-patients acting as community pharmacies, [1] as of 31 December, SD = self-dispensing

Source: Eco-Santé France 2006, IRDES

Figure 2.4: France - Number of community pharmacies and number of inhabitants per pharmacy 1990, 1995 and 2000-2005



Source: Eco-Santé France 2005

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 (cf. Table 3.5). Details are given here:

- for ex-factory price < € 22.90, the margin is 26.1% of ex-factory price
- for ex-factory price from € 22.91 to € 150.00, the margin is 10.0%
- For ex-factory price > € 150.00, the margin is 6.0%
- + an additional € 0.53 fee per pack.

Cf. 3.5.2 for further details.

2.1.3.3.2 Other pharmacy outlets

Not applicable.

2.1.3.3.3 Internet pharmacies

There are no French-based Internet pharmacies, but pharmaceuticals are available from non-French Internet pharmacies. However, the Pharmaceutical Association (CNOP) is currently looking into this issue and trying to work out how to legalise and control this channel of distribution.

2.1.3.3.4 Dispensing doctors

In some remote areas authorised doctors can dispense pharmaceuticals. This is the case on some small islands, in some mountain valleys and some rural areas. The total number of dispensing doctors is 122.

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

2.1.3.4 Hospitals

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

Hospital pharmacies are allowed to dispense pharmaceuticals from a special list for out-patients (cf. 2.1.3.3). The number of hospital-only medicines (Médicament de la réserve hospitalière, HOM) dispensed 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 pharmaceuticals. The list is drawn up by a Hospital Committee (one in each hospital, whether public or private) from a special list of pharmaceuticals approved for hospital use. 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 pharmaceutical in the hospital's list.

The composition and operating mode of Hospital Committees are regulated (Decree No. 2000-1316 of 26/12/2000, Art. 5104-52 to 56). There are currently three main purchasing procedures, explained here.

- At standard price, upon invoice (used only marginally).
- Negotiations with the manufacturer.
- Public tendering for equivalent pharmaceuticals, 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.

Based on Decree No. 2006-975 of 1 August 2006, a national tendering procedure is to be implemented for public hospitals.

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

The pharmaceutical lobbies put a lot of pressure on the younger hospital doctors in particular, in order to persuade them to include new pharmaceuticals in the hospital's list, as a way of enhancing primary care prescribing.

Hospital pharmacies are funded mostly out of the hospital budget. The cost of the pharmaceuticals is included in the in-patient's daily fee. However, prices are regulated for a number of highly innovative and costly pharmaceuticals, for which the hospital can claim reimbursement from the Health Insurance Funds for in-patients.

2.1.3.5 Doctors

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 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 unions sign an agreement with sickness funds. The latest one was signed on 12 January 2005 between the National Union of Complementary Health Insurance Funds (UNCAM) and the

Union of Self-employed Doctors (SML), the Confederation of French Medical Unions (CSMF) and ALLIANCE. It was published in the official bulletin on 11 February 2005. This new agreement is unique 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”.

This agreement promotes guidelines for rational use of pharmaceuticals in the activities of doctors and determines targets on the use of pharmaceuticals 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. 5.2 for further details.)

2.1.3.6 Patients

Retail prices for reimbursable pharmaceuticals are in fact the same in all pharmacies, but differences in prices exist for non-reimbursable pharmaceuticals. Few patients’ lobbies influence pharmaceutical policy on pricing in the reimbursed pharmaceutical sector for chronic diseases. However, groups of patients are lobbying with the Agency for the Medical Safety of Health Products (AFSSAPS) regarding treatments for specific diseases or to obtain rapid access for orphan pharmaceuticals or for special products with temporary utilisation authorisation (ATU) status (cf. 2.1.1.2).

Since the introduction of the Law of 13 August 2004, a patient must choose a “médecin traitant”, a doctor of first choice. If s/he refuses to do so, reimbursement will be decreased by 10%.

2.2 Funding

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

2.2.1 Pharmaceutical expenditure

The French pharmaceutical expenditure (PE) accounted for € 32,947 Mio. in 2005. It increased significantly (+66%) from 1995 to 2004 (5.8% annual growth rate). Per inhabitant, it amounted to € 547 in 2004 compared to 342 in 1995, a rise at an annual pace of 5.4%. This significant increase is partly explained by the structural effect of the pharmaceutical sector; medical progress and the fact that new pharmaceuticals are increasingly more expensive. Consumption volumes are also responsible, to a lesser extent, despite incentives to limit them.

From 1995 to 2004, the share of public pharmaceutical expenditure (PE) in total health expenditure (Dépenses totales de santé, THE) rose from 10.8% to 13.4%, whereas the share of private pharmaceutical expenditure (PE) decreased by 1.2% (from 6.8% to 5.6%). In France, the 2004 share of pharmaceutical expenditure (PE) in both the gross domestic product (Produit intérieur brut, GDP) (2.0%) and the total health expenditure (THE) (18.9%) were above the European averages (1.5% and 17.9% respectively).

Table 2.9: France - Total pharmaceutical expenditure (TPE) 1995, 2000-2005

Pharmaceutical expenditure (PE)	1995	2000	2001	2002	2003	2004	2005
TPE in Mio. €	19,809	26,890	29,141	29,046	31,026	32,947	n.a.
TPE as a % of THE	17.6	20.3	20.9	18.7	18.8	18.9	n.a.
TPE per capita in €	342	456	491	487	517	547	n.a.
Public PE as a % of THE	10.8	13.2	13.8	13.1	13.2	13.4	n.a.
Private PE as a % of THE	6.8	7.1	7.1	5.6	5.6	5.6	n.a.

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

Source: OECD Health Data 2006

2.2.2 Sources of funds

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:

- social contributions (55% 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 (43%) including mainly 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 and accounts for 35% of health insurance funding).

The income for health insurance was divided as follows in 2005:[2]

- social contributions: 54.8%
- general social contribution (CSG): 35.6%
- taxes: 7.6%
- state contribution and transfers: 2.0%.

Public pharmaceutical expenditure (PE) (social security and state or local funds) accounted for 69% of the out-patient pharmaceutical expenditure (PE) in 2005. The remaining 31% from private expenditure included 18.4% of expenses for private health insurance and 12.7% of out-of-pocket payments (OPP) (including cost-sharing and self-medication) of households.

Private health insurance in France corresponds to complementary health insurance which patients subscribe to on a (usually) voluntary basis. A total of 94% of the population is covered by complementary health insurance, including 8% covered by the free Complementary Universal Health Insurance Coverage (CMUC), provided for people with low incomes (cf. 2.2).

