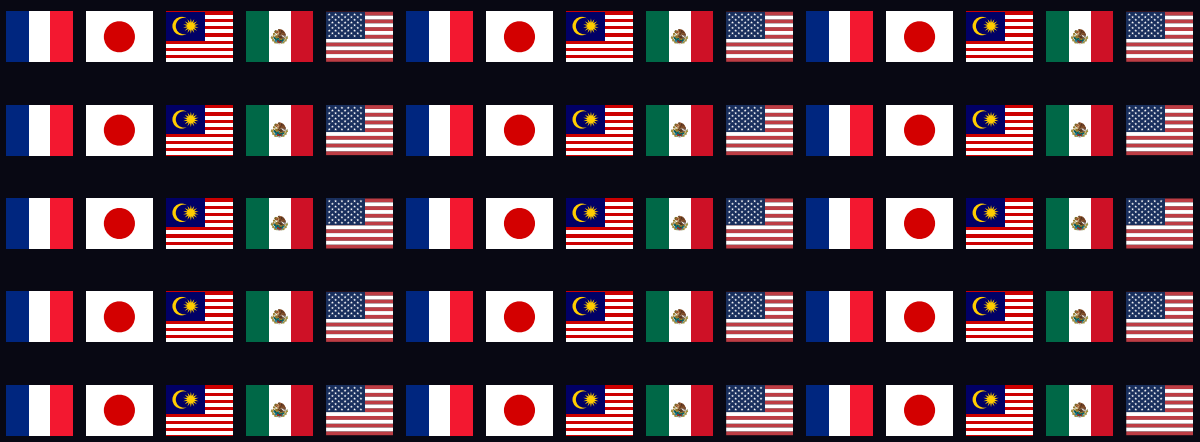
HEALTHCARE ENFORCEMENT & LITIGATION

France



LEXOLOGY
Getting The Deal Through

Consulting editor
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Healthcare Enforcement & Litigation

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Quick reference guide enabling side-by-side comparison of local insights into the applicable regulatory, enforcement and litigation framework (for pharmaceutical products and medical devices, relationships between healthcare professionals and suppliers, and healthcare delivery); private enforcement, cross-border enforcement and extraterritoriality; and recent trends.

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OVERVIEW

Healthcare funding

In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The French healthcare system is based on universal health protection. Every individual who lives or works in France benefits from the total or partial reimbursement of medical costs, whether or not they contribute to social security.

Both public and private operators – including state and local communities, social security, complementary health cover organisms of the private sector, and individuals – contribute to healthcare funding.

Schematically, the state principally contributes to prevention, healthcare professionals' training and the care of individuals in precarious situations. The other funders mostly contribute to the Consumption of Medical Goods and Care, which includes major risks (eg, hospitalisation and long-term disease) and is principally funded by social security, and minor risks (eg, optic and audio prostheses) supported by private complementary health cover organisms. The remaining part is at the expense of patients.

Indirectly but significantly, private initiatives also play an indirect but significant role in healthcare funding, notably through the financing of research, product innovation and the development of private clinics.

Complementary health cover from the private sector is optional, but allows more comprehensive reimbursements of medical costs considering that the reimbursement of medical acts and health products by social security is subject to the medicine, medical devices or medical acts being included in lists created by the Ministry of Health. Inclusion on these lists depends on the product's or act's therapeutic rating evaluated by the Commission of the High Health Authority (HAS).

Law stated - 18 July 2023

Delivery

In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare is delivered in healthcare facilities (ie, hospitals or private practices) of variable capacity and competencies. In 2020, there were around 2,983 facilities, including 1,342 that were state-owned, 667 run by private non-profits and 974 with private owners. Healthcare facilities are subject to different laws and regulations regarding their financing, organisation and activity depending on their status (eg, public hospitals are subject to specific obligations under public tender regulations).

Delivery of healthcare involves different professions with regulated scopes of intervention, for example, doctors, pharmacists, nurses and at-home care services. The Public Health Code (CSP) and specific nomenclatures determine the acts that can be performed by each professional (eg, doctors have a monopoly over diagnosis, treatment and certain medical acts).

