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France

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Abstract

The French health system is often considered one of the best and is envied by the whole world. It is characterised by a financing model based mainly on activity-based pricing that favours the amount of care produced, which varies greatly according to the care sectors.

Deloitte's health barometer shows a very strong attachment of the French to their health system. Indeed, 81% of French people say they are satisfied with the quality of care; 80% with the safety of care; and 75% with the competence of healthcare staff. However, most rural residents remain dissatisfied with the issue of geographical proximity (54% dissatisfied compared to only 28% in the Paris area). The study shows that the French are worried about the so-called "medical desert".

The French healthcare system is known worldwide as a solidarity-based system that is very comprehensive and protective for its users. One result, however, is relatively high expenditure that is becoming harder for the government to sustain.

French policy is to ensure the highest reimbursements for drugs and treatments that are determined to be the most necessary. Developments in medical research as well as policy changes can influence prices too, but reimbursements cover only those products that have received regulatory approval.

Market introduction/overview

The French population has a high life expectancy of 82.4 years. It is therefore above average for all OECD countries, which is 82.4 years of life expectancy. France has the 6th-highest life expectancy, with Japan (83.9 years) remaining in the lead.

The French healthcare system, called Social Security, is internationally known as an efficient and generous system. While it was ranked as best among its 191 members by the WHO, according to a study published by the British medical journal *The Lancet* in April 2017, France's system was ranked 15th among 195 countries and territories in terms of quality and accessibility.

The healthcare system incorporates a variety of organisations, institutions and resources in order to fulfil four main functions: providing services; supplying resources; ensuring funding; and administrative management.

In France, there are five types of healthcare workers:

- Professional service providers, which include:
  - Health establishments: public hospitals and private clinics.
  - Mobile professionals and auxiliaries: doctors, pharmacists, midwives, nurses and

physiotherapists.
- Emergency medicine.
- Social welfare services and associations.
- Ambulatory surgery.
- Telemedicine.
- Home hospitalisation and treatments.
- Nursing home services.
- Specialised establishments for accommodating patients with specific needs, such as neurovascular units or centres for obese patients.

- Producers of goods and services (pharmaceutical industry).
- Public health institutions: the French healthcare system is overseen by the Minister of Health and the Minister of Social Affairs.
  - At the *national* level, the central government is in charge of implementing public health and safety policies. It oversees all health institutions, setting prices for products and treatments while maintaining funding for health institutions. For example, the National Institute of Health Monitoring and Public Health Council belongs to the public health institutions.
  - At the *regional* level, regional health agencies adapt national policies to a community's needs and constraints. They ensure the coordination between prevention, care and support as well as consistent resource management in order to ensure equal access to healthcare.
  - At the *local* level are the institutions and professionals who are in closest contact with patients and other people in the system. They are supervised by the regional health agencies.
- Providers of compulsory or supplementary health insurance plans.
- Recipients of healthcare (patients).

Access to care

In France, there are different types of health insurance depending on the professional situation:

- The general system covers more than four people out of five in France. It funds 78% of health expenses and includes employees in the private sector and, since January 1, 2018, the self-employed workers (Article L. 311-2 of the Social Security Code). It is managed by the Sickness Insurance Primary Fund (SIPF).
- The agricultural system concerns farm and ranching workers.
- A series of smaller public systems set up to address the needs of specific professions, such as railway workers, notary clerks and employees, and public servants.

The social security is available to employees, students, professional interns, beneficiaries of a minimum revenue allowance, pensioners or the unemployed receiving jobless benefits.

Some family members of insured people may also benefit from the same rights including a spouse or any children under 16 years old (or until 20 years old if they are students). They must register separately for Social Security and obtain their National Health Service card which proves their affiliation.

The SIPF general fund partially refunds most healthcare costs, but in order to receive full compensation for outlays, users often must adhere to supplementary healthcare coverage, known in France as "*mutuelles*".

Since January 2016, the French Universal Disease Protection programme allows any person resident in France on a continuous and legal basis to be able to benefit from medical fees reimbursement. The procedures are accordingly simplified.

Moreover, this protection ensures that unemployed people, or individuals whose personal situation has changed, can keep their same health insurance coverage.

Incidence and prevalence of disease

The National Institute of Statistics and Economic Studies (INSEE) published in 2018 the following data about prevalence of diseases as follows:

Disease	Prevalence rate per 100,000 persons as of 31 December 2015
Type 1 and 2 diabetes	4063
Malignant tumour	3330
Long term psychiatric conditions	2111
Coronary artery disease	1851
Heart disease	1645
Severe arterial hypertension	1176
Chronic arteriopathy with ischemic events	866
Disabling stroke	662
Chronic and serious respiratory failure	641
Alzheimer's disease and other dementia	542

Important issues discussed in national press

Social security gap

The national press often reports the problem of financing social security, known as the "social security gap". A report submitted to the Minister of Solidarity and Health, Agnès Buzyn, specifies reform of the financing of the health system. Indeed, the continuous increase in the number of patients with chronic diseases requires an evolution of management methods to better meet the need for long-term follow-up and coordination of their management. The report states that combined payment methods, on the other hand, can provide a more appropriate response to the diversity of patients' needs and promote the necessary transformations of the health system.