In France, there are three types of complementary health insurer:

[2] http://www.securite-sociale.fr/chiffres/lfss/lfss2007/plfss2007.pdf
http://www.legifrance.gouv.fr/imagesJOE/2006/1222/joe_20061222_0296_0001.pdf

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

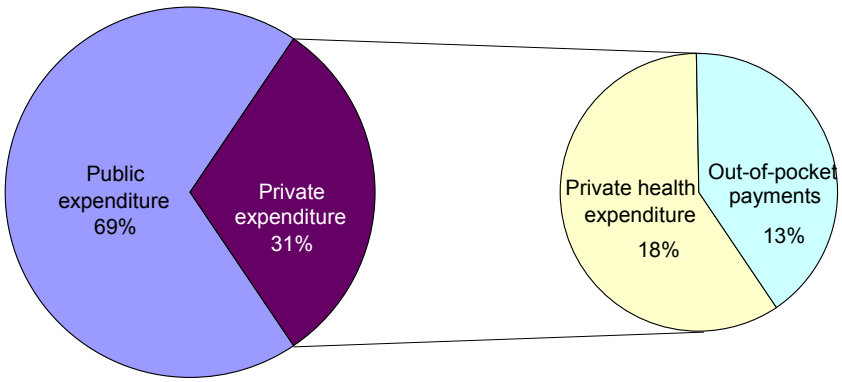
The mutual insurance associations (cf. 1. Background) play a dominant role in providing complementary health insurance coverage, financing 12% of total health expenditure (THE), while private insurance companies account for 4%, and the provident institutions for 2.5%.

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 to by their employers and 32% subscribe to one individually, on a voluntary basis (cf. 4.4).[3]

Self-medication, defined as pharmaceuticals bought without a medical prescription, represented 8% of the pharmaceutical sales at ex-factory price in France in 2005 (17% in volume), accounting for € 1.5 billion.[4] At pharmacy retail price (Prix à la consommation ou prix public, PRP) level, excluding value-added tax (Taxe sur la Valeur Ajoutée, VAT), the Association of the European Self-Medication Industry (AEGSP) estimated self-medication to be at € 1.4 billion in 2005.

In 2005, non-reimbursed prescription pharmaceuticals accounted for 2% of the pharmaceutical market.

Figure 2.5: France - Share of private and public out-patient pharmaceutical expenditure (PE) 2005



Source: CNAMTS from DREES, Health national accounts 2005

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

[4] Self-medication market in France, A. Coulomb et A. Baumelou 2006

3 Pricing

3.1 Organisation

After having obtained market authorisation, the manufacturer can decide on which market to place the pharmaceutical. A key distinction is on the hospital market for in-patients and the market for out-patients who buy pharmaceuticals in pharmacies (cf. Table 3.1). 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 pharmaceuticals only. There is free pricing for non-reimbursable pharmaceuticals. 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 (cf. 4.2.2), and a Level of improvement of clinical benefit (ASMR) against the comparable products existing in the market, from ASMR 1 to ASMR 5 (cf. 5.1).

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 sickness fund for salaried people;
- one representative for other sickness 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 reimbursed product, a dossier is submitted simultaneously to the High 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 Complementary Health Insurance Funds (UNCAM) for the reimbursement rate.

The time allotted 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 registration 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 Complementary Health Insurance Funds (UNCAM) are all published in the same issue of the country's official bulletin.

There is a 3-year plan to reduce prices, in order to reduce the total reimbursement amount.

3.2 Pricing policies

France was one of the first countries to exhibit 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 web sites of sickness funds:[5]

Table 3.1: France - Ways of pricing pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free pricing	Free pricing for all non-reimbursable pharmaceuticals in out-patient care Free pricing as well for almost all products on the hospital positive list		Free pricing for non-reimbursed products
Statutory pricing	Controlled for reimbursable pharmaceuticals	Regressive mark-up scheme for wholesalers for reimbursable pharmaceuticals	Reimbursable pharmaceuticals via a regressive mark-up scheme, which can be reviewed by the Minister
Price negotiations	Between manufacturers and CEPS		
Discounts / rebates	Yes, for sales volumes exceeding negotiated sales forecasts	Possible by decree, with certain limits	Possible but in fact not used
Public procurement	➢ Cf. 3.2.4		
Institution in charge of pricing	➢ CEPS ➢ Ministry of Social Affairs (MAS) and Ministry of Finance and Industry (MINEFI) for margin scheme		

[5] For more information: http://www.ameli.fr/professionnels-de-sante/medecins/exercer-au-quotidien/codage/medicaments/index.php

Legal basis	➢ Art. 162-16-4 of CSS, which means a price is set by agreement between manufacturer and CEPS or, if this is not the case, by the Ministry of Health, Ministry of Social Affairs (MAS) and Ministry of Finance ➢ The price is in relation with the improvement of the medical service provided, the prices of the pharmaceuticals with the same therapeutic objective, the planned volume of sales, and the planned and real extent(s) (target and joined populations) of use

CEPS = Economic Committee for Health Care Products, CSS = Social Security Code

Source: CNAMTS, CEPS

3.2.1 Statutory pricing and negotiations

For products listed on a positive list and available from community pharmacies, the ex-factory price and wholesalers' and pharmacists' margins are regulated. The ex-factory price, excluding value-added tax (VAT) and the pharmacy retail price (PRP), including value-added tax (VAT) (cf. 3.5.4) (including wholesalers' and pharmacists' margins) are published in the country's official bulletin.

Since 2004, pharmaceuticals for out-patients only available from hospital pharmacies 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).

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 pharmaceuticals, at all price levels. A new agreement was signed at the beginning of 2007.

3.2.2 Free pricing

Non-reimbursable pharmaceuticals 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 pharmaceuticals purchased by hospitals.

3.2.3 Public procurement / tendering

A tendering procedure exists for pharmaceuticals with alternatives purchased by hospitals (e.g. generics). In the public procurement procedure, favourable prices offered are an important criterion in the decision process.

3.3 Pricing procedures

The pricing procedure in France is a mixture of internal price referencing and external price referencing, as described in Table 3.2.

Table 3.2: France - Pricing procedures

Pricing procedure	In use: Yes / no	Level of pricing[1]	Scope[2]
Internal price referencing	Yes	Ex-factory price Wholesaler's margin Pharmacist's margin Internal price referencing is only carried out at ex-factory price level; the margins are then added according to the regulations	Reimbursed product Retrocession = Hospital outpatient prescribing The comparison with the prices of other products is systematically performed for all reimbursable pharmaceuticals "Retrocession" means - the dispensing of hospital-only medicines (HOM) to outpatients in hospital pharmacies
External price referencing	Yes	Ex-factory price	Part of reimbursable pharmaceuticals: those with the highest level of improvement of medical service (reference countries United Kingdom, Germany, Italy, Spain)
Cost-plus pricing	No		
Other, e.g. indirect profit control	No		

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

[2] Scope = a pricing procedure does not always refer to all pharmaceuticals: e.g. a pricing procedure could only refer to reimbursable pharmaceuticals, whereas for over-the-counter (OTC) pharmaceuticals there is free pricing.