Law stated - 18 July 2023

Key legislation

Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

In France, most legislation is gathered into codes. The main legislation governing healthcare is codified in the CSP. This contains both statute law and regulatory provisions governing the professions and the healthcare facilities that are entitled to deliver healthcare or medical goods, as well as the rules applying to healthcare products, healthcare industries and operators, and the relationships between these actors and healthcare professionals – notably regarding transparency and anti-kickback rules.

Other provisions can be found in the Social Security Code, the Public Procurement Code (which entered into force in April 2019), and in commercial, civil and penal codes respectively for commercial matters, contracts and liability and criminal offences.

Key principles and legislation often result from European legislation, notably regulations and directives applying to clinical trials, medicinal products, medical devices and related good practices. French law also provides national rules specific to the French system.

Soft laws (ie, rules that are not legally binding but may be indirectly enforceable) setting standards of conduct or rules of good practice issued by the Ministry of Health and competent agencies (in particular, those issued by the National Agency for the Safety of Medicines and Health Products (ANSM) and HAS) must be taken into account as well.

Law stated - 18 July 2023

Responsible agencies

Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Ministry of Health is primarily concerned with the enforcement of laws and regulations applicable to the delivery of healthcare, and supervises the implementation of the national health policy through the French Health General Directorate (DGS) and the French General Directorate for Health Services. Responsibility for enforcement is shared with administrative bodies, which are provided with powers of control and sanctions for this purpose, notably:

- regional health agencies: these are in charge of controlling hospitals as well as the work of healthcare professionals;
- regional prefects: these officials oversee local applications of the national health policy;
- health insurance funds: these notably register practitioners and audit activities if fraud is suspected;
- professional organisations (eg, the National Council for Doctors Order and National Council for Pharmacists Order): these ensure healthcare professionals meet ethical obligations; and
- the Office of the Prosecutor: this investigates allegations of criminal offences, at its initiative or following an alert from an above-mentioned stakeholder.

Other agencies, such as HAS, also contribute to enforcement via certifying healthcare facilities and professionals, and quality controls.

Law stated - 18 July 2023

Scope of enforcement

What is the scope of their enforcement and regulatory responsibilities?

These administrative bodies oversee and control the delivery of healthcare by, for instance, granting authorisation.

They contribute to enforcement by issuing interpretative guidelines, offering support to physicians, investigating when

malpractice is suspected and taking appropriate measures if needed (eg, suspensions or withdrawal of the right to practise medicine).

Within the agencies, qualified units conduct investigations into possible breaches of applicable laws and regulations. Depending on the findings, agencies may use their powers of sanction and inform the Office of the Prosecutor of possible breaches of criminal law. The Office of the Prosecutor has a dedicated section responsible for investigating and prosecuting criminal offences related to public health.

Law stated - 18 July 2023

Regulation of pharmaceutical products and medical devices

Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The principal agency in charge of regulating pharmaceutical products and medical devices is ANSM. This is a public establishment under the supervision of the Ministry of Health and entirely funded by the state.

Pursuant to article L5311–1 of the CSP (amended in July 2022), ANSM is notably responsible for the regulation and supervision of:

- medicines;
- contraception and abortion products;
- medical devices and their accessories;
- products with no medical purpose listed in Annex XVI of Regulation (EU) 2017/745;
- in vitro diagnostic medical devices and their accessories;
- biological products including labile blood products; organs, tissues, cells and products of human or animal origin, including when removed during surgery; cellular products for therapeutic use; and breast milk collected, qualified, prepared and stored by milk banks);
- certain processes and devices intended for the specification of premises and vehicles;
- cosmetic products;
- micro-organisms and toxins mentioned in article L5139-1;
- tattoo products;
- certain types of software that are not medical devices and that are used by medical biology laboratories for the management of medical biology examinations and during the validation, interpretation, appropriate communication and archiving of results;
- devices for non-strictly medical use used in medical biology laboratories for carrying out medical biology examinations; and
- stools approved by the establishments or organisations designated in article L513-11-1 and intended for the manufacture of a drug.

