

4. Market Access in France

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4.1 General Outlook of Healthcare System

National health insurance coverage is mandatory for all residents in France for more than three months (Statutory Health Insurance – SHI). Health care in France is characterized by a national health insurance (*Sécurité Sociale*), where universal access is ensured by schemes for people on low incomes and/or with chronic conditions. The state manages entirely the healthcare system, which is financed by both employee and employer payroll contributions, and earmarked taxes. However, treatments are not free at the point of use and patients contribute with up-front payments, which are partially reimbursed by the government.

The rate of SHI coverage varies across goods and services, but some patients – such as those with chronic conditions (diabetes and AIDS), pregnant women after the fifth month, disabled children, and war pensioners – are exempt from co-payments [1].

However, patients may opt for a private Voluntary Health Insurance (VHI) and they could be reimbursed for most of the out-of-pocket payments that are known as the *ticket modérateur*. For this reason, the compulsory government scheme is accompanied by a significant voluntary private insurance sector, which covers the costs that are not covered by SHI.

Some of the co-payments are not reimbursed by either national or private health insurance systems, in order to improve patient cost-consciousness without causing great financial strain. These co-payments are limited to an annual ceiling of € 50 and include: € 1 per doctor visit, € 0.50 per prescription drug, and € 18 for hospital treatment above € 120 [2].

Approximately 90% of the population has joined a private plan and this number has been increasing over the years. For this reason, the VHI sector is increasingly making up for shortages in SHI funding, through taxes on its increasing income. This in exchange for a bigger involvement in the management of the healthcare provision.

Although the healthcare management and financing comes mainly from public sources, the provision of healthcare is more mixed: providers of outpatient care are largely private, whilst approximately three-quarters of hospital beds are provided by public or non-profit hospitals [3].

4.2 Pathways of Market Access (Regulation, Pricing and Reimbursement)

In France, due to economic downturns and the growing healthcare needs of an aging population, budget and cost controls have become key issues, as in most other developed countries. Over the past twenty years, authorities faced large deficits and the government focused on driving down healthcare costs to ensure sustainability.

In order to decrease the government-sponsored reimbursement rates for some types of treatment and population, the authorities implemented several reforms, leaving some patients with higher co-payments and co-insurance. The reimbursement, through private insurance, of certain types of co-payments (some drugs, doctor visits, and ambulance transport) has recently been discontinued, despite the fact that more than 90% of the country's population has a prominent voluntary private health insurance [4,5].

The French Government regulates the healthcare spending through several mechanisms, such as decreased reimbursement, removal of more than six hundred drugs from public reimbursement, reduction in the number of acute-care hospital beds, monitoring and sanctioning of medical practitioners for prescribing too many drugs, and promotion of the uptake of generics and over-the-counter medicines.

With these mechanisms, in addition to the changes to its health technology assessment (HTA) process, the French Government aims to cut an additional € 10 billion over the next three years [6].

In France, after the marketing approval, the manufacturer can ask for the reimbursement, and therefore the price is regulated. For non-reimbursed drugs, the manufacturer freely defines the price.

The Transparency Commission (*Commission de la Transparence – TC*) decides whether a drug is reimbursed or not by the SHI, by determining the comparative evidence-based value.

Among other factors, the Transparency Commission takes in consideration the level of innovation the drug brings to the market, and how important it is for the health of the population. It assigns a score from 1 to 5 to determine the drug's improvement of medical benefit (*Amelioration du Service Medical Rendu – ASMR*) compared to the current standard of care [7,8]. The ASMR answers the question: Does the drug improve the patients' clinical situation vs. existing therapies? The consequences of ASMR rating and price level are listed below.

- ASMR V: no improvement. The drug can be listed only if the cost is lower than the comparators. Discounted pricing for the new drug is typical.
- ASMR IV: minor improvement. The drug can be listed if the cost is not higher than the comparators. The price of the new drug can be higher if it has a better effect in a more restricted population.
- ASMR III: moderate improvement.
- ASMR II: important improvement.

- ASMR I: major improvement. This is reserved for the few drugs that have demonstrated a substantial effect on mortality in a severe disease.
- ASMR I, II, III, and IV: the drug can have a higher price than the comparators.