Source: CNAMTS

3.3.1 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).[6]

[6] http://www.leem.org/industrie/ind_frame.htm and http://www.leem.org/industrie/legal13.htm

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

- the product has a Level of improvement of clinical benefit (ASMR) I or II for the major indication; or
- the product has a Level of improvement of clinical benefit (ASMR) III, but the level of sales in the third year of marketing is expected to be < € 40 Mio. (for the Level of improvement of clinical benefit (ASMR)) (cf. 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 volume of the sales. If that agreement is not respected, the company must pay a claw-back payment (cf. 4.6.4). 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".

3.3.2 Internal price referencing

Comparisons in prices are systematically carried out for all reimbursable pharmaceuticals with the indications mentioned by the Transparency Commission in the advice given on the pharmaceutical. 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.

3.3.3 Cost-plus pricing

Not applicable.

3.3.4 (Indirect) Profit control

Not applicable.

3.4 Exceptions

3.4.1 Hospitals-only

Most hospital pharmaceuticals 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. In 2007 a public tendering procedure will gradually be 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.

3.4.2 Generics

Two types of incentives exist for the pricing of 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 pharmaceutical 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. 3.5.2).

To calculate the ex-factory price of a generic of an original product, the ex-factory price of the original product is multiplied by 0.6 (until the year 2005) and by 0.5 (from 2006 onwards). The pharmacy retail price (PRP) is the sum of the ex-factory price plus the wholesale margin plus the pharmacist's margin, which is the same for the original product. In application of the Ministerial Order of 8 August 2003, the pharmacy retail price (PRP) of a generic is calculated as the sum of the ex-factory price plus the wholesale margin plus the pharmacist's margin, which is the same for the original product.

3.4.3 Over-the-counter pharmaceuticals

Over-the-counter (OTC) pharmaceuticals are freely priced. The wholesalers' and pharmacists' margins are also free. Over-the-counter (OTC) pharmaceuticals are not reimbursed, but in certain therapeutic classes they are in direct competition with reimbursable products. This situation limits the growth of the over-the-counter (OTC) market because reimbursable products are always cheaper.

3.4.4 Parallel traded pharmaceuticals

The pricing system for parallel traded pharmaceuticals has been the same as for other pharmaceuticals in France since the integration of the relevant European legislation by Decree No. 2004-83 of 23 January 2004.

3.4.5 Other exceptions

To the authors' knowledge there are no other exceptions.

3.5 Margins and taxes

This section contains a description of the wholesale and pharmacy margins and mark ups, dispensing fees and sales taxes applied to pharmaceuticals.

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

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

For hospital pharmaceuticals 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 pharmaceuticals has been the same Ministerial Order for many years. Before 1990 this was worked out based on a proportion of the ex-factory price.

From 2 January 1990 a regressive mark-up scheme was in place. 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.

Table 3.3: France - Regulation of wholesale and pharmacy mark ups 2006

	Wholesale mark up			Pharmacy mark up		
	Regulation (yes / no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope***
France	Yes	Regressive mark ups	Reimbursed pharmaceuticals	Yes	Regressive mark ups	Reimbursable pharmaceuticals

*Scope = a pricing procedure does not always refer to all pharmaceuticals: e.g. a pricing procedure could only refer to reimbursable pharmaceuticals, whereas for over-the-counter (OTC) pharmaceuticals there is free pricing.

Source: CNAMTS

Table 3.4: France - Structure covered by social insurance, i.e. for reimbursable pharmaceuticals

Country	Ex-factory price	% Wholesaler's margin	Controlled price	% Pharmacist's margin	% Value-added tax (VAT)
France	Published	For ex-factory price (excluding VAT) ranging from: € 0-22.90: 10.3% € 22.91-150.00: 6.0% > € 150.00: 2.0%	Ex-factory price excluding VAT Wholesaler margin Pharmacist's margin Pharmacist's price including VAT	For ex-factory price (excluding VAT) ranging from: € 0-22.90: 26.1% €22.91-150.00: 10.0% > €150.00: 6.% + a flat fee of € 0.53 excluding VAT per pack	2.1

Source: CNAMTS

3.5.1 Wholesale remuneration

Wholesale margins are regulated for reimbursable pharmaceuticals. 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 12 February 2004.

Table 3.5: France - Wholesale mark-up scheme for reimbursable pharmaceuticals 2006

Ex-factory price in € (excluding value-added tax (VAT))	Maximum mark up as a % of ex-factory price	Wholesale price in € (excluding VAT)
0.00-22.90 example 22.90	10.3	25.26
22.91-150.00 example 150.00	6.0	159.98
>150.00 example 200	2.0	210.98

Source: CNAMTS, Decree of 4 August 1987, current version.

3.5.2 Pharmacy remuneration

Pharmacists' unions indicated an average margin on reimbursable pharmaceuticals of 24% in 2001 and 23.8% in 2004. If the rate goes down, the total amount continues to increase with the growth of the turnover.

Table 3.6: France - Pharmacy mark-up scheme for reimbursable pharmaceuticals 2006

Ex-factory price in € (excluding value-added tax (VAT))	Maximum mark up in % of ex-factory price + € 0.53 per pack excluding VAT	Public price in € excluding VAT
0.00-22.90 example 22.90	26.1	31.77
22.91-150.00 example 150	10.0	179.20
>150.00 example 200	6.0	233.20

Source: CNAMTS

For generics, there is a special type of pharmacy remuneration that provides the same margin for pharmacists as there is for delivering the original product (cf. 3.4.2).

A flat fee of € 0.53 (due only for reimbursable pharmaceuticals) is included in the price, and the patient pays this. This amount is also refunded by the sickness funds, and by complementary health insurance.

3.5.3 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 pharmaceuticals, 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 pharmacists.

3.5.4 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 pharmaceuticals and 5.5% on non-reimbursable pharmaceuticals.

3.5.5 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 pharmaceuticals or on parallel import pharmaceuticals ranges from € 250 to € 17 000. These taxes are paid to the Agency for the Medical Safety of Health Products (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' pharamceuticals turnover.

3.6 Pricing-related cost-containment measures

3.6.1 Discounts / Rebates

For one product and for large quantities, pharmacy purchasing prices (Prix d'achat des médicaments par les pharmaciens, PPP) including discounts are negotiated between the supplier and the pharmacist.

For reimbursable pharmaceuticals 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. For this type of pharmaceutical the rate is 10.74%. In fact, for generics the previous maximum limit was not respected and the legislation was changed.