Other institutions play a significant role, notably HAS, the Economic Committee for Health Products (CEPS) and the High Council for Public Health (HCSP).

Law stated - 18 July 2023

Scope of enforcement

What is the scope of their enforcement and regulatory responsibilities?

ANSM authorises clinical trials and the marketing of products where required by law, controls advertising, and conducts some inspections, notably on manufacturing sites. It also centralises vigilance data and controls products' benefits-to-risks ratios. For this purpose, ANSM has legal powers to verify and sanction breaches of compliance with applicable law, notably health policing powers. ANSM collaborates with other state agencies and European bodies.

The general director of ANSM has specific missions, one of the most important being the issuance of rules of good practice in the fields of manufacturing, laboratory practices, distribution and vigilance, and the adoption of health policing decisions.

Regarding other institutions, HAS conducts medico-economic evaluations prior to reimbursements and pricing (which is set by CEPS), assesses professional practices and takes part in the organisation of healthcare delivery. The Ministry of Health also plays a role and is assisted by HCSP, which has very specific expertise.

Law stated - 18 July 2023

Other agencies

Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Ministry of Economy, through the General Directorate for Competition, Consumption and Fraud Repression, has jurisdiction over health product-related cases, as do the Competition Authority, the Nuclear Safety Authority, the Organisations for the Collection of Social Security and Family Benefit Contributions, and prosecutors, among others.

Law stated - 18 July 2023

Simultaneous investigations

Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

As long as agencies act within their respective legal frameworks, they can conduct investigations simultaneously and independently. It may happen that different aspects of the same case are investigated several times. An agency can also inform or mandate another on a matter falling under the other's scope of competency. Collaboration may be organised by law (eg, new anti-kickback laws oblige stakeholders to share information).

For instance, in a recent major case concerning implantable medical devices that were suspected to be defective, while ANSM was completing an investigation, DGS mandated HAS' National Commission for the Evaluation of Medical Devices and Health Technologies to reassess the products.

The Prosecutor's Office may decide to investigate a case as well. Such investigations do not prevent the administration from imposing sanctions (article L5312–2 of the CSP expressly supports this).

In an important recent case, ANSM notified a potential criminal offence to the Prosecutor's Office for the purpose of investigation under criminal law in addition to its own instruction from a regulatory compliance angle.

Agencies are permitted to reach different conclusions when completing a parallel investigation.

Law stated - 18 July 2023

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

What powers do the authorities have to monitor compliance with the rules on drugs and devices?

French law provides authorities with wide-ranging powers to monitor regulatory compliance, notably health policing and administrative powers. Health product suppliers can be investigated and be subject to on-site inspections. If a company refuses access to its premises, the visit has to be authorised by a judge and is conducted under his or her supervision. A decision allowing a visit can be appealed.

Article L1421–3 of the Public Health Code (CSP) lists inspectors' prerogatives during an on-site inspection by the National Agency for the Safety of Medicines and Health Products (ANSM), which include:

- collecting, on-site or upon request, all information, justification and necessary documentation with regard to the inspectors' objectives;
- obtaining communications by seizing all documentation from any person, provided it is potentially useful for the inspection;
- accessing all software and data (including communications where necessary);
- collecting samples for analysis; and
- accessing individual medical data (this power is restricted to inspectors that have valid medical licences).

Legal rights and procedural guarantees balance these powers and protect the rights of companies and individuals. The administration must comply with the contradictory principle (ie, the obligation, prior to any decision or pleading, to inform its opponent of its intention, and to allow the opponent to share his or her position, defences and evidence). In an emergency situation, the contradictory phase can be bypassed.

Law stated - 18 July 2023

Investigation time frames

How long do investigations typically take from initiation to completion? How are investigations started?

Investigations may result from new data communicated to ANSM, such as vigilance events, deviations found during an inspection, or requests to investigate matters from the Ministry of Health, the European Union or other competent agencies. A complaint or denunciation from patients or competitors, which are often made anonymously, may also lead to investigations.

Every year, ANSM sets out inspection programmes, which are often sector focused. This reveals ANSM's priorities but does not bar it from investigating other sectors, matters or companies. Inspections may be announced or carried out without notice or after a very short notice period.

