HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT[1]

1. Please provide a bird's eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

In France, the government is directly involved in the financing of public healthcare. As such, the Ministries of Labor, Health, Solidarity, and Families; Public Action; and the Economy have a wide range of responsibilities, including steering and implementing public health policies; supervising all care and support establishments; providing financial support to health and medico-social establishments; setting service charges and controlling healthcare costs; supervising health insurance organisations; and training healthcare professionals.

The government also ensures that healthcare, medico-social and outpatient facilities are properly distributed across the country.

Each year, Parliament passes the Social Security Financing Act (loi de financement de la sécurité sociale or LFSS), which sets the national target for health insurance expenditure, including expenditure on primary care, hospital care and medico-social care.

At regional level, regional health agencies (agence régionale de santé or ARS) coordinate prevention, care and support. They ensure that resources are managed coherently to give everyone equal access to continuous, high-quality, safe care. The ARS draw up regional health programmes comprising prevention plans; organisation of local and hospital care; and plans for the medico-social organisation of dependent people.

In France, health protection is the subject of a national policy.[2] The main insurer of healthcare in France is the social security system, which includes health insurance. The social security system in France is characterised by compulsory membership and contributions. It is based on broad solidarity, with contributions based on income, and access to care defined according to need.

In addition to the compulsory public health insurance scheme, citizens can also subscribe to one or more optional supplementary private schemes, which may be a mutual insurance company, insurance company or provident institution, all of which offer insurance contracts. These supplementary schemes are the second-largest funder of healthcare, after compulsory health insurance, and paid out a total of €29.7bn in benefits for care and medical goods in 2022 (ie, 12.6 per cent of healthcare expenditure).[3] Unlike the public scheme, these

[1] This French chapter of the Global Survey was drafted on 27 January 2025.
[2] Art L1411-1 of the Public Health Code: 'The Nation defines its health policy in order to guarantee everyone's right to health protection. Health policy is the responsibility of the State'.
[3] See https://drees.solidarites-sante.gouv.fr/publications-communique-de-presse/panoramas-de-la-drees/240710_Panorama_ComplementaireSante2024 accessed 5 May 2025.

supplementary schemes are based on solidarity restricted to the scope of their membership and offer variable cover, defined by the type of contract taken out, to cover the portion of healthcare expenditure not covered by the compulsory basic scheme (hospital lump sums, cover for optical care, orthotics or equipment etc).

Finally, a proportion of the costs may be borne by the beneficiaries. In France, patients' associations are not involved in the financing or reimbursement of healthcare on a global scale.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

The legal framework for drug pricing and reimbursement is laid down by law (adopted by Parliament) and by decrees or orders (adopted by the government). All these texts set out the conditions and criteria for setting the prices of medicines and healthcare, as well as their reimbursement.

The financing and reimbursement of healthcare is governed by the LFSS. Article 34 of the French Constitution states that social security financing laws 'determine the general conditions of its financial equilibrium and, taking into account their revenue forecasts, set its expenditure targets, under the conditions and subject to the reservations provided for by an organic law'. In France, there are no standards, private legislation or industry codes governing the financing and reimbursement of healthcare.

Only health product prices are determined by an agreement between each pharmaceutical or medical device company and the pricing authority (the Economic Committee for Health Products (Comité économique des produits de santé or CEPS)), which is an interministerial body under the joint authority of the ministries of health, social security and the economy. In the absence of an agreement, prices are set unilaterally by the CEPS.

Regarding drugs, for instance, Article L162-16-4 of the French Social Security Code[4] provides for the establishment of a framework agreement[5] between Leem (ie, the professional organisation representing pharmaceutical companies based in France) and CEPS, to specify certain conditions or specific procedures concerning the fixation of drug prices.

Regulation relating to the pricing and reimbursement of health products is subject to certain mandatory consultations with the relevant public authorities, such as the Caisse Nationale d'Assurance Maladie (CNAM) or the Commission des Comptes de la Sécurité Sociale (CCSS). There is no mandatory consultation of private parties, including in the case of amendments to existing laws or for the adoption of governmental regulations. However, the government often consults professional organisations representing pharmaceutical companies or medical device manufacturers, such as Leem or Snitem, on draft legislation.[6] Private individuals or other stakeholders (eg, professional organisations or companies) can submit comments to the government or members of Parliament, and propose amendments to draft legislation or regulations.