The Ministerial Order of 29 December 2005 limits the amount of discounts/rebates given by producers to pharmacists (e.g. in trade cooperation). This could exceed 20% in 2006, and 15% in 2007. If the advantages exceed this level the pharmacist must reduce the consumer price.

For non-reimbursable products the level of discount/rebate is not set. It can be either in cash or in additional packs of pharmaceuticals given free of charge. It is always possible to provide rebates/discounts to consumers (for information on claw-backs cf. 4.6.4).

3.6.2 Margin cuts

At the time of writing, wholesale and pharmacy margins on reimbursable pharmaceuticals are regulated through a regressive mark-up scheme (cf. 3.5.1 and 3.5.2). In 1999, 2003 and on 21 February 2004, pharmacy margins and wholesale margins were amended by regulations.

3.6.3 Price freezes / Price cuts

Minister of Social Affairs (MAS), Martine Aubry, had decided to submit all reimbursable pharmaceuticals for a new evaluation by Transparency Commission. After this examination the usual procedure was to remove products from the positive list. However, in fact the Minister decided to reduce prices for pharmaceuticals with insufficient clinical benefit (SMR). After this, Minister Guigou followed this course of action and the Economic Committee for Health Care Products (CEPS) negotiated price cuts with the manufacturers.

Following this, Minister Douste Blazy introduced a new plan to reduce prices for patented products during the period 2004-2007. The plan focused on cost-containment in different areas: generics expenditure (rate of substitution); de-listing some products; offering greater pack sizes for chronic diseases; reducing hospital prices; decreasing prices of patented products, e.g. statins, proton pump inhibitors (PPI), antihypertensive products and generics; and decreasing the reference price (Tarif Forfaitaire de Responsabilité, TFR) level.

3.6.4 Price reviews

Table 3.7 shows for each first code the change of prices between 2002 and the beginning of 2007.

Table 3.7: France - Price reviews and price cuts 2002-2006

NAME	PUBLIC PRICE, VALUE-ADDED TAX (VAT) INCLUDED		DIFFERENCE IN %
	JANUARY 2007	JANUARY 2002	
PLAVIX 75MG CPR BT28	57.02	61.53	-7.33
TAHOR 10MG CPR BT28	18.87	25.44	-25.83
SERETIDE DISK500/50Y 60DOS	66.73	71.57	-6.76
ARIMIDEX 1MG CPR BT28	127.79	149.51	-14.53
PREVENAR INJ SRG0,5ML 1 A	63.34	63.45	-0.17
NEULASTA 6MG INJ SRG0,6ML 1	1230.51	1308.25	-5.94
TAHOR 20MG CPR BT28	37.81	44.21	-14.48
GLIVEC 400MG CPR BT30	2557.53	2557.53	0.00
SYMBICORT TURB 400/12 60DOS 1DISP	55.05	57.78	-4.72
INEXIUM 20MG CPR BT28	24.24	38.58	-37.17
ELISOR 20MG CPR BT28	21.57	29.74	-27.47
TAHOR 40MG CPR BT28	43.16	47.47	-9.08
AMLOR 5MG GELU BT30	18.51	17.68	4.69
INEXIUM 40MG CPR BT28	38.83	49.19	-21.06
COVERSYL 4MG CPR BT30	27.45	28.08	-2.24
AVONEX 30MCG/0,5ML INJ SRG 4	950.02	1007.30	-5.69
PYOSTACINE 500MG CPR BT16	24.97	25.05	-0.32
NEORECORMON 30000 INJ SRG 4	1208.46	1208.46	0.00
ARICEPT 10MG CPR BT28	93.53	93.98	-0.48
ELISOR 40MG CPR BT28	40.37	50.17	-19.53
ENBREL 25MG INJ FL+SRG 4 +NEC	573.67	603.04	-4.87
SINGULAIR 10MG CPR PELL BT28	39.89	41.82	-4.62
LAMISIL 250MG CPR BT28	58.82	58.92	-0.17
HUMIRA 40MG INJ SRG0,8ML 2 .	1175.38	1175.38	0.00
VASTEN 20MG CPR BT28	21.57	29.74	-27.47
COAPROVEL 300/12,5 CP PEL 28	29.86	31.40	-4.90
MOPRAL 20MG GELU FP28	41.85	48.40	-13.53
FOSAMAX 70MG CPR BT4	34.16	37.53	-8.98
LANTUS 100UI/ML OPTISET 3ML 5	67.49	67.59	-0.15
ACTONEL 35MG CPR BT4	34.16	37.53	-8.98
TANAKAN 40MG CPR BT90	17.42	17.91	-2.74
PARIET 20MG CPR BT28	37.76	40.64	-7.09

NAME	PUBLIC PRICE, VALUE-ADDED TAX (VAT) INCLUDED		DIFFERENCE IN %
	JANUARY 2007	JANUARY 2002	
ZYPREXA 10MG CPR BT28	116.94	117.04	-0.09
VASTAREL 35MG LM CPR BT60	11.07	11.10	-0.27
ART 50MG GELU BT30	19.65	19.71	-0.30
PIASCLEDINE 300MG GELU BT15	7.88	7.90	-0.25
SERETIDE DISK250/50Y 60DOS+DISP	50.17	52.41	-4.27
ORELOX 100MG CPR BT10	13.73	13.77	-0.29
XALATAN 0,005% COLLY FL2,5ML 1	17.61	18.77	-6.18
GRANOCYTE 34 INJ FL+SRG 1	115.46	115.46	0.00
CRESTOR 10MG CPR BT28	27.45	27.45	0.00
AERIUS 5MG CPR BT30	12.35	13.03	-5.22
CHONDROSULF 400MG GELU BT84	21.36	21.43	-0.33
VASTEN 40MG CPR BT28	40.37	50.17	-19.53
INIPOMP 20MG CPR BT28	21.56	22.96	-6.10
CASODEX 50MG CPR BT30	140.74	140.85	-0.08
ENBREL 50MG INJ FL+SRG 4 +NEC	1129.77	1129.77	0.00
INIPOMP 40MG CPR BT28	40.28	43.43	-7.25
EZETROL 10MG CPR BT28	45.11	45.11	0.00
SUBUTEX 8MG CPR SUBLING BT7	22.24	24.25	-8.29

4 Reimbursement

4.1 Organisation

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 High 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 Agency for the Medical Safety of Health Products (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 Committee 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 (SMR) (cf. 4.1) 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 normal rate is 65%. For products for the treatment of diseases without special gravity and homeopathic products the rate is 35% by law (art. R322-1 of Social Security Code (CSS)).
- The level of improvement of clinical benefit (ASMR) or added value of a pharmaceutical 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 1): 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 Level of improvement of clinical benefit (ASMR), the pharmaceutical must be cheaper than therapeutic equivalents in order to be included in the positive list of reimbursable pharmaceuticals.