The duration of an investigation depends on its nature, the collaboration of interested parties, and the complexity and sensitivity of the case. On-site inspections generally take a few days, but the decision process is much longer and can take months. Except for emergencies, when it is necessary to act without delay, agencies allow a reasonable period of time for interested parties to present their observations and may discuss these observations with the parties. They may also issue some requests that can lengthen the duration of the procedure.

Law stated - 18 July 2023

Access to investigation materials

What rights or access does the subject of an investigation have to the government investigation files and materials?

The inspection report is a key element of a proceeding. This gathers all the elements noticed during the inspection and substantiates the authority's decisions. Save in duly substantiated cases of urgency, the contradictory principle must be respected. Accordingly, inspectors must keep written minutes of on-site inspections, signed by all stakeholders (refusal by the investigated entity to sign is mentioned in the minutes). Moreover, authorities must provide a preliminary report and grant a reasonable delay, of not less than 15 days, to the investigated company to present its own observations. Except in restricted cases, the administration must also provide the investigated company with the elements supporting its decision or a projected decision.

If the administration refuses to grant access to documentation, the request can be transmitted to the Commission for Access to Administrative Documents and an appeal can be raised based on the Commission's opinion.

With regards to ongoing criminal procedures, French law allows an incriminated person's constituted attorney to access the procedure's files. This right is strictly limited to the incriminated person's lawyer and cannot be extended to third parties.

Law stated - 18 July 2023

Investigations abroad

If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

French criminal law addresses extraterritoriality and allows the Prosecutor's Office to conduct some investigations of foreign manufacturers.

The French authorities investigate foreign entities as well, including manufacturing sites of products intended for importing into France (subject to ANSM's authorisation) and distributors or sub-contractors, notably with regard to quality control and vigilance requirements. ANSM may require documentation from foreign manufacturers.

In 2021, 623 inspections (compared to 441 in 2020) were carried out by ANSM, 2 per cent of which were carried out abroad.

French authorities cooperate with foreign agencies to conduct on-site investigations.

Law stated - 18 July 2023

Enforcement proceedings

Through what proceedings do agencies enforce the rules?

Administrative bodies can use their policing powers to investigate companies and take decisions to protect public health.

In this respect, an agency can conduct on-site inspections and require, if necessary, the assistance of the police to this end, and can sanction a company found to be in breach of the rules, often providing a company with the opportunity to present its observations according to the contradictory principle (which does not apply if public health concerns justify acting without delay). The decision can be appealed before an administrative court.

Criminal proceedings are initiated and directed by the Office of the Prosecutor against individuals or companies, who are represented by their legal representatives. A prosecutor cannot sanction a company: the case has to be ruled on by a criminal court, and the convicted party may raise an appeal before the Court of Appeal.

Law stated - 18 July 2023

Sanctions

What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

Measures vary, from injunctions to comply with the rules to sanctions such as fines and suspension of authorisations or rights.

Article L5312–1 et seq of the CSP notably allow ANSM to submit to specific conditions or suspend, among others, clinical trials, manufacturing, preparation, importation, exploitation, distribution, marketing, promotion and delivery of a product that is suspected of presenting (under normal conditions of use or within predictable conditions of use) a danger to human health or that does not comply with legal and regulatory requirements. A suspension can cover any of the company's activities. Such a decision may be published on the ANSM's website and shared with other authorities (eg, the Economic Committee for Health Products (CEPS)) and can be appealed.

In criminal proceedings, a company may be exposed to significant fines of up to five times those applicable to individuals. Complementary sanctions on the company may also be taken, such as its dissolution, exclusion from public tenders or publication of a decision in certain locations (eg, within the company's offices or its website, or on sales sites).

Law stated - 18 July 2023

Actions against employees

Can the authorities pursue actions against employees as well as the company itself?

Actions against employees, in parallel with actions against their employer, are possible under French law but are subject to conditions. This doctrine of parallel action is particularly sensitive as it often requires employees to build their own defences separately from the company.