In addition, unions are responsible for negotiations between healthcare professionals and the

[4] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000044628577 accessed 5 May 2025.
[5] See https://sante.gouv.fr/IMG/pdf/accord_cadre_21-24_signe.pdf accessed 5 May 2025.
[6] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000044628577 accessed 5 May 2025.

health insurance scheme concerning fees and all issues relating to medical practice (medical agreements defining the relationship between the health insurance bodies and self-employed doctors).[7]

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

The main regulators and control bodies for healthcare funding and reimbursement within central government are the Ministry of Health and CEPS. For instance, certain drugs or medical devices can be delisted by a decision of the Ministry of Health, following recommendations from the High Authority for Health (Haute Autorité de Santé or HAS), or the Health Insurance System (Assurance Maladie).[8] Similarly, the Mission d'Evaluation et de Contrôle des Lois de Financement de la Sécurité Sociale (MECSS) monitors the implementation of social security funding laws on an ongoing basis.[9]

The HAS is an independent, scientific public authority, which is notably responsible for contributing, through its opinions, to the preparation of decisions relating to the registration and reimbursement by the health insurance scheme of pharmaceutical products or medical devices and for ensuring, by any appropriate means, the validation of methods and the coherence of initiatives relating to quality improvement in the field of patient care.[10]

The French National Agency for the Safety of Medicines and Health Products (agence nationale de sécurité du médicament et des produits de santé or ANSM) is a public body under the authority of the Minister for Health. The agency assesses the benefits and risks associated with the use of health products intended for human use.[11] Similarly, the Agency participates in the application of laws and regulations and, in cases covered by specific provisions, takes decisions relating to the assessment, testing, manufacture, preparation, import, export, wholesale distribution, brokering, packaging, conservation, use, marketing, advertising, commissioning or use of products. It also ensures the implementation of vigilance systems.

Ministerial decisions on registration, renewal of registration or removal from the list of reimbursable health products, as well as those setting the rates of reimbursement, may be challenged by means of an appeal for misuse of power in front of the Conseil d'Etat, France's highest administrative court. Companies marketing medicinal products or medical devices may lodge an appeal with the administrative courts on the grounds of *ultra vires* against ministerial decisions relating to registration, amendment, refusal of registration or removal from the list of reimbursable specialities. Other persons may also have sufficient interest to lodge appeals, such as trade unions or associations of healthcare professionals, or users.

Similarly, Articles L142-1 et seq of the Social Security Code provide a framework for social security litigation, which includes disputes relating to the recovery of contributions, payments

[7] See www.ameli.fr/sites/default/files/Documents/convention-medicale-2024-2029-integrale.pdf accessed 5 May 2025.
[8] Art R163-1 of the French Social Security Code.
[9] Social Security Policy Assessment Report – 2022.
[10] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000048580976 accessed 5 May 2025.
[11] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000046871876 accessed 5 May 2025.

and contributions, and the determination of the status or degree of disability in the event of accident or illness.[12] Litigation must be preceded by a preliminary appeal. The courts then have jurisdiction to hear disputes relating to social security.[13]

4. Has there been a change to healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

In France, between January 2021 and August 2022, the health crisis led to almost one million hospitalisations and 154,000 deaths in institutions (hospitals or medical centres for elderly persons, also called établissement d'hébergement pour personnes âgées dependants or EHPAD).[14] In 2021, spending on vaccinations totalled €3.8bn, and spending on prevention tripled between 2019 and 2021 because of the health crisis. It represented €5.5bn in 2019, €8.6bn in 2020 and €16.9bn in 2021.[15]

As a result, the health insurance contribution to the financing of prevention expenditure has increased considerably with the pandemic. By 2021, it was financing 75 per cent of prevention expenditure, compared with 30 per cent in 2019. Expenditure on vaccination and screening has been almost entirely covered by the French health insurance system.[16] Private companies paid €1.7bn for occupational medicine. Similarly, funding from households accounted for three per cent of prevention expenditure, or €0.5bn.

In 2021, the National Health Insurance Expenditure Target (objectif national de dépenses de l'assurance maladie or ONDAM) was successively revised by Parliament to increase exceptional expenditure linked to the health crisis.[17]

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

Access to the French health system, social security, is guaranteed for any person working or residing in France on a stable and regular basis and is thus not restricted to people who hold French nationality.