The social security deficit, which fell to €1.2 billion last year, is expected to "widen" again to at least €1.7 billion in 2019, according to a summary by the Audit Committee.

This could even increase to €4.4 billion if the State does not compensate the Social Security for the emergency measures adopted at the end of 2018. Anticipating the return of Social Security to balance, the State exceptionally required Social Security to bear €2.4 billion of uncompensated expenses by: desocialisation of overtime (at a cost of €1.2 billion); social lump sum for companies (€600 million); smoothing of thresholds for the Generalised Social Contribution (CSG) for pensioners (€300 million); and reduction of VAT from the State to the Social Security system (€300 million).

Medical desert

Regarding access to care, the national press often speaks of "medical deserts", which are territories where the medical supply is insufficient to meet the needs of the population. A report issued in October 2018 by the national delegates on access to care recommends to:

- encourage outpatient internships and support installation projects;
- develop the coordinated exercise;
- deploy telemedicine;
- support new modes of practice;
- promote inter-professional delegations and cooperation; and
- simplify liberal practice and free up medical time.

Euthanasia

France retains the ban on euthanasia, but the issue continues to generate debate, including within the medical profession.

Pharmaceutical pricing and reimbursement

Regulatory classification

Pharmaceutical products – more commonly known as medicines or drugs – are a fundamental component of both modern and traditional medicine. According to article L.5111-1 of the Public Health Code, "*a drug is any substance or composition presented as having curative or preventive properties against human or animal diseases, as well as any substance or composition that may be used or administered to humans or animals, with a view to establishing a medical diagnosis or restoring, correcting or modifying their physiological functions by exercising a pharmacological, immunological or metabolic action.*

"In particular, dietetic products are considered to be medicinal products if their composition contains chemical or biological substances that are not themselves food, but whose presence confers on these products either special properties sought in dietetic therapy or test meal properties.

"Products used for disinfecting premises and for dental prostheses are not considered to be medicinal products.

"Where, having regard to all its characteristics, a product is likely to satisfy both the definition of a medicinal product provided for in the first subparagraph and that of other categories of products governed by Community or national law, it shall, in case of doubt, be considered a medicinal product".

Different types of pharmaceutical products

In France, some pharmaceutical products require a medical prescription while others can be bought without medical prescription depending on the composition of the medicine or its use.

There are three types of pharmaceutical products:

- those requiring a medical prescription;
- those which do not require medical prescription; and
- more specialised treatments, including those reserved for hospital use or that can only be prescribed by a hospital, or that need a specific doctor's prescription or require more detailed monitoring during their use.

Article L. 5121-1 of the Public Health Code distinguishes drugs according to their preparation such as, for instance:

- *Bulk compounding:* drugs prepared for a particular patient due to the lack of available pharmaceutical products.
- *Hospital preparation:* drugs prepared according to pharmacopoeia instructions and in compliance with proper practices mentioned in the Article L. 5121-5 of the Public Health Code due to the lack of available or adapted pharmaceutical products.
- *Compounded medication:* drugs prepared in a pharmacy that are registered to the pharmacopoeia or on a national form and aimed to be directly dispensed to patients by the pharmacy.
- *Generic drug:* prepared with the same molecule of the reference medicinal products and with the same composition of active substances, the same pharmaceutical form and efficacy as the model of reference.
- *Biologic drugs:* the active substance of which is produced from a biological source and the quality of which requires a combination of physical, biological and chemical tests.
- *Biosimilar drugs:* biological drugs that have the same composition of active substances and pharmaceutical form as a reference biological medicine, which cannot be considered as generic drugs due to differences linked to the raw material or production process.

Refundable pharmaceutical products

In order to be eligible for reimbursement by Social Security, drugs must be covered by Chapter 3 of the Security Code.

Moreover, drugs have to be prescribed by a healthcare professional within the limits of prescription rights and must have a therapeutic use.

Currently, it is likely that homeopathic drugs may become non-refundable.

Process for getting a new drug approved

Before any drug is marketed in France, it is necessary to go through the marketing authorisation procedure as defined by article L.5121-8 of the Public Health Code and the following.

The marketing authorisation is subject to three main criteria: quality, safety, and efficacy according to article L. 5121-9 of the Public Health Code. It must be verified that: the actual qualitative and quantitative composition corresponds to that declared by the manufacturer; the medicinal product is not harmful under normal conditions of use; and the therapeutic effect announced is not lacking or is sufficiently justified by the applicant.

Marketing authorisations are issued by the Director of the ANSM (*Agence Nationale de Sécurité du Médicament et des Produits de Santé*) or his European equivalent, the Director of the European Medicines Agency (EMEA). They are then published in the Official Journal.

For new medicinal products intended to be marketed in more than one country, market access has been Community-based in the European Union since 1st January 1998, either through the centralised procedure defined in Regulation No 2309/93/EEC as amended by Regulation No 726/2004/EEC, or through the mutual recognition procedure provided for in Directive 2001/83/EC as amended by Directive 2004/27/EC and, since October 2005, through the decentralised procedure provided for in Directive 2004/27/EC.