Actual benefit (SMR)	Reimbursement rate (%)	
	Illness usually benign	Serious illness
Important	35	65
Moderate	30	30
Mild	15	15
Insufficient	0 (not included in the positive list/not reimbursed)	0 (not included in the positive list/not reimbursed)

Table 1. Reimbursement rates according to the severity of the disease and evaluation of the SMR (2014). Modified from [8]

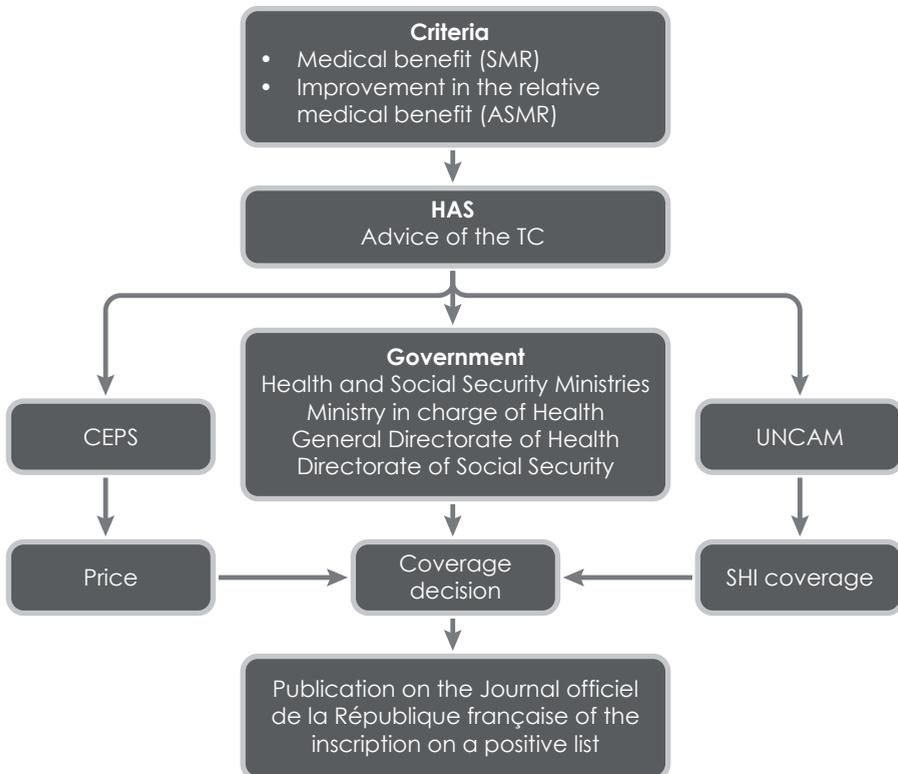


Figure 1. Pricing and reimbursement process. Modified from [8]

CEPS = Economic Committee on Health Care Products; HAS = French National Authority for Health; SHI = Statutory Health Insurance; TC = Transparency Commission; UNCAM = National Union of Health Insurance Funds

- ASMR I, II or III: faster access (price notification instead of negotiation) and price consistent with the lowest price within the ones defined in Germany, UK, Spain, and Italy [7,8].

In addition to the ASMR, the Transparency Commission also determines the the product's medical benefit (*Service Medical Rendu – SMR*) by answering the question: Should the drug be reimbursed? Is the drug clinically differentiated (interesting)? The SMR takes into account five criteria:

- Severity and impact on morbidity and mortality of the disease.
- Clinical efficacy/effectiveness and safety of the drug.
- Aim of the drug (preventive, symptomatic or curative).
- Position, as regards to comparator, within the treatment strategy.
- Public health considerations (burden of disease, health impact at community level, transposability of clinical trial results, etc.) [7,8].

Based on the SMR and the severity of the disease, a reimbursement rate is then attributed (Table 1).

The *Comité Economique des Produits de Santé (CEPS)*, after considering the ASMR and SMR ratings, negotiates the reimbursement price and rate of the drug with the manufacturer. Both the ASMR level and the expected annual sales volume (partly defined based on the estimation of the target population by the TC) are key considerations for the CEPS when establishing the price.

For drugs that are not covered by the French reimbursement system, pricing is free [8].