Healthcare providers' access to public funding/reimbursement by (mandatory) health insurers

For a healthcare service, drug or medical device to be eligible for public funding and reimbursement by the French health insurance system, it must be included on a list.[18] Requests for the registration of a procedure or service are sent by the Union nationale des caisses d'assurance maladie or the ministers responsible for health and social security to the HAS[19] for its opinion. In addition, national medical agreements signed between health

[12] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000042683979 accessed 5 May 2025.
[13] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038314480 accessed 5 May 2025.
[14] National Health Strategy 2023-2033 https://sante.gouv.fr/IMG/pdf/projet_sns.pdf accessed 5 May 2025.
[15] Social Security Financing Bill - PLFSS - Annex 5 - ONDAM and healthcare expenditure www.securite-sociale.fr/files/live/sites/SSFR/files/medias/PLFSS/2023/PLFSS2023_Annexe%205.pdf accessed 5 May 2025.
[16] Social Security Financing Bill – PLFSS – Annex 5 – ONDAM and healthcare expenditure www.securite-sociale.fr/files/live/sites/SSFR/files/medias/PLFSS/2023/PLFSS2023_Annexe%205.pdf accessed 5 May 2025.
[17] Social Security Financing Bill - PLFSS - Annex 5 - ONDAM and healthcare expenditure www.securite-sociale.fr/files/live/sites/SSFR/files/medias/PLFSS/2023/PLFSS2023_Annexe%205.pdf accessed 5 May 2025.
[18] Art L.162-1-7 of the French Social Security Code.
[19] *Ibid.*

insurance organisations and doctors define the conditions designed to prevent the insured party from having to pay doctors' fees directly.[20]

French residents staying temporarily in a European country are covered for medically necessary treatment. This care is covered by the European Health Insurance Card (EHIC), which provides proof of entitlement to French health insurance.[21] In addition, Article R.160-4 of the Social Security Code states that 'agreements between social security bodies on the one hand, and certain health care establishments abroad on the other, may, after joint authorisation by the minister responsible for social security and the minister responsible for health, lay down the conditions for the stay of the persons concerned in the said establishments, as well as the terms and conditions for reimbursement of the care provided'.

Non-residents in an irregular situation are eligible for state medical aid (aide médicale de l'etat or AME), which entitles them to a 100 per cent reimbursement of healthcare costs, with no advance payment required.[22] To qualify for the AME, beneficiaries must apply and, if successful, the AME is granted for a period of one year and for the following healthcare: medical and dental care; medicines reimbursed at 100 per cent, 65 per cent or 30 per cent; analysis costs; hospitalisation and surgery costs; costs relating to certain vaccinations; and costs relating to contraception and voluntary interruption of pregnancy.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

Health insurance, which is compulsory, is based on the principle of national solidarity and guarantees 'workers against risks of any kind likely to reduce or eliminate their income. This guarantee is provided by the affiliation of the persons concerned to one or more compulsory schemes'.[23] Thus, 80 per cent of health insurance is financed by workers, via employers and employee contributions.

Health insurance contributions are determined by theLFSS passed by Parliament.

Supplementary insurance premiums are determined by the parties to the insurance contract and are assessed in two ways: fixed premiums, which cannot be changed during the term of the contract without the policyholder's agreement; and variable premiums, which depend on the situation of the person. Insurance premiums are set according to the health risk, cover taken out and level of cover. The government regulates the methods used to set premiums (prohibition of discriminatory criteria).[24]

According to Article L244-1 of the Social Security Code, 'any contributor who has failed to comply with the provisions of social security legislation shall be prosecuted before the police court, either at the request of the public prosecutor, possibly at the request of the minister responsible for social security, or at the request of any interested party and, in particular, any social security body'.

7. How is the coverage of medical services by health insurance carriers regulated?

[20] Art L162-5 of the French Social Security Code.
[21] Art R.160-1 of the Social Security Code.
[22] Art L.251-1 of the French Social Action and Family Code.
[23] Art L111-1 of the Social Security Code.
[24] See www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006073189/LEGISCTA000006141695/ accessed 5 May 2025.

Are there differences in coverage for in-person medical appointments and telemedicine appointments?