The national procedure is increasingly being used less and less: it only applies to requests for the marketing of medicinal products limited to the national territory, which represents a limited number of medicinal products. It also continues to apply for the maintenance of marketing authorisations historically issued at national level.

In Europe, in the centralised procedure, the time limit for obtaining a marketing authorisation is 210 days, and may be shorter in the case of accelerated approval. In France, in the case of national procedures or national phases of decentralised or mutual recognition procedures, the time limits are also defined by the regulations. However, there are regular delays in these procedures. At the end of the mutual recognition procedure, the marketing authorisation shall be issued at national level within 30 days.

Who is/are the payers?

In France, the financing of the medical expense reimbursement system is organised into two main levels: compulsory and supplementary schemes.

Basic compulsory health insurance schemes are characterised by compulsory membership and contributions and are therefore based on broad solidarity, based on income-based contributions, and access to care defined according to need.

Supplementary schemes (mutual insurance companies, insurance companies, provident institutions) are based on a solidarity restricted to the members' field and offer variable coverage, defined by the type of contract subscribed. They cover the part of health care expenditure that is not covered by the compulsory basic scheme.

Some expenses are covered by the State. These include expenditure on prevention, medical and pharmaceutical research, and training of health professionals, universal complementary health insurance (CMU-C), and grants for military hospitals, emergency care, as well as benefits paid to beneficiaries of State Medical Assistance (AME).

Finally, a portion of the expenses may remain the responsibility of the care recipients.

Prescribed drugs are covered entirely or partially by the health insurance system. In general, a patient purchases the drugs and is later refunded though the spread of healthcare cards equipped with electronic chips, and internet-connected card readers, meaning the refunds can often be applied automatically at the time of purchase.

People who have signed up for supplementary health insurance policies often have the full cost of their treatments reimbursed, based on the terms of their contract.

Health insurance

At a departmental level, a health insurance policy is applied by 101 Primary Health Insurance Funds, one common Social Security Fund and five Social Security Funds. These Funds are private law bodies with a public service mission, and manage interactions and contacts with patients.

How is social security funded?

Resources which fund the social protection are:

- Social contributions: Charges collected directly based on salary and which must be paid by both employees and employers.
- The Generalised Social Contribution (CSG): a tax collected on all incomes.
- A series of other taxes dedicated to funding Social Security, including a flat-fee social tax, the social solidarity contribution required by companies, and a value-added tax on tobacco products.
- Other sources of funding from the State, different social security systems or other social security bodies.

Complementary health coverage

Any person can subscribe to complementary coverage plans in addition to Social Security,

which may also benefit family members. Many people do so because in general, the system does not fully refund doctor visits, drug prices or other treatments.

Such complementary plans, or *Mutuelles*, are financed by member contributions and organised as a non-profit-providing solidarity and assistance for its clients (article L. 111-1 of the Mutual Societies Code).

Individual contributions to a *Mutuelle* depend on a variety of personal circumstances (age, status of employee or unemployed person, place of residence, income, and the desired level of protection).

Pharmaceutical products eligible / ineligible for reimbursement

To be covered by the Health Insurance, a drug must be included in the list of pharmaceutical specialities reimbursable to social security contributors (positive list), published in the Official Journal, which specifies the only reimbursable therapeutic indications. The mission of examining drugs is the responsibility of the Transparency Commission integrated into the HAS (*Haute Autorité de Santé*). Its missions are to evaluate medicinal products that have obtained their marketing authorisation, when the laboratory that operates them wishes to obtain their inclusion on the list of reimbursable medicinal products and to give an opinion on the coverage of medicinal products by the Social Security and/or for their use in hospital, by assessing their "medical service rendered". Drugs with medical service rendered insufficient compared to other available drugs or therapies are not included in the list of reimbursable specialties.

The drug is scheduled for reimbursement for five years, but the Transparency Commission may, at any time, reassess the medical service provided if changes occur in therapeutic strategies. The scope of reimbursable therapeutic indications is based on the therapeutic strategy recommended by the Transparency Commission that, in certain cases, may lead to a restriction with regard to the marketing authorisation.

What is the process for securing reimbursement for a new pharmaceutical product?

To enable the reimbursement of a pharmaceutical product, companies have to obtain a product marketing authorisation.

Marketing authorisation

The marketing authorisation is issued by either:

- The European Commission, after receiving an opinion from the European Medicines Agency (EMA). The pharmaceutical laboratory chooses the rapporteur State or the referent State within the EU for submitting its product to the EMA, which has authority across the European Union. These procedures are used when the product is intended for several Member States of the European Union.
- The Director General of National Agency for Security of Medicinal product who scrutinises the product according to scientific criteria of quality, safety and efficiency. The new product must have a risk-benefit balance at least equal to products already on the market. It can submit a favourable or unfavourable opinion or a request for some additional information.

The product marketing authorisation must be accompanied by a summary of the product characteristics, as well as its labelling and packaging, and the accompanying information notice.