A company's directors (and responsible pharmacists in pharmaceutical companies) and their delegates are usually the first to be affected by parallel action. How power is delegated within the company is thus a key element in identifying liability and qualifying fault. Judges decide if a delegate meets all the requirements to be rendered liable.

As healthcare professionals are subject to codes of ethics, responsible pharmacists, as well as other doctors and pharmacists working within a company, can also be sanctioned by their professional organisations.

Law stated - 18 July 2023

Defences and appeals

What defences and appeals are available to drug and device company defendants in an enforcement action?

During administrative proceedings, parties have the chance to present their observations, except in the exceptional circumstances of emergencies. In any case, defendants have the ability to formally address the authorities with their

defences, should the procedure not respect rules or be questionable.

In cases where an administrative decision is issued, the interested party can attempt an amicable recourse. If the defendant does not receive any reply within two months, or if its demand has been rejected, an appeal may be raised before the competent administrative court. In cases of duly substantiated urgency and manifest legal defect of the decision, the company can also introduce a summary procedure to request the suspension of the decision until a judge rules on the merits. In any case, to get the decision annulled, the company must prove its unlawfulness, demonstrating that the decision is vitiated by form (eg, there is a lack of competency of the authority or a lack of motivation for the decision) or because of its content (eg, a misinterpretation of the facts or misapplication of the law). Administrative appeals and claims must begin within strict legal deadlines (usually two months). Claims for damages are possible as well, subject to the demonstration of harm or loss due to an unlawful decision by an administrative body.

Professional bodies' ethical proceedings are also subject to procedural rules and guarantees and can thus be appealed. An appeal can be raised before the organisation's national chamber should sanctions not comply with applicable rules.

In cases of criminal proceedings, the company can appeal each procedural decision before the competent instruction court and defend itself before the competent criminal court on the merits (ie, request that a judge rule on the case).

Law stated - 18 July 2023

Minimising exposure

What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Usually, when an enforcement action is initiated, the company has a very limited time to set up its defence, and inspectors expect quick and unequivocal answers. It is thus advisable to be prepared for such actions. This means that procedures and responsibilities at both the entity and group level must be clearly identified and documented. Training and simulations may help the company's readiness to face such actions. Based on our experience, lack of preparation can be detrimental to the company.

Once an action starts, the company should mandate a team – including staff responsible for regulatory, legal and business aspects of the company's operations – to internally investigate the case without delay. Involving attorneys at the very beginning of the internal investigation (especially where criminal proceedings may be, or have been, initiated) is advisable to assess and, if necessary, minimise risk and to benefit from legal privilege, as in France, correspondence with in-house lawyers is not protected.

The preparation of the defence must also consider the risk of exposure in the media from the very beginning of the case, especially in sensitive cases.

Within pharmaceutical companies, according to the pharmacist ethical code, pharmacists must maintain trustful relationships with authorities and allow inspectors to complete their investigations. Violations of this obligation are punishable by sanctions. Experience of ANSM investigations demonstrates that inspectors appreciate efforts to cooperate.

Law stated - 18 July 2023

Recent enforcement activities

What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Owing to recent critical liability cases and scandal within the sector of implantable medical devices (called 'implant files'), authorities have reinforced their control over health products considered to be at risk.

The latest sanctions were sanitary police decisions issued to companies marketing products as 'cosmetic' when those products legally fall under the qualification of medicinal products, ordering the suspension of the importation or exportation, placing on the market, distribution, advertising and use of such products and issuing injunctions to various sites requiring them to comply with the law.

In the future, ANSM intends to strengthen financial sanctions in the case of non-compliance with the regulation, notably in matters of supply disruptions and vigilance.

Law stated - 18 July 2023

Self-governing bodies

Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

In France, the pharmaceutical, medical devices, and cosmetics sectors have active industry associations. Major associations include LEEM for drug companies, SNITEM for the medical devices sector, SIDIV for in-vitro diagnostic medical devices, COMIDENT for the dental sector, and FEBEA for cosmetics.

These groups all issue recommendations and police their members through charters and codes of conduct that those working in the industry and companies commit to comply with (eg, the LEEM Professional Deontological Provisions).