Private insurers are free to define the cover provided by their insurance policies. In general, insurance contracts provide reimbursement for benefits not covered by social security.[25]

The coverage of medical services by health insurance is defined by Parliament in Article L160-8 of the Social Security Code, which states that social protection against the risk and consequences of illness includes coverage of the costs of general and special medicine; dental care and prostheses; pharmaceuticals and appliances; and medical biology tests, including coverage of the costs of individual investigative procedures; hospitalisation and treatment in care; functional rehabilitation and re-education or vocational training establishments; the costs of counselling sessions and surgical interventions; including coverage of contraceptive drugs, products and objects; and the costs of medical examinations and biology ordered with a view to contraceptive prescriptions.

Reimbursements are calculated on the basis of social security rates,[26] which are set by agreement or ministerial decree.[27] For example, 'the insured person's contribution is between 15 per cent and 25 per cent of the fees paid to practitioners and medical auxiliaries for care provided during hospitalisation in a public or private health establishment'.[28]

Since 15 January 2018, there has been no difference in reimbursement between face-to-face consultations and telemedicine consultations.[29] However, various conditions must be met for them to be covered:[30] compliance with the coordinated care pathway; compliance with alternating face-to-face and teleconsultation care; and compliance with the territoriality principle. The cost of a teleconsultation, like that of a standard consultation, is €25. The same applies to reimbursement, which is 70 per cent by the social security system, or 100 per cent depending on the patient.[31] Tele-expertise is reimbursed at 100 per cent by compulsory health insurance.[32] The fee for a tele-expertise by the requested doctor will be €23 from 1 January 2026.[33] The fee for the requesting doctor remains at €10.

As far as orphan drugs are concerned, it is a matter of principle that patients suffering from rare diseases should be able to benefit from the same quality of treatment as others. In France, for an orphan drug to be reimbursed by the social security system or available in hospitals, the Transparency Commission of the HAS must give a favourable assessment of the drug's contribution compared with existing therapies.[34]

There is no provision for covering off-label use.

[25] Art L111-1 of the Mutual Code.
[26] Art L160-13 of the Social Security Code.
[27] See www.legifrance.gouv.fr/jorf/id/JORFTEXT000049424947 accessed 5 May 2025.
[28] Art R160-5 of the Social Security Code.
[29] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000050420807 accessed 5 May 2025.
[30] Art 1 of the decision of 7 December 2021 of the Union nationale des caisses d'assurance maladie relating to the list of procedures and services covered by the health insurance scheme, and Art 87-3 of the Medical Agreement.
[31] See www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006072665/LEGISCTA000022933202/ accessed 5 May 2025.
[32] Order of 1 August 2018 approving rider no 6 to the national agreement organising relations between private practitioners and the health insurance scheme signed on 25 August 2016.
[33] Art 90-1 Medical agreement between Ucan (the Social Security Accounts Unions) and unions of medical doctors in private practice for the period from 2024 to 2029.
[34] See https://sante.gouv.fr/soins-et-maladies/medicaments/le-circuit-du-medicament/article/les-medicaments-orphelins accessed 5 May 2025.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

Following a trial run from 2000 onwards, the Social Security Financing Act (LFSS) for 2004 provided for the introduction of activity-based pricing (tarification à l'activité or 'T2A'), which now bases the financing of all healthcare establishments, both public and private, on the activity they perform. Activity-based pricing is based on measuring the nature and volume of activity, rather than on authorising expenditure.[35] As a result, since 2008, activity-based pricing has completely replaced the previous methods of financing healthcare establishments, whether public or private, for-profit or not.[36] Medicine, surgery, gynaecology-obstetrics and odontology activities are now financed by national tariffs specified by decree of the Council of State[37] by funding allocations relating to territorial and national public health objectives, and by funding allocations relating to specific missions and contractualisation aids.[38]

For example, accommodation and care with or without accommodation are covered by lump sums, which are billed per session, day or stay. Similarly, the cost of care provided in emergency departments and reception and treatment units, except for care provided in a short-term hospital unit, is covered by lump sums billed for each visit to the establishment.[39]

Charges for services provided by outpatient hospitals are based on the forecast number of half hours for land-based procedures and minutes for air-based procedures.[40]

Reimbursement for inpatient hospital services is determined on the basis of national tariffs, which in turn serve as the basis for calculating the insured person's contribution. The pricing of services is set by ministerial decree. It should be noted that the insured person is exempt, for the part covered by compulsory health insurance schemes, from the advance payment of hospitalisation costs and costs relating to outpatient procedures and consultations.