A special procedure is possible under the third paragraph of art. R 163-2 of the Social Security Code (CSS), called “medicament 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. At the time of writing, 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 hormone.

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 Complementary 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).

4.2 Reimbursement schemes

4.2.1 Eligibility criteria

The French reimbursement scheme is both product and disease specific. 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 Complementary Health Insurance Funds (UNCAM).[7]

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) “nominative” for one patient or “cohorte” for a group of patients (cf. 2.1.1.2). No co-payment is required. This authorisation is granted by the Agency for

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

the Medical Safety of Health Products (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"[8].

4.2.2 Reimbursement categories and reimbursement rates

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

Table 4.1: France - Reimbursement of pharmaceuticals

Reimbursement category by clinical benefit (SMR)	Reimbursement rate for severe disease	Reimbursement rate for non-severe disease	Characteristic of category
Major	65%	35%	Normal rate determined by Minister of Health, UNCAM can modify it, +or- 5 points
Moderate	35%	35%	Normal rate determined by Minister of Health, UNCAM can modify it, +or- 5 points
Weak	35%	35%	Rate determined by Minister of Health, UNCAM can modify it, +or- 5 points
Insufficient	Not listed	Not listed	Not listed

UNCAM = National Union of Complementary Health Insurance Funds

Source: Social Security Code (CSS)[9]

Table 4.2: France - Exceptions for reimbursement of pharmaceuticals

Reimbursement category by clinical benefit (SMR)	Reimbursement	Characteristic of category
For severe chronic diseases e.g. cancer	100% rate for severe disease	Special list approved by Minister of Health
"Pending de-listing"	Listing at 15% rate New temporary rate for vein tonics determined by law	Pending de-listing

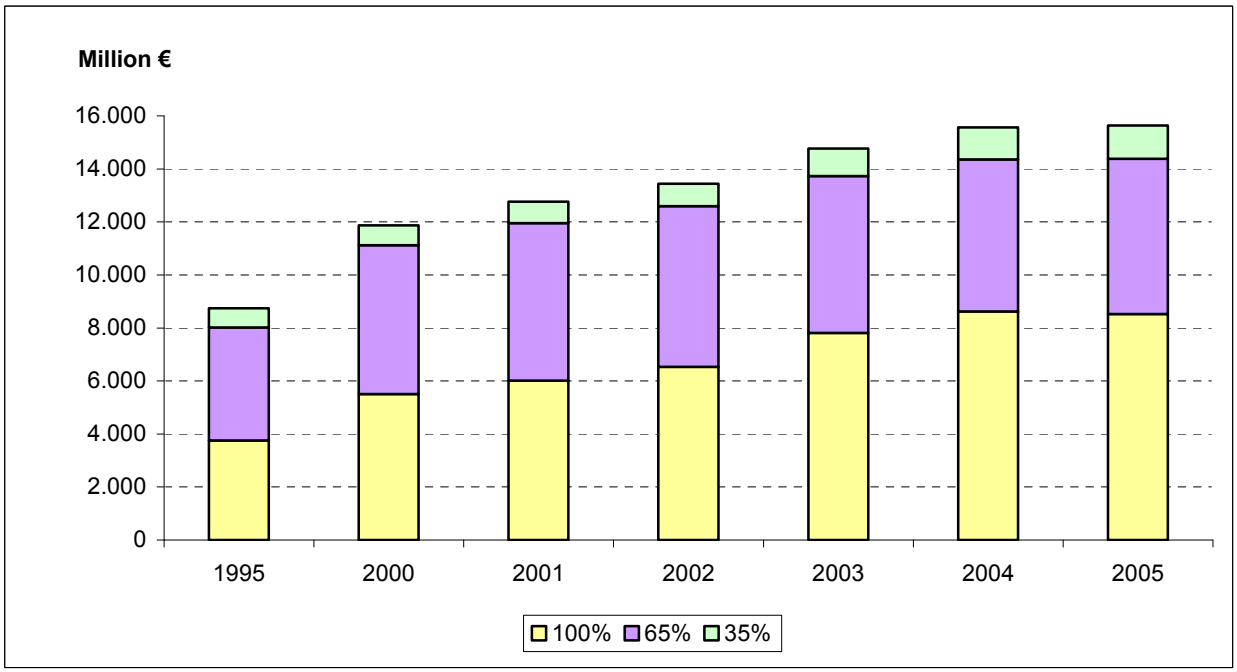
Source: CNAMTS

The law sets the rate, but now the National Union of Complementary Health Insurance Funds (UNCAM) is responsible for ensuring that the National Target for Health Insurance Expenditure (ONDAM) have the power to change the rate by +or- five points. E.g. 35% can become 30% or 40%.

[8] http://agmed.sante.gouv.fr/htm/5/atu/indatu.htm

[9] http://www.legifrance.gouv.fr/WAspad/Visu?cid=725389&indice=1&table=JORF&ligneDeb=1#

Figure 4.1: France - Development of pharmaceuticals in Reimbursement Code[1]



Source: LEEM/CNAMTS

4.2.3 Reimbursement lists

There is a positive list of reimbursable pharmaceuticals (art. L 162-17 of the Social Security Code (CSS)) for the out-patient sector. The list mentions only 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 High Authority for Health (HAS).[10]

The positive list is updated on a day-to-day basis by official bulletin. For the Health Insurance Funds the positive list is updated every week, like a database. The current list is available from: http://www.codage.ext.cnamts.fr/codif/bdm_it/index.php?p_site=AMELI.

Inclusion of a pharmaceutical 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.

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

4.3 Reference price system

In France there is no reference price system like the one in Germany. However, for part of the generics sector there is a reference price system (TFR), i.e. the same level of reimbursement for a generic group. The 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, the patient must make up the difference.

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 implement a new 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 Complementary Health Insurance Funds (UNCAM) upon generic substitution, through a convention with pharmacists.

The first list was implemented on 27 August 2003. A total of 153 generic groups come under the reference price system at the time of writing, which represents approximately 12% of the generics market.

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).

4.4 Private pharmaceutical expenses

Public pharmaceutical expenditure (PE) (social security and state or local funds) accounted for 69% of out-patient pharmaceutical expenditure (PE) in 2005. The remaining 31% from private expenditure included 18.4% of expenses for private health insurance and 12.7% out-of-pocket payments (OPP) (including cost-sharing and self-medication) of households.

Private health insurance in France corresponds to complementary health insurance patients subscribe on a (usually) voluntary basis. 94% of the population is covered by complementary health insurance, including 8% covered by the free complementary universal health insurance coverage (CMUC) provided for people with low incomes. Cf. 2.2.