In France, most of the hospital-only products are not subject to assessment by CEPS, since they are reimbursed from the budget allocated to the hospital. Therefore, manufacturers are free to negotiate prices directly with the hospitals that purchase the drugs, through a competitive bid process.

Since 2004, payment for innovative and expensive hospital drugs has been financed through the Diagnosis Related Group (DRG) flat rate (*Tarifification à l'Activité – T2A*) payment and costs are completely reimbursed by the health insurance system [9].

Figure 1 summarizes the pricing and reimbursement process.

4.3 Mapping and Structure of Decision Makers

French National Authority for Health (*Haute Autorité de Santé – HAS*)

In order to improve the quality of patient care and to guarantee equity within the healthcare system, in August 2004 the French government created the HAS (*Haute Autorité de Santé*) or French National Authority for Health. HAS brings together several activities, from the assessment of drugs and medical devices, to the accreditation of healthcare organizations and certification of doctors.

HAS has been built on three founding principles: a very broad field of action, a high degree of scientific rigor, and independence.

Despite not being a government body, HAS liaises closely with government health agencies, healthcare professional unions, national health insurance funds, patients' representatives, and research organization [10].

Transparency Commission (**Commission d'Évaluation des Médicaments** – TC)

The purpose of the Transparency Commission (TC), which is the Commission for drug and health technology assessment, is to provide scientific opinions concerning the usefulness, interest and good use of drugs. It is the body responsible for the assessment of the medical service provided by a new drug, as well as the improvement of this medical service subsequent to its use. This opinion will be used in the price negotiation and for the establishment of the reimbursement rate applied by the social security organizations [11].

National Agency for Medicines and Health Products Safety (**Agence Nationale de Sécurité du Médicament et des Produits de Santé** – ANSM)

The National Agency for Medicines and Health Products Safety (ANSM) was created by Law 29 December 2011 on reinforcing the safety of medicines and health products. The ANSM, entrusted with new responsibilities and missions, replaced the French Agency for the sanitary safety of medicines and health products (Afssaps) on 1 May 2012. ANSM has two central missions: providing equitable access to innovation for all patients and ensuring the safety of health products throughout their life cycle, from initial trials to post-marketing surveillance [12].

Furthermore, ANSM develops several activities in France and on behalf of the European Union:

- Scientific and technical evaluation of the quality, efficacy and safety of drugs and biological products.
- Ongoing monitoring of predictable or unexpected adverse effects of health products.
- Inspection of facilities engaged in manufacturing activities;
- Importation, distribution, pharmacovigilance and expertise of clinical trials.
- Laboratory control for the release of batches of vaccines and medicines on the market, control of products on the market, samples taken during inspections, seizures by judicial authorities or customs [12].

Organizations Who Determine the Reimbursement

1. Health and Social Security Ministers: Ministry in charge of Health, General Directorate of Health, and Directorate of Social Security determine whether a drug is included in the refundable list [11].
2. National Union of Health Insurance Funds (*Union Nationale des Caisses d'Assurance Maladie* – UNCAM): it was created following the reform law of 12 August 2004. It has

two main roles, which are to obtain a better health insurance management by coordinating the three mandatory disease funds and linking with complementary scheme and with healthcare professionals, and to attend the negotiation of agreements with medical professionals regarding the decisions on drug prescription and healthcare reimbursement procedures [11].

3. Economic Committee on Health Care Products (*Comité Economique des Produits de Santé* – CEPS): after negotiation with the manufacturer, CEPS fixes the drug price [11].

4.4 Challenges and Catalyzers for Market Access in France

In France, almost 80% of the total expenditure on health is publicly funded.

Health spending is one of the most important item, when compared with the OECD average, however, is still below the health expenditure of Germany and Switzerland [15].

After the economic crisis in 2008, many reforms have been implemented to contain health expenditure and to decrease the cost supported by the government. These reforms include strict accounting cost-containment policies, which are mainly focused on reducing the size of the profit benefit basket and levels of coverage, and medical-based cost-containment policies, which are mainly focused on reducing the loss of money and quality due to medical practice changes and aim to improve medical practice as a whole [13].

4.5 Acknowledgements

The chapter has been contributed and reviewed by Ann Dandon.

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