This authorisation can be changed or removed. Another option is to file for a temporary authorisation of use.

Primarily, the authorisation is requested by laboratories and granted to drugs whose security and efficiency are strongly presumed by the results of therapeutic tests. The authorisation request has to be filed or to be subject to a commitment to be filed within a specific period.

Secondly, the nominative authorisation is requested by the doctor to the benefit of a specific patient, who may not participate in biomedical research. The expected efficiency and safety should be based on current scientific knowledge.

These authorisations are granted for a limited period not exceeding one year, although they can be renewed.

Inscription on the List of Reimbursable Drugs (article L. 162-17 of the Social Security Code)

A pharmaceutical laboratory is free to set prices for the treatments it offers. However, for a drug to be eligible for Social Security reimbursement, a request must be submitted to the High Health Authority (HHA). The request is reviewed by the HHA's Commission on Transparency, which assesses the medical service provided (e.g. a drug must be sufficiently beneficial) and the improvement of the medical benefit – that is, the drug must make a major contribution compared with similar products (article R. 163-5 I 2° of the Social Security Code).

The Commission on Transparency's opinion is transmitted to the economic committee of a health product and the national union of medical insurance funds.

Article R. 163-5 of the Social Security Code provides that some drugs cannot be entered on list of reimbursable drugs:

- drugs that have forms, dosing and presentation not justified by a therapeutic use;
- drugs that do not improve medical service according to the Commission on Transparency or do not generate savings in the drugs' treatment;
- drugs that might generate an increase in consumption or unjustified expenditures;
- drugs whose price is not justified; and/or
- drugs that do not mention on their packaging, labelling, leaflet or advertisement a therapeutic use.

Both France's health minister and the Social Security minister adopt the final decision on reimbursement of the drugs.

Decisions regarding the inscription of the drugs on the list of reimbursable treatments are notified to a company within 180 days from the receipt of the request, as required by article R. 163-9 of the Social Security Code. The decisions are also published in France's official government bulletin (*Journal Officiel*).

The inscription is valid for five years and may be renewed (articles R. 163-2 and R. 163-10 of the Social Security Code).

Article R. 163-14 of the Social Security Code provides that refusal decisions are notified to the company with the grounds of refusal, legal remedies and periods.

Drugs that are no longer reimbursable

This decision belongs to the Health minister on the recommendation of the High Health Authority. The arrival of new drugs on the market which are less expensive and more efficient, for example, could justify a decision to withdraw some drugs from the list.

Who influences decisions?

According to article R. 163-16 of the Social Security Code, the opinions of the Transparency Commission are subject to a dual requirement of motivation and publicity. Where the notice relates to the listing, amendment of listing conditions or renewal of the listing of a drug on

the list of reimbursable specialties or on the list of drugs approved for community use, the notice is immediately communicated to the company producing the drug.

The company may, within 10 days of receipt of this opinion, request to be heard by the commission or send its written comments to it. The committee may modify its opinion in the light of the comments submitted.

In the event of a request for a hearing, the committee shall hold the date of the hearing, which shall be fixed by the committee, within a maximum period of 45 days following receipt of the company's request. Upon a reasoned request from the Minister of Health or Social Security to the Commission, this period may be reduced to one month.

Process to appeal a decision

The Court of Justice of the European Union has ruled that any decision not to include a medicinal product on the list of reimbursable specialities shall include a statement of reasons based on objective and verifiable criteria, including, if necessary, the opinions or recommendations of the experts on which the decisions are based. In addition, the applicant shall be informed of the means of appeal available to him under the legislation in force, and of the time limits within which such appeals may be lodged. When setting up their procedures for admission to reimbursement of medicinal products, Member States are required to comply with the requirements of Directive 89/105 of December 21, 1988, in particular to provide for the possibility of bringing legal and not only administrative proceedings against decisions refusing to include them on the positive list of reimbursable medicinal products (ECJ, November 27, 2001, Case C-424/99, *Commission v Austria*, ECR I, p. 9285).

In the event of refusal to include a drug on the list of reimbursable drugs, it is possible to bring an appeal for exceeding powers before the administrative judge. In one such case, a laboratory exercised this remedy following the refusal to include *Palexia LP* on the list of reimbursable specialties (French Council of State, 1st Chamber, December 26, 2018).

How is the reimbursement amount set? What methodology is used?

Article L. 162-16-4 of the Social Security Code provides that the Economic Committee for Medicinal Products sets the price based on the results of: economic and medical evaluations; the prices of other drugs with same therapeutic effect; expected volume sales; and foreseeable and actual conditions of use of the drugs, with the undertaking that operates the drug.

The French national union of medical insurance (*Union nationale des caisses d'assurance maladie*) is composed of representatives of the general system, the agricultural system and social security for self-employed persons. It sets the support rate of healthcare as well as the reimbursement rate of drugs. The medical service provided (MSP) takes into account the severity of the concerned disease, the efficiency of undesirable effects, the therapeutic strategy and the preventive, curative or symptomatic character of the drugs treatment.