Furthermore, international codes of conduct may apply to member companies (eg, those of the European Federation of Pharmaceutical Associations and Industries, and MedTech).

Sanctions, from reprimands to exclusion, may be taken, but remain rare.

Law stated - 18 July 2023

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

Independence is one of the key principles of medical ethics. It commands doctors to refuse anything (eg, remuneration, gifts or other benefits) that might compromise their judgement in favour of a supplier of products or services. Professional orders can sanction healthcare professionals who disrespect these professional duties.

The French anti-kickback law notably prohibits healthcare professionals (as well as students intending to qualify as healthcare professionals, healthcare professionals' associations and public officials within health authorities and agencies) from obtaining, directly or indirectly, advantages from companies marketing health products listed and persons performing health services. French law penalises these companies and those offering such advantages. However, this principle has exceptions, which are detailed in the Public Health Code (CSP) and are strictly interpreted. For example, remuneration for a service is not considered an advantage and may thus be acceptable under certain circumstances detailed in the CSP.

Financial relationships between healthcare professionals and suppliers of products and services may also fall under the scope of general criminal law provisions, in particular, those dealing with corruption and bribery.

The transparency regime obliges life science companies to disclose certain information on these financial

relationships and the advantages granted.

Law stated - 18 July 2023

Enforcement

How are the rules enforced?

Any agreement concluded with a healthcare professional, including payment or any advantage granted, must be submitted to the relevant professional body prior to granting the advantage or performing the service, and made public through a specific portal.

In the event of a breach of the rules on financial relationships and reporting requirements, both parties can be sanctioned with prison sentences (two years for the offeror and one year for the beneficiary) and significant fines (€150,000 for the offeror, and €75,000 for the beneficiary, plus 50 per cent of the expenses incurred by the practice constituting the offence – the beneficiary's fine may be five times higher for a company).

Professional organisations may also suspend healthcare professionals' licences to practice for up to 10 years.

An important case was ruled in 2023 in the medical devices sector involving a €6.6 million sanction, divided into a €1.13 million fine and a criminal seizure of €5.4 million (Tribunal Judiciaire of Dijon, 27 January 2023, Cases No. 2023/62 and No. 2023/63). Several investigations are ongoing, which may lead to more sanctions.

Law stated - 18 July 2023

Reporting requirements

What are the reporting requirements on such financial relationships? Is the reported information publicly available?

Reporting requirements include the following:

- Notification of contracts to healthcare professionals' organisations prior to implementation. New legislation (Ordinance No. 2017-49) reinforces the control of financial relationships by requiring prior authorisation should the value exceed a certain amount. This amount will be defined by the application decree, which has not been passed yet.
- Publication of conventions by the entity granting remuneration or advantages (including details of remuneration and advantages exceeding €10) through a dedicated portal. This data is made available on the Health Transparency Database, a public website.

Law stated - 18 July 2023

REGULATION OF HEALTHCARE DELIVERY

Authority powers

What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

By law, the opening of a healthcare facility is subject to specific authorisation being granted by the territorially competent regional health agency (ARS) that would have powers of control upon the facility's operation (articles L6122–1 et seq of the Public Health Code (CSP)). An ARS can conduct inspections and is granted wide powers in this

regard.

The Ministry of Health and the Commission of the High Health Authority also perform controls based on indicators jointly defined with the General Inspection Body of Social Affairs. Controls are delegated to ARS agents regarding infection events and patients' medical files held by clinical practices.

If a complaint is made, professional organisations can ask healthcare professionals for information to assess their practices' compliance with deontological rules. They do not have any specific investigation powers. Professional organisations apply the rules of administrative proceedings.

In the case of criminal proceedings, a prosecutor has the right to perform investigations that are delegated to police agents and officers (including raids under the supervision of a judge and the collection of data and any available document or information).

Law stated - 18 July 2023

Investigation time frames

How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The duration of investigations into healthcare professionals varies from months to years, depending on the number of incriminated people and the complexity of the case.

Investigations can be based on a complaint from a competent authority, a ministry or a patient.

Law stated - 18 July 2023

Access to investigation materials

What rights or access does the subject of an investigation have to the government investigation files and materials?