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

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

Sickness funds pay 100% of the expenses for a list of 30 chronic and costly diseases[11]. Some diseases which are not in the list of 30 are also free of charge, where 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 formulary 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 policy-holder. This doctor sends the protocol to the medical department of the relevant sickness fund to obtain an agreement.

The policy-holder (the patient) must sign the formulary approved by medical service. In 2004, the expenditure under the long-term illness (ALD) category, covering nearly 8 Mio. patients (12% of the general scheme policy-holders), amounted to 60% of reimbursable expenditure. This represented a total of € 55.7 billion: € 17.5 billion for heart disease, € 14 billion for cancers, € 10.2 billion for psychiatric affections and € 9 billion for diabetes. The first five long-term illnesses (ALD) in 2005 were malignant tumours (244,139 cases), diabetes (146,792), severe arterial hypertension (91,223), psychiatric diseases (84,880) and heart failure (67,287).

Table 4.3: France - Number of patients with long-term illness exempt from co-payment 1995, 2000-2005

Year	1995	2000	2001	2002	2003	2004	2005
No. of persons in ALD 30	601,558	830,718	868,665	896,302	947,771	951,058	963,491

ALD = long-term illness

Source: http://www.ameli.fr/245/DOC/2194/article.html#

The continuous growth of expenditure is due to the increase in population numbers, in prevalence (e.g. diabetes, cancers, hepatitis), in life expectancy, and due to the expansion of the cri-

[11] http://www.ameli.fr/229/DOC/2259/fiche.html?page=4

teria 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).

Table 4.4: France - Average reimbursement rates 1995, 2000-2005

Real rate of reimbursement for pharmaceuticals	1995	2000	2001	2002	2003	2004	2005
Rate	70.60	73.58	73.91	74.76	74.93	75.35	75.10

Source: CNAMTS, LEEM

On average, patients (including the people in the "long-term illness" (ALD) category, covered at 100% rate) receive treatment funded at the 75% level.

2. For sociably disadvantaged patients

Universal Health Insurance Coverage (CMU)

Created by Law No. 99-641 of 27 July 1999 and introduced on 1 January 2000, Universal Health Insurance Coverage (CMU) was an important development in France. 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 pharmaceuticals, hospital charges and normal charges per day in hospital (if they have the complementary assurance).

State Medical Aid

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.

Table 4.5: France - Number of persons covered by the different health insurance schemes 1995, 2000-2005

No. of persons in Mio. covered by:	1995	2000	2001	2002	2003	2004	2005
Base CMU		1.127	1.200	1.426	1.553	1.635	1.697
Complementary CMUC		4.977	4.600	4.468	4.650	4.664	4.735
AME				0.145	0.170	0.145	0.180

CMU = Universal Health Insurance Coverage, CMUC = Complementary Universal Health Insurance Coverage, AME = State Medical Aid

Source: CNAMTS

4.4.1 Direct payments

There is free pricing for the over-the-counter (OTC) market, and for margins of wholesalers and pharmacists. The patient pays the full consumer price.

4.4.2 Out-of-pocket payments

4.4.2.1 Fixed co-payments

The maximum annual out-of-pocket payment (OPP) is € 50.- for a consultation or visit with a doctor only. The patient also pays a fixed co-payment of € 0.53 for each pack of pharmaceuticals, but this is reimbursed at the same rate as the product and is also reimbursed by the “mutuelles”, if they agree to this.

4.4.2.2 Percentage co-payments

The percentage co-payment is the difference between the rate of reimbursement and 100%.

4.4.2.3 Deductibles

Not applicable.

4.5 Reimbursement in the hospital sector

Hospitals can buy pharmaceuticals if they are on a positive list registered by the Minister of Health under art. L5123-2 of the Public Health Code (CSP). This list is available at: http://www.codage.ext.cnamts.fr/codif/bdm_it/index.php?p_site=AMELI.

Most pharmaceuticals dispensed in hospitals to in-patients are included in the daily rate, i.e. in the hospital’s budget. However, for some highly innovative pharmaceuticals with regulated prices, hospitals can claim reimbursement from the Health Insurance Funds on a 100% basis, in addition to the daily rate.

For pharmaceuticals dispensed to out-patients, hospitals claim reimbursement directly from the Health Insurance Funds, including a margin, but this is gradually changing to a system with a fee-for-service payment per dispensation. Until recently, in private hospitals, in-patients had to pay for pharmaceuticals on top of the daily rate. At the time of writing, the system is the same in all hospitals, whether public or private.

4.6 Reimbursement-related cost-containment measures

Since the Law of 14 August 2004, the National Union of Complementary Health Insurance Funds (UNCAM), after consultation with the body representing the complementary insurance and mutual funds (Union Nationale des Organismes Complémentaires d'Assurance Maladie, UNOCAM), can change the reimbursement rate for reimbursed pharmaceuticals between five points above or below the current level. This means, in theory, if at the standard rate of 65% (60% to 70%) the National Target for Health Insurance Expenditure (ONDAM) seems to be not reachable, this power could be exercised to rectify the situation.

4.6.1 Major changes in reimbursement lists

In France several decisions were made after the global assessment beginning in 1999. Certain products have seen their reimbursement level revised to a lower level, often from 65% to 35%, and/or their prices have been reduced.

As a second step, three waves of assessment were put into operation:

1. First wave: 60 pharmaceuticals with insufficient clinical benefit (SMR) and not adapted with the updated therapeutic value lost their market authorisations and were removed from the positive list. (Arrete of 24 September 2003.[12])

2. Second wave: 245 pharmaceuticals with non-prescription obligation have been examined. The Minister of Health decided to reimburse some of them (essentially products for vein disease) at 15% until 1 January 2007 and the remaining products were removed from the positive list.

3. Third wave: Advice from the High Authority for Health (HAS) on 18 October 2006, principally on Vasodilatators. The Minister of Health decided that their rate is to be 15%.

4.6.2 Introduction / review of reference price system

Since its introduction, no major changes have taken place. The products concerned are still only the generic groups. In the government plan to reduce deficit, all reference price (TFR) levels and the prices of original products (princeps) in a generic group were reduced by 15% at the beginning of 2006.

4.6.3 Introduction of new / other out-of-pocket payments

Not applicable.

[12] http://www.legifrance.gouv.fr/WAspad/Visu?cid=626338&indice=8&table=JORF&ligneDeb=1#

4.6.4 Claw-backs

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 works like a tax.