There are several levels of medical service provided (major, moderate or low) that affect the reimbursement rate of the drugs. They are classified by the French Government as follows:

Drugs for which the MSP is insufficient do not get included on the list.

Categories of drugs	Reimbursement rate
Irreplaceable drugs for serious and debilitating diseases	100%
Drugs with a major or significant MSP and Bulk Compounding	65%
Drugs with moderate MSP	30%
Drugs with low MSP	15%

The reimbursement rate applies to the basis of the sale price or a "flat rate of responsibility" that is a reference rate for the reimbursement of some drugs. The "flat rate of responsibility" aims to cover equivalent products in terms of efficiency (generic drugs) on the basis of a single tariff. This tariff is calculated from the price of the cheapest generic drugs.

A franchise of €0.50 is levied on reimbursable drugs by the health insurance. The amount of the health franchise is capped to €50 per person each year.

The Health Insurance (Social Security) reimburses part or all of the medicines purchased in pharmacies. This depends on the drug concerned, as well as the conditions of prescription and delivery. The reimbursement rate depends on the medical service provided for the drug.

Since January 2019, 65% of nicotine substitutes have been reimbursed on medical prescription. To be reimbursed they must appear on the list of nicotine substitutes reimbursed.

How are drug prices set? What is the relationship between pricing and reimbursement?

Fixing the price

Two types of drugs may be distinguished:

- Drugs sold directly to the health establishment: the price is negotiated directly by health establishments.
- Drugs sold by pharmacies or by hospitals: the sale price to the public is set by convention between the pharmaceutical company and the Economic Committee for Medicinal Products. If no agreement can be reached, the committee sets the price itself. If the Health and Social Security ministers oppose it, they set the price, within 15 days after the committee's decision (article L. 162-16-4 of the Social Security Code).

Criteria for fixing the price

As previously mentioned, in setting the price the Committee takes into account: the improvement provided by the drug; the results of economic and medical evaluations; the price of drugs with the same therapeutic effect; sales volumes; and the foreseeable and actual conditions of use of the drugs.

The criteria of the improvement of the medical service provided correspond to: the added value of the new drug over and above existing drugs; and the efficiency and the tolerance levels for patients. There are five levels of the improvement of the medical service provided which are: major, important, moderate, low and insufficient.

The Economic Committee for Medicinal Products implements the directions received by the competent ministers. These directions are intended to ensure, in particular, respect of the government's goals for national health insurance expenditures (article L. 162-17-3 of the Social Security Code).

The detailed price of drugs

The public price of the drugs is composed of the pre-tax manufacturer's price, margins (wholesaler's margin, official margin and dispensation fees) and the value-added tax.

It comprises the payment of wholesalers, notably through margin and discounts. The ministerial order dated December 26, 2011 created a unique payment of the wholesalers equal to 6.68% of the pre-tax manufacturer's price. This coefficient only concerns the part of the price ranging from €0 to €450. Beyond this amount, the coefficient is equal to 0.

For the retail pharmacist's margin, several coefficients are applied according to the different tranches of the product's pre-tax manufacturing price (ministerial order dated December 12, 2017):

Part of the pre-tax manufacturer price between	Pre-tax coefficient from 2018
€0 and €1.91	10%
€1.92 and €22.90	21.4%
€22.91 and €150.00	8.5%
€150.01 and €1515.00	6%
Beyond €1515.00	0%

Evolution of the sales of reimbursable drugs in pharmacies[1]

	Sales, pre-tax manufacturer price (billion euros)	Sales, public price including tax (billion euros
2015	18.0	25.1
2016	18.0	24.9
Evolution	0.0%	-0.50%

The overall growth rate of drugs expenditure is based on three effects:

- The *price effect*, corresponding to changes in the unit prices of drugs on the market.
- The *box effect,* or the difference between the number of units sold in 2015 and those in 2016, for example.
- The *structure effect*, reflecting the evolution of market share. For example, if it is negative for a certain drug, that may indicate sales migrating towards more expensive alternatives.

The average price of drugs, in pharmacies:

	2012	2013	2014	2015	2016
Average pre-tax manufacturer price of one box (€)	7.46	7.25	7.15	7.15	7.15
Average public price, including tax of one box (€)	10.39	10.15	10.00	9.96	9.90
Average margin[2] (€)	2.72	2.70	2.64	2.60	2.55

The average pre-tax manufacturer price has decreased from 2008 to 2014, when it stabilised at €7.15. The average public price, including tax and the average margin, continues to decline.

Market	Average pre-tax manufacturer price (€)	Average public price, including tax (+ fees) (€)	Average margin (€)
Generic	3.86	6.27	2.29
Originals	6.34	8.89	2.36

Discounts

There are two types of discounts: conventional and the unconventional discounts.

- *Conventional discounts*

  Article L. 162-18 of the Social Security Code provides the companies (laboratories) that may offer a discount through a national convention with the National Health Insurance Fund.