Some patients have their hospitalisation costs fully covered by the health insurance scheme due to their status or the nature of their illness. In other cases, the health insurance covers only part of the cost (80 per cent, on average). The remaining 20 per cent is paid by the patient; to this must be added the accommodation and maintenance costs incurred during hospitalisation.

Hospital federations are critical of 'hospital tariffs', which represent the largest share of funding for healthcare establishments, because of the complexity of setting them up. Furthermore, hospital tariffs do not fund all the care provided in hospitals and clinics.

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[35] See https://sante.gouv.fr/professionnels/gerer-un-etablissement-de-sante-medico-social/financement/financement-des-etablissements-de-sante-10795/article/financement-des-etablissements-de-sante accessed 5 May 2025.

[36] See www.lamyline.fr/Content/DocumentChapterComp.aspx?params=H4sIAAAAAAAEAE2QsXLDIAyGnyYsWYSdxGFgSJy5HeLOPgJqzZWAiyCp376QDI3uPp0EPz86_WSMy4C_SZLyaZUBUKwJdcIc11Og2SblLEZGiw9-ucohZmRJXUgKYEqnrNwpaMlrbW84qEu9CNFgPC4SGE3h_qZu9kslG_xRxaeDNUaeBijBYdtuGnbDSEUgG-AtNNAx57-L8RlV1NPzjQl6WGaspo_Td--Wg3PhjqYo8xV9oqdST2ruw3U-EFnqg0E59PAI3rYw_jfQjRxGsdvzUYh2yyx9eFtHUe71Z0JXV2LOIUeNJGHVaV5oCpttSW0tCrtC7XdVsS90BSFqYp_WJYwvJn96rwPxfAEAAA==WKE accessed 5 May 2025.

[37] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000048702931 accessed 5 May 2025.

[38] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000048702942 accessed 5 May 2025.

[39] See www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000020303276/2009-09-17 accessed 5 May 2025.

[40] See https://sante.gouv.fr/IMG/pdf/tarifs_de_prestations-3.pdf accessed 5 May 2025.

Each year, the ministers responsible for health and social security issue a decree setting a health insurance expenditure target for the activities carried out by healthcare institutions.

This target is based on the annual amount of expenditure borne by the compulsory health insurance schemes for these activities in respect of care provided during the year. In 2022, social security financed 92.9 per cent of hospital care expenditure (complementary organisations financed 4.5 per cent, the state 1.1 per cent and households 1.5 per cent).[41]

9. How are the prices of such services determined? How is economic efficiency controlled?

The rates for hospital services are set by decree[42] by the government and Parliament in the preparation of the LFSS.

Since 1 January 2018, the fixed hospital charge has been €20 per day in a hospital or clinic and €15 per day in a psychiatric ward.[43]

Hospital associations and federations can give advice on setting the price of hospital services. The price is determined on the basis of an assessment of the costs incurred by the establishments and the efficiency gains achieved or that may be achieved in the sector.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

Public health establishments and private establishments participating in the public hospital service (participant au service public hospitalier or PSPH) have had an annual operating budget, known as a global allocation. For their part, for-profit health establishments bill the health insurance scheme directly for fixed-rate services and procedures based on historical tariffs, which vary geographically and are negotiated with the ARS. Fixed charges for services are governed by national quantified objectives (objectif quantifié national or OQN) designed to regulate funding in relation to activity. These establishments already benefit from activity-based payments, based on variable regional tariffs rather than a single national tariff.[44] The remuneration of private hospitals not covered by an agreement depends on the activity of each establishment.

Patients are free to choose between public and private establishments, as the Assurance Maladie makes no difference as to the reimbursement of treatment because it is based on a single conventional tariff defined by the procedures performed and not by the location of the treatment. Excess fees are only more common in private establishments.

Private medical practitioners are either under convention with social security or not. When under convention, professionals apply the rate defined by social security (Doctors in Sector 1) or a free rate that remains measured (Doctors in Sector 2). Doctors who have not signed an agreement with social security are not covered by the convention and are free to charge

[41] See www.vie-publique.fr/fiches/37926-comment-les-soins-hospitaliers-sont-ils-finances accessed 5 May 2025.
[42] See www.legifrance.gouv.fr/jorf/id/JORFTEXT000048658374 accessed 5 May 2025.
[43] See www.ameli.fr/assure/remboursements/rembourse/hospitalisation-chirurgie#:~:text=Le%20montant%20du%20forfait%20hospitalier,d a%20%C3%A9institution%20of%20health%C3%A9 accessed 5 May 2025.
[44] See https://sante.gouv.fr/professionnels/gerer-un-etablissement-de-sante-medico-social/financement/financement-des-etablissements-de-sante-10795/article/financement-des-etablissements-de-sante accessed 5 May 2025.