In principle, all manufacturers of pharmaceuticals are concerned with the claw-back system. However, if they engage in an agreement with the Economic Committee for Health Care Products (CEPS), they are not concerned 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 is possible through the application of the law relating to claw-backs. If turnover increases faster than a predetermined rate, the companies must pay part of this amount back to sickness fund (between 55% and 68.1% for an excess between 1% and 8%).

The Law of 13 August 2004 fixes the threshold ("taux K") to 1% for 2005, 2006 and 2007.

Table 4.6: France - An overview of the growth of the amount paid by sickness funds 2000-2005

	2000	2001	2002	2003	2004	2005
Rate K in %	2	3	3	4	3	1
Gross out-patient reimbursable turnover (A) in Mio. €	13,500	14,330	14,930	15,840	16,820	17,970
Annual growth in %	8.9	7.2	4.2	6.1	6.2	6.8
Excess/rate K in Mio. €	854	559	171	330	510	980
Return of the system						
Fall of prices and de-listing in Mio. €	183	360	107	nc	24	160
Gross discount in Mio. €	411	262	204	254	381	501
Credit side used in Mio. €	137	79	75	64	32	93
Net discount (B) in Mio. €	**274**	**183**	**129**	**190**	**349**	**408**
Theoretical claw-back amount (safeguard contribution) in Mio. €	442	370	100	150	296	523
Discount (B)/turnover (A) in %	2.03	1.27	0.86	1.20	2.07	2.27
Discount (B)/growth of turnover (A) in %	24.9	22.0	21.5	20.9	35.6	35.5

Source: HCAAM report on medicines

The claw-back system returns only a part of the excess of the previous turnover sum. However, Table 4.6 shows that the larger the excess, the more significant the return (in percentage).

4.6.5 Reimbursement reviews

Cf. 4.6.1.

5 Rational use of pharmaceuticals

5.1 Impact of 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 sickness funds, after consultation with the High Authority for Health (HAS). Through this, doctors are encouraged to prescribe the most economically viable pharmaceutical (generics) from several therapeutically similar alternatives.

In 2007, doctors can see their prescription profile on the sickness funds' web site.[13]

The sickness 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 pharmaceuticals that are available in a community pharmacy, preferably generic ones if possible.

5.2 Prescription guidelines

The availability of computer-assisted prescription software certified by the High Authority for Health (HAS) should foster generic substitution, particularly through the method of prescription according to International Nonproprietary Name (Dénomination Commune Internationale, INN).

Since the implementation of the Law of 13 August 2004, the High Authority for Health (HAS) is required to develop guidelines for each of the 30 diseases fully reimbursed by sickness fund. At the beginning of 2007 the High Authority for Health (HAS) published 11 sets of guidelines, e.g. on diabetes type 1 and type 2, chronic hepatitis c, etc. [14]

5.3 Information to patients / doctors

Advertising of pharmaceuticals 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 Agency for the Medical Safety of Health Products' (AFSSAPS) body, "Committee in charge of pharmaceuticals advertising control and recommendations on proper use".

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

[14] http://www.has-sante.fr/portail/display.jsp?id=c_5267&pcid=c_5267

Direct advertising of over-the-counter (OTC) pharmaceuticals 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 obligatory pharmaceuticals 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 sickness fund during this period (art. D 5172-7-1 of the Public Health Code (CSP)).

Advertising of a pharmaceutical to people qualified to prescribe or supply is allowed. The Agency for the Medical Safety of Health Products (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 of pharmaceuticals on the Internet is allowed. The Agency for the Medical Safety of Health Products (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;
- 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));
- 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 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.

Sickness funds manage the means of informing patients on rational use of pharmaceuticals (e.g. the famous “Antibiotics are not automatic” campaign on the uses of antibiotics), on prevention (through the preventive fund campaign on flue 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.

In mid-2003 the national sickness fund (National Insurance Fund for Salaried Employees (CNAMTS)) implemented sickness insurance representatives (DAM) to visit doctors and phar-

macists and explain the setup of the sickness fund's risk management arrangements (cf. 2.1.1.2).

5.4 Pharmacoeconomics

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.

5.5 Generics

In 2004, three measures affected the possible growth of the generics market, listed here.

1. Art. 19 of the Finance Law of the Social Security System (LFSS) for 2004 provides that market authorisation for a generic pharmaceutical 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, 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.

As a result of these changes, the generics market will be less dependent on the actions of innovative firms for delaying entrance to the market of any new generic, and the Agency for the Medical Safety of Health Products (AFSSAPS) has become responsible only for the evaluation of bioequivalence in the course of the market authorisation procedure.

Table 5.1: France - Development of the generics market in the out-patient sector 2000-2005

Generics market share	2000	2001	2002	2003	2004	2005
Volume (no. of packs counted in %)	5.5	7.0	7.5	10.1	12.5	14.0
Value (in %)	3.0	3.7	4.0	6.0	7.0	8.2

Source: CNAMTS

5.5.1 Generic substitution

Generic substitution has been allowed in France since 11 June 1999 (art. L5125-23 of the Public Health Code (CSP)). The Agency for the Medical Safety of Health Products (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 sub-

stances are not protected by licence but are not included in a group by the Agency for the Medical Safety of Health Products (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 pharmaceutical (e.g. the original product) but the substitution must be cheaper for the sickness funds. This 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 pharmaceutical 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.

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

5.5.2 Generic prescription

Physicians are not obliged by law to prescribe generics, but by agreement with sickness funds they have an indirect interest in prescribing generics. Physicians have a stake in the increase of generic prescriptions because the rise in the price of a consultation or a visit depends on the evolution of pharmaceutical expenditure (PE) under the convention signed with the sickness funds.

Physicians are encouraged by agreement (5 June 2002) to write prescriptions by International Nonproprietary Name (INN) by agreement. In the most recent study carried out by the mutual funds it appears that doctors prescribe by International Nonproprietary Name (INN) in the generics market at a rate of 12% (in terms of volume).[15] The rate of generic prescription is growing significantly.

15

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

5.5.3 Generic promotion

Generics are promoted by the Government, sickness funds, pharmacists and generics manufacturers to reduce public expenditure. By saving money through generic promotion, it is possible to reward real innovative pharmaceuticals with a good price. The method of promoting generics is by creating a financial incentive for pharmacists by substituting a brand name pharmaceutical with a generic.

The Government, sickness funds, manufacturers and pharmacists run television (TV) advertising campaigns aimed at consumers. The sickness funds promote the acceptance of generics on the back of the reimbursement forms sent to patients, and provide physicians with information about their own rate of generic prescription, as well as comparing this with other physicians in the same area. The sickness funds have signed an agreement with pharmacists to increase the rate of substitution from 60% to 70% by the end of 2006 and this goal was almost achieved.