The inspection report is a key element of a proceeding. This gathers all of the elements noticed during an inspection and substantiates the authority's decisions. Save in duly substantiated cases of urgency, the contradictory principle must be respected. Accordingly, inspectors must keep written minutes of on-site inspections, signed by all stakeholders (a refusal by the investigated entity to sign is mentioned in the minutes). Moreover, authorities must provide a preliminary report and grant a reasonable period, of not less than 15 days, to the investigated company to present its own observations prior to releasing its decision. Except in restricted cases, the administration must also provide the investigated company with the elements supporting its decision or projected decision.

Under certain conditions, the subject of an investigation may request to be supplied with the administrative documents. If the administration refuses to grant access to the requested documentation, the subject of the investigation can ask for a position from the Commission of Access to Administrative Documents. If the administration persists in refusing to supply the documents, in spite of the Commission ruling in favour of the subject, the subject may ask for a ruling from an administrative court as recourse.

With regard to ongoing criminal procedures, French law allows an incriminated person's constituted attorney to access the files regarding the procedure. This right is strictly limited to the incriminated person's lawyer and cannot be extended to third parties.

Law stated - 18 July 2023

Enforcement agencies

Through what proceedings do agencies enforce the rules?

At the end of the contradictory proceeding, administrative bodies can enforce the rules by making decisions on the basis of the inspection's results that must be applied by hospitals (except in the case of a public health threat, article L6122–13–1 of the CSP). An ARS director can deliver an injunction on a hospital requiring it to comply with legal requirements, or even suspend its authorisation to perform patient care.

Regarding healthcare professionals, professional bodies can enforce the rules by taking administrative judicial decisions following administrative proceedings.

Law stated - 18 July 2023

Sanctions

What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

If a deviation is found during an inspection, an ARS director can impose an injunction requiring a healthcare provider to comply with legal and regulatory requirements by a deadline. The director may even suspend or totally or partially withdraw authorisation to perform patient care. Such administrative decisions can be challenged before a competent administrative court. If the ARS director finds no further compliance issues, he or she can decide to end his or her measures. Otherwise, the ARS director can make a final decision after getting an opinion from a Regional Health and Autonomy Conference (an advisory body that works alongside the ARS), which can be appealed.

Regarding healthcare professionals, professional bodies, following ordinal proceedings, can make disciplinary decisions as blame (warning), or suspension or withdrawal of the right to practise.

In criminal proceedings, a prosecutor will seek the imposition of financial penalties or imprisonment.

Law stated - 18 July 2023

Defences and appeals

What defences and appeals are available to healthcare providers in an enforcement action?

During administrative proceedings, parties have the chance to present their observations, except in the exceptional circumstances of emergencies. In any case, defendants have the ability to formally address the authorities with their defences, should the procedure not respect rules or be questionable.

In cases where an administrative decision is issued, the interested party can attempt an amicable recourse. If the defendant does not receive any reply within two months, or if its demand has been rejected, an appeal may be raised before the competent administrative court. In cases of duly substantiated urgency and manifest legal defect of the decision, the company can also introduce a summary procedure to have the decision suspended until a judge rules on the merits. In any case, to get the decision annulled, the company must prove its unlawfulness, demonstrating that the decision is vitiated by form (eg, there is a lack of competency of the authority or a lack of motivation for the decision) or because of its content (eg, a misinterpretation of the facts or misapplication of the law). Administrative appeals and claims must begin within strict legal deadlines (usually two months). Claims for damages are possible as well, subject to the demonstration of harm or loss due to unlawful decisions of the administrative body.

Professional bodies' ethical proceedings are also subject to procedural rules and guarantees and can thus be

appealed. An appeal can be raised before the organisation's national chamber should sanctions not comply with applicable rules.

In cases of criminal proceedings, the company can appeal each procedural decision before the competent instruction court and defend itself before the competent criminal court on merits (ie, request a judge rule on the case).

Law stated - 18 July 2023

Minimising exposure

What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Usually, when an enforcement action is initiated, the company has a very limited time to set up its defence, and inspectors expect quick and unequivocal answers. It is thus advisable