  These discounts correspond to sums due in application to the clauses provided in the contract between the Economic Committee for Medicinal Products and the laboratories. In 2016, the gross amount of such discounts amounted to €1,005 million. Most of these discounts only concern certain laboratories and certain drugs (50% of the rebates consist of those from the five main laboratories operating in France, and 44% are made up of just 10 drugs). Price or volume clauses represent a combined 41% of the total discounts, an amount of €409 million.

- *Unconventional discounts*

  Article L. 162-16-5-1 of the Social Security Code contains provisions regarding discounts for drugs which benefit from a temporary authorisation of use.

  According to the activity report of the Economic Committee for Medicinal Products, in 2016, the amount of such rebates amounted to €136 million.

Since December 21, 1988, the European Directive 89/105/EEC, known as the Transparency Directive, has imposed a regulatory framework for European countries to set prices. These provisions essentially concern regulators, who must display the criteria used to determine the price of medicines, respect response times and justify their decision on price regulation. Marketing authorisation holders must provide information for the regulator's decision. The regulation therefore concerns the manufacturer's price excluding tax.

In France, drug prices are mostly administered, although free prices exist for some specialties. Non-refundable specialities have a completely free price and distribution margins. These are either drugs for which the manufacturer has not claimed reimbursement from health insurance (the most common case), or drugs that have not been included on the list of products that can be reimbursed in a particular town or hospital.

Ambulatory drugs are reimbursed at an administered price, and were regulated until 2003. The price was the result of negotiations between the laboratory and the CEPS (Economic Committee for Health Products).

Since 2003, the price of innovative specialities has been subject to a certain degree of freedom, since the laboratory proposes it and it is then approved by the CEPS.

Hospital drug prices were completely unregulated until 2003 and were the result of negotiations between laboratories and hospitals. The implementation of activity-based pricing in hospitals has set rules for retroceded drugs as well as for expensive drugs.

Issues that affect pricing

Several facts and issues can affect the price of drugs in France.

The presence of generic and biosimilar drugs on the market

The availability of generic drugs leads to a decrease in the price of drugs for two reasons:

- The partial substitution of the original drug for the generic, as the price of the original decreases automatically under French regulations. Minimal price decreases are

implemented at the time of the generic product launching (20%) and 18 months later (12.5%).

- The price of the original is often also cut by laboratories in order to keep their product competitive.

A decrease of generic drugs is also implemented 18 months after the marketing launch (7%).

The price decrease of both drugs is linked, since the price of generic drugs is calculated according to the price of the original drugs.

These decreases apply to the pre-tax manufacturer's price.

Furthermore, French policy encourages consumers to choose less expensive generic options, with measures including:

- The "flat rate of responsibility" known as "TFR" concerning drugs where the penetration of generic drugs is considered to have been too low. The rate of reimbursement is single and is calculated on the basis of the lowest price of generic drugs. The laboratories are nonetheless free to set the price, though in practice this tends to produce an alignment between original drugs and generic drugs.
- The so-called "third-party payment against generic": Automatic reimbursement at the time of purchase (for example, in pharmacies) is possible only if patients accept generic versions of drugs if they are available.
- Various policies aimed at encouraging both doctors and pharmacies to favour the use of generics.

The development of biosimilar drugs may contribute to a decline in the price of biologic drugs (those produced from a living cell).

The public authorities assign annual price decreases to the Economic Committee for Medicinal Products. In 2016, for example, these directives led to savings of €794 million.

Supply chain

The cost of distribution can influence drug prices. As seen above, the public price includes margins that are applied to wholesalers and pharmacists, which can fluctuate.

To decrease the cost of distribution, the French court of Audit recommends regular reviews of pharmacy remunerations. The goal is for remuneration of the wholesalers to be based on the volumes delivered and not on a drug's price.

Drug counterfeiting

Drug counterfeiting may refer to various concepts, depending on the instances.

On May 29, 2017, the 7th World Health Assembly of the World Health Organisation (WTO) agreed to adopt the new name "substandard and falsified" (SF) medical products for what were designated as "substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC)" medical products. The new reference focuses only on the public health implications and not on intellectual property rights.

The WHO uses the following definitions:

- *Substandard:* also called "out of specification", which are authorised medical products that fail to meet either their quality standards or specifications, or both.
- *Unregistered/unlicensed* medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

- *Falsified* medical products that deliberately/fraudulently misrepresent their identity, composition or source.

The European Medicines Agency, EMEA, also distinguishes Falsified Medicines defined as "fake medicines that are designed to mimic real medicines" from Counterfeit Medicines, described as "medicines that do not comply with intellectual-property rights or that infringe trademark law".

Counterfeit medicines can take different forms relating to the exterior packaging, the primary packaging of the drug, or the drug itself.

Falsified Medicines are fought at both the national and the European Union level with a broad legislative framework, notably:

- Directive 2001/62 on the prevention of entry into the legal supply chain of falsified medicinal products;
- Commission Delegated Regulation 2016/161 on how medicine authenticity should be verified; and
- Regulation 699/2014 on the design of the common logo to identify persons offering medicinal products for sale at distance to the public.

Drug counterfeiting is also combated through the general rules that aim to protect intellectual property rights, which involve police and customs authorities as well as civil and criminal law courts.