The pharmacist's margin is the same in value for a generic pharmaceutical as for the brand name pharmaceutical, it is not a percentage of the ex-factory price. This provides an incentive for the pharmacist, whereas at the same time the cost for the sickness funds is lower, as the reimbursement rate is based on the price of the generic pharmaceutical, which is significantly lower than that of the equivalent brand name pharmaceutical. However, when the reference price (TFR) becomes applicable to a generic pharmaceutical class, there is no longer any incentive for the pharmacist, whose margin will be based on a percentage of the generic's ex-factory price, which is 30-50% lower than that of the equivalent brand name pharmaceutical.

In hospitals the generic market has been developed. The sickness funds try to convince doctors to write the first prescription for patients leaving the hospital with a pharmaceutical from the list of health care establishments.

5.6 Consumption

Each year a special declaration is requested from all pharmaceutical manufacturers. They must declare for each pharmaceutical the volume and the financial value of sales in ambulatory care and in hospitals (art. L5121-17 and L5121-18 of the Public Health Code (CSP) and art. L162-17-5 of the Social Security Code (CSS)).

Each year the national sickness funds publish data for each code. The sickness funds can monitor each individual patient's consumption or pharmaceuticals prescribed by each doctor.[16]

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

6 Current challenges and future developments

6.1 Current challenges

In 2005, the pharmaceutical expenditure (PE) of the compulsory health insurance schemes reached € 20.9 billion, i.e. 33.5% of ambulatory care expenses, representing a 5% increase on 2004. This is still in a growth phase despite increasing generics sales and price reductions implemented in 2005. In 2006, the reimbursed pharmaceutical expenditure (PE) should decrease significantly, due partly to price reductions initiated in 2005 and partly to the 2006 pharmaceutical plan.

Considering that the pharmaceutical expenditure (PE) per inhabitant is higher in France than in other European countries, especially with prescriptions of pharmaceuticals in disagreement with the summary of product characteristics (SPC), the Law of 13 August 2004 provides for a reduction in pharmaceutical volumes through medical control of prescriptions, development of generic prescription and gradual implementation of a reference price (TFR) system.

6.2 Future developments

The measures initiated in 2006 should lead to a series of savings in 2007, shown here.

- The generics policy should generate € 340 Mio. savings, due to price cuts implemented at the beginning of 2006 and to the launch of new generics.
- De-listing of 152 pharmaceuticals and cuts in the reimbursement rates of 61 veinotonics in March 2006 should generate € 460 Mio. savings in 2007. Additionally, the third step of the reassessment of pharmaceuticals whose medical service has been considered as insufficient (mostly prescription-only medicine(s) (POM)) is on the way to completion. Reimbursement of these pharmaceuticals represents € 210 Mio. expenditure for the Health Insurance Funds.
- Price cuts in brand name pharmaceuticals occurred in 2006 and more should occur in 2007, generating approximately € 140 Mio. savings.
- Marketing of bigger packs (volume) of pharmaceuticals was delayed. The first larger packs for the treatment of osteoporosis were launched in 2005, but bigger packs for the treatment of other diseases were not available until mid-2006.

In the future three sectors must be explored in greater depth:

- the impact of hospital prescription to in-patients who are later to be out-patients with treatment to follow;
- the influence of prescription status on expenses for sickness funds;
- ways to control the prices of new pharmaceuticals, especially temporary utilisation authorisation (ATU) products and orphan pharmaceuticals.

7 Appendixes

7.1 Further reading

High Committee for the Future of Social Security (Haut comité sur l'avenir de l'assurance maladie, HCAAM) report on pharmaceuticals

Reports of Court of Account

Reports of Economic Committee for Health Care Products (CEPS)

Reports of the High Authority for Health (HAS)

Reports of the National Insurance Fund for Salaried Employees (CNAMTS)

Reports of Commission des Comptes de la Sécurité Sociale

7.2 Web links

Abbreviation	Name	Link
LIR	International Research Laboratories	http://www.lir.asso.fr/
LEEM	Association of Pharmaceutical Industry	http://www.leem.org/htm/accueil/accueil.asp
GEMME	Generic Producers Association	http://www.presstvnews.fr/moisgenerique/gemmepresent.htm
FSPF	Federation of Pharmacists in France	http://www.fspf.fr/
UNPF	National Union of Pharmacists of France	http://www.unpf.org/
USPO	Union of Pharmacists	http://www.uspo.fr/article.php3?id_article=1
CSMF	Confederation of French Medical Unions	http://www.csmf.org/
MG FRANCE	French Federation of General Practitioners	http://www.medsyn.fr/mgfrance/
SML	Union of Self-employed Doctors	http://www.lesml.org/
FMF	Federation of Doctors in France	http://www.fmfpro.com/plan.php3
UCCMSF	Doctors Association	http://www.uccms-idf.com/
CNAMTS	National Insurance Fund for Salaried Employees	http://www.ameli.fr/
MSA	Agricultural Mutual Insurance Fund (for farmers and farm employees)	http://www.msa.fr/

Abbreviation	Name	Link
MF	Mutualiste Française	http://www.mutualite.fr/web/frameset.nsf/(home_page)/home http://www.mutualite.fr/web/frameset.nsf/site2002?OpenFrameSet&Frame=Une&Src=%2Fweb%2Fframeset.nsf%2FMutuelles%2FintroEtu_1%3FOpenDocument%26AutoFramed
RSI	National Insurance Fund for Self-employed Workers	http://www.le-rsi.fr/
CEPS	Economic Committee for Health Care Products	http://www.sante.gouv.fr/ceps/
HCAAM	High Committee for the Future of Social Security	http://www.securite-so-ciale.fr/institutions/hcaam/hcaam.htm
HAS	High Authority for Health	http://www.anaes.fr/anaes/anaesparametrage.nsf/HomePage?ReadForm
COMMISSION DE LA TRANSPARENCE	Transparency Commission	http://www.has-sante.fr/has/transparence/index.htm
IRDES	Research Institute for health economy	http://www.irdes.fr/
INSEE	National office for statistics	http://www.insee.fr/fr/home/home_page.asp
AFIPA	French Association of Self-medication Industry	http://www.afipa.org/
MINEFI	Ministry of Finance and Industry	http://www.minefi.gouv.fr/
LEGIFRANCE	Government official site for law and regulations	http://www.legifrance.gouv.fr/
MAS	Ministry of Social Affairs	http://www.sante.gouv.fr/assurance_maladie/index.htm
AFSSAPS	French Agency for the Medical Safety of Health Products	http://agmed.sante.gouv.fr/
DREES	Research Department for Ministry of Social Affairs (MAS)	http://www.sante.gouv.fr/drees/index.htm
COUR DES COMPTES	Court of Accounts	http://www.ccomptes.fr/FramePrinc/frame-rapports.htm

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