higher fees that are taken care of in a very limited way by social security or, mainly, patients or their private insurance.[45]

Social security funds 70 per cent of the activities of biological laboratories. Over the last ten years, the structure of funding has changed slightly: the proportion paid for by households has increased by 1.3 points between 2012 and 2022.[46]

Social security reimburses biological analyses are reimbursed at a rate of 60 per cent, and up to 100 per cent for certain procedures.

11. How are the prices of such services determined? How is economic efficiency controlled?

National collective agreements in the private hospital sector determine the prices of healthcare[47] provided in private establishments, as well as salary levels for healthcare staff.[48]

Unlike public health establishments, private establishments and clinics are allowed to charge higher fees, provided they inform the patient.

National collective agreements also set tariffs with unions of certain categories of healthcare professionals, including medical doctors in private practice.

Economic efficiency is monitored by social security authorities in coordination, among others, with unions of the relevant healthcare professionals.

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

For a pharmaceutical product to be reimbursed by the French social security scheme, the pharmaceutical company must apply to the HAS. The opinion issued by the HAS Transparency Committee is then forwarded to the CEPS and the Union nationale des caisses d'assurance maladie (UNCAM). Based on the assessment of the medical benefit (service médical rendu or SMR) and improvement in medical benefit (amélioration du SMR or ASMR), UNCAM determines the reimbursement rate. There are four reimbursement rates for drugs:

- 100 per cent for drugs recognised as irreplaceable and expensive;
- 65 per cent for drugs with major or significant medical benefits;
- 30 per cent for drugs with moderate medical benefits and certain magistral preparations; and
- 15 per cent for drugs with a low medical benefit.

Reimbursable medicines must then be included on the 'list of medicines reimbursed by social

[45] See www.ameli.fr/medecin/exercice-liberal/vie-cabinet/convention-secteurs-adhesion/secteurs-conventionnels#:~:text=Ce%20secteur%2C%20dit%20conventionn%C3%A9%20%C3%A0,aux%20m%C3%A9decins%20de%20secteur%201) accessed 5 May 2025.

[46] See https://drees.solidarites-sante.gouv.fr/sites/default/files/2023-11/Fiche%2012%20-%20Les%20laboratoires%20de%20biologie%20m%C3%A9dicale.pdf accessed 5 May 2025.

[47] See www.legifrance.gouv.fr/conv_coll/id/KALICONT000005635813 accessed 5 May 2025.

[48] See www.legifrance.gouv.fr/conv_coll/id/KALITEXT000005659975/?idConteneur=KALICONT000005635813&origin=list accessed 5 May 2025.

security', which is set by ministerial decree.

In the case of medical devices reimbursement by the French social security scheme is also subject to their inclusion on a list drawn up on the basis of advice of a commission of the HAS.[49] To obtain reimbursement for their medical devices for individual use, manufacturers must, after obtaining the Conformité Européenne (CE) mark, submit reimbursement applications to two bodies which carry out additional assessments: the commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDiMTS), a specialist commission of the HAS; and the CEPS, which is responsible for setting a reimbursement rate or a maximum sales price with manufacturers. Registration on the list of reimbursable products and services (liste des produits et prestations remboursables or LPPR) is carried out either by means of a generic description of all or part of the product concerned, or in the form of a brand or trade name.

It should be noted that certain medicines or medical devices may be delisted by decision of the Ministry of Health on the basis of recommendations from the HAS, health insurance scheme and pharmaceutical industry. For instance, since 1 January 2021, homeopathic medicines and homeopathic magistral preparations (préparations magistrales homéopathiques or PMH) have no longer been reimbursed by the French social security scheme.

Mutual insurance companies may then reimburse the portion not covered by social security, depending on the contract chosen by the policyholder.

In the case of expensive, rare or time-consuming procedures, doctors must first complete a claim form for them to be reimbursed. These include certain drugs (expensive or currently being tested); or certain medical devices. The caisse primaire d'assurance maladie then decides whether or not to reimburse them. In that respect, most orphan drugs are reimbursable.