The link between the price of drugs and research and development

According to the pharmaceutical industry,[3] the price of drugs is linked to the necessary investments in researching, developing and manufacturing processes which can require significant funding over several years. Indeed, if the costs of research are high, the price of drugs are also quite likely to be high.

Thus, considering the high price of some medicines, reports from Expert Panels from the European Union[4] and from the United Nations[5] have proposed exploring delinkage between the costs of research and development from sales.

Competition

Competition authorities look very carefully at the medicines market and pricing. For instance, on December 19, 2013, the Competition Authority (*Autorité de la concurrence*) issued opinion n°13-A-24 about competition in the sector of drugs distribution downstream. The Authority held that dysfunctions in full competition can influence the development of the market, and thereby impact drug prices. Thus, the Authority observed a lack of information about drug pricing and suggested more transparency so that consumers would be able to compare prices between different pharmacies, promoting competition. On April 26, 2016, the Competition Authority issued an opinion on electronic commerce of medicine. Furthermore, since November 21, 2017, the Competition Authority has been investigating competition in the medicine and biological markets. Also, the European Commission has initiated formal investigation regarding Aspen Pharma' s pricing practices, and the European Court of Justice ruled on drug pricing in Germany.[6]

Transparency

Due to the rise in drug prices due to an opaque system, a group of associations called on the French government to commit itself to the "transparency" resolution presented to the WHO General Assembly on Health from 20 to 28 May 2019 in Geneva.

In France, unprecedented rationing was introduced on Hepatitis C treatments between 2014

and 2017 because it was impossible to reimburse all those who needed it. Similarly, treatments for various cancers are subject to administrative barriers to prescription, due to their price.

These associations denounce the lack of transparency in the development, manufacturing and marketing of medicines.

Foreign direct import

According to the Leem organisation (drug companies), in 2017, France imported €18.3 billion worth of medicines. These imports came mainly from Germany (17.1%), the United States (16.1%), Switzerland (12%) and Ireland (9.6%). The trade in medicines represented a trade surplus of €6.8 billion for France in 2017, but this is down sharply from 2016 (-12%).

The parallel intra-Community import of medicinal products has its origins in the coexistence of free movement and the right of States to set an administrative price for reimbursable medicinal products.

Parallel trade is the result of government decisions in some southern European countries (Greece, the Iberian Peninsula, but also France), where prices are administered to the detriment of other countries that have price freedom.

In the States concerned, parallel trade benefits only intermediaries and, exceptionally, social protection bodies. As for patients, they are exposed to supply disruptions in the French market.

In 2015, European parallel trade was estimated at €5.4 billion, without the organisation of distribution by companies being able to provide satisfactory solutions. It remains a key concern for laboratories.

Policy issues that affect pricing and reimbursement

The French government can influence pricing and reimbursement in several ways. The French Court of Audit (*la Cour des comptes*) identifies several policies in its report "Social Security 2017" dated September 2017.

Legal criteria according to Article L. 162-16-4 of the Social Security Code

Please see section, "How is the reimbursement amount set? What methodology is used" in "Pharmaceutical pricing and reimbursement".

The framework agreement

This agreement, concluded on December 31, 2015 between the Economic Committee for Medicinal Products and the pharmaceutical industry, aims to allow pharmaceutical companies to maintain an attractive price on the market, and is influenced by the initial price of a drug along with the conventional discounts.

The guarantee of the European price of the 2003 agreement influences the price of drugs by introducing a minimum price for drugs. A company cannot introduce a drug with a price lower than the minimum price in the four following countries: Germany; Spain; Italy; and the United Kingdom.

This guarantee applies to all drugs with an improvement of medical service provided (classified I to IV), and to antibiotic drugs with a substance offering a determined level IV of improvement.

The European price is granted for five years and may be renewed by a maximum of one year. This guarantee slows down the price decline for a drug.

The ministerial guidelines

Ministerial guidelines set objectives for the chairman of the Economic Committee for Medicinal Products regarding price negotiations with pharmaceutical companies.

The objectives are the following: speed of access to drug treatments; upgrading of the therapeutic progress; transparency; the proper use of drugs; the efficiency of expenditure; and in order to comply with the national health insurance system's spending objectives.

The savings targets

As seen above, the public authorities determine the amount that should be saved on individual drugs. This can take different forms: medical control of prescriptions; development of the distribution of generic drugs; deeming some drugs to be no longer reimbursable; or tariff reductions.

Population growth

In just over a decade, the world will probably have about 8.5 billion people, and nearly 10 billion by 2050, compared to 7.7 billion today according to the United Nations Population Division (World Population Prospects, 2019 Revision).

In France, the ageing of the population has led to the multiplication of certain diseases. The main expenditure item remains one-off hospitalisation, at more than €31 billion per year. Growth has been very rapid in six years, with 566,000 more patients for a total of €4 million. Diabetes, with 3.2 million patients treated and a bill of €7 billion, is also associated with age.

According to the magazine *Le Quotidien du Pharmacien*, France has 20 million chronic patients. Indeed, the medicalised mapping of health expenditure for 2017, presented by the *Caisse nationale d'assurance-maladie* (CNAM), reveals that 20 million French people have used care related to the management of a chronic pathology, representing 35% of the 57.6 million beneficiaries of the general scheme.

Cost of healthcare as a percentage of GDP

According to the 2017 edition of the *Panorama of Health* published by the OECD, France spends US$4,600 *per capita* on health, a 15% increase over the OECD average of about US$ 4,000. With 11% of GDP devoted to health expenditure, France ranks 5th among OECD countries, after the United States, Switzerland, Germany and Sweden. The number of doctors and nurses *per capita* is close to the OECD average, but the number of hospital beds is much higher (6.1 beds per 1,000 inhabitants in France compared to 4.7 beds on average).

Cost of research and development

The costs associated with the development of new medicines are increasing (almost €1 billion) according to the Leem organisation, which justifies strong protection of innovation. This is why intellectual property is one of the fundamental elements in the development of innovation. Because research companies invest in long and costly scientific programmes, they must be able to rely on the protection afforded by these rights. In 2016, France carried out 10% of international industrial studies.

Cost of innovation

Therapeutic innovation is contributing to increased spending. In total, 2.6 million people are now treated for cancer, including 1.2 million in the active phase, for an annual cost of €15 billion. Lung cancer costs on average €20,000 per year per patient, with a total expenditure of €1.6 billion. In 2017, the "list in addition" item will increase from €1,600 to €4,000. This special reserve allows hospital patients to use the most innovative and expensive drugs without draining the institution's normal budget.

Affordable access to care

Access to care is one of the fundamental rights of the user. It can be defined as the right of everyone to receive preventive or curative care without reference to a social or health situation. This is why, on January 1, 2000, universal health coverage (CMU) was introduced for the poor in order to generalise access to health insurance and to ensure that everyone has effective access to health care through the introduction of social security coverage.

How do politics affect pricing and reimbursement policy?

Unlike in other European countries, it is not social security that negotiates drug prices and reimbursement rates, but an inter-ministerial committee, the Economic Committee on Health Products (CEPS), under the joint authority of the Ministry of Health and the Ministry of the Economy.

Even if the pharmaceutical industry is not a member of this committee, it is sometimes forced to accept relatively high prices, as the Court of Auditors' 2017 report on the financing of social security still notes. For example, Crestor, a very expensive statin for social security, achieved a price four times higher than other similar generic drugs, without improving the medical service provided.

The Court of Auditors' 2017 report notes several cases where a drug manufacturer, to maintain a relatively high price, has openly used the employment and investment argument.

Emerging trends

On February 8, 2018, the French government issued an information notice in which the pharmaceutical industry was reminded to implement European Regulation 2016/16, which aims to secure the legal supply of drugs and prevent counterfeit products from being introduced in the supply chain. The regulatory rules came into force on February 9, 2019.

Possibility for pharmacists to dispense certain medicines

The draft law on the organisation and transformation of the health system opens up the possibility for pharmacists to dispense certain medicines currently on prescription.

Social regime for students

On February 15, 2018, the government definitively put an end to the social regime for students by adopting the draft law on guidance for student success. The regime will disappear on August 31, 2019. From that date, students are linked to the general social security system and will no longer pay contributions.

Therapeutic cannabis

The National Drug Safety Agency (ANSM) has announced the conditions for the delivery of cannabis for therapeutic purposes, which will initially be carried out on an experimental basis, subject to validation by the Ministry of Health.

This will be reserved for some patients whose symptoms could not be relieved by other medications.

Five indications have been selected by the Temporary Scientific Specialty Committee (TSC): neuropathic pain; certain forms of severe epilepsy; supportive cancer care; palliative care; and painful spasticity (contraction) of multiple sclerosis or other diseases of the central nervous system.

Tens of thousands of patients could be affected. A two-year experiment is planned to verify the relevance of the proposed framework.

Cannabis will be prescribed on a secure prescription by volunteer and trained doctors, specialists in the diseases concerned and working in multidisciplinary referral centres. It will then be available, from next year, in pharmacies, in the form of capsules, oil or dried flowers.

Successful market access

Successful market access will necessarily involve a balance between research costs and the prevention of competition in the drugs market. Constant innovation through patents is the key to ensuring constant revenue streams amid the steady introduction of generic alternatives.

* * *

Endnotes

1. Extract from the activity report 2016 of the Economic Committee for Medicinal Products.
2. The distribution margin corresponds to margin of the wholesaler, margin of the pharmacist and fees for the dispensation.
3. Extract from the article, "The patent and the brand, two invaluable sesames" on the official website of pharmaceutical industry (*Les entreprises du medicament)*.
4. European Commission, Expert Panel on Effective Ways of Investing in Health, Opinion on Innovative payment models for high-cost innovative medicines, January 17, 2018.
5. United Nations Secretary-General's High Level Panel Report of the United Nations Secretary-General's High Level Panel on Access to Medicines, September 14, 2016.
6. ECJ, case C-148/15, October 19, 2016.

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