Early access products may also be reimbursed on a derogatory basis

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

A framework agreement signed between the Leem and CEPS specifies certain conditions or specific procedures for setting drug prices. Prices are determined by an agreement between each company and the pricing authority (CEPS). Once negotiations between the company and CEPS have been completed, they sign an agreement specifying prices, discounts and other specific conditions, where applicable. Prices are only set unilaterally in the absence of such an agreement. More precisely, the reimbursement and price-setting process is carried out by two separate bodies: the HAS Transparency Committee and CEPS. The Transparency Committee determines whether or not a drug is reimbursable. Following review by the Transparency Committee, the CEPS sets the price of the drug.

Different price-setting criteria are defined in Article L162-16-4 of the French Social Security Code. These take into account the length of time the medicinal product in question has been registered; the net price of the medicinal product and of medicinal products with the same therapeutic purpose; the purchase price recorded for the medicinal product and for medicinal products with the same therapeutic purpose by health establishments or wholesale or retail distributors, taking into account discounts, rebates and commercial and similar financial

[49] Art L 161-5 of the Social Security Code.

advantages of any kind, including remuneration for services; the net cost of the medicinal treatment covered by compulsory health insurance; the amounts reimbursed; and the existence of lower prices, after the deduction of various discounts or taxes in force, in other European countries whose total market size is comparable and whose list is set by decree.

There are various categories of discounts, which are set out in the Social Security Code (Article L162-18 of the Social Security Code). For example, companies that operate, parallel import or parallel distribute one or more pharmaceutical specialities reimbursable by social security may collectively undertake, under a national agreement, to grant the national health insurance fund a discount on all or part of the sales of these specialities generated in France.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

In practice, most disputes concerning healthcare financing and drug reimbursement concern: (1) the setting of prices at which drugs or medical devices are sold to the public; and (2) whether or not the product is reimbursed by the health insurance system.

In most cases, the decision to set the price is the result of a bilateral agreement between the CEPS and the company operating it. However, and as mentioned above, in the absence of an agreement, CEPS sets the price unilaterally. The price is set on the basis of several criteria: improvement in the medical service rendered, price of drugs with a similar therapeutic objective and so on.

Decisions taken by CEPS can therefore be challenged by companies marketing the product in question. For instance in a recent ruling, the French Conseil d'Etat annulled a CEPS decision setting the reference price of a product, considering that CEPS had committed an error of assessment in setting the price (Conseil d'Etat, 11 February 2022, No 446426).

The reimbursement of a product by the social security scheme is also the subject of significant litigation.

As mentioned above, certain drugs are reimbursed by social security if they are included on the list provided for in Article L 162-17 of the Social Security Code. Inclusion on this reimbursement list is based on a number of criteria (notably medical service in relation to other available drugs, the drug's efficacy and adverse effects, the seriousness of the condition for which it is intended, etc).

Ministerial decisions refusing to include a drug on the list of reimbursable drugs are frequently challenged by the companies marketing these drugs. However, Ministers have a wide margin of appreciation in refusing to include a drug on this list. For instance, the Conseil d'Etat very recently ruled that a drug intended to treat serious illness and benefiting from a marketing authorisation could be excluded from this list if it had adverse effects and if there was insufficient proof of its efficacy (Conseil d'Etat, 1st Chamber, 30 December 2024, No 489134).

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes or trends for healthcare financing and reimbursement, and briefly indicate how these may foreseeably affect the medical sector in the near future.

The Social Security Financing Bill for 2025[50] was presented to the Council of Ministers on 10 October 2024. However, following the National Assembly's rejection of the text on 4 December 2024, and the Government's censure, the Social Security Financing Bill for 2025 is currently still under discussion (as of the date of drafting this French Chapter, that is, 27 January 2025). It will be up to the new government to adopt the text or propose a new one.

The Social Security Financing Bill for 2025 provided for an increase in the national health insurance spending target budget to €263m. There were also plans to improve mental healthcare and setting limits to the sharing of medical practices through telehealth with certain non-medical healthcare professionals.

In addition, the medical agreement for 2024–2029[51] has been signed and the first pricing measures were implemented from 22 December 2024.

[50] See www.assemblee-nationale.fr/dyn/17/dossiers/plfss_pour_2025 accessed 5 May 2025.
[51] See www.assurance-maladie.ameli.fr/presse/2024-12-05-cp-deploiement-convention-medicale accessed 5 May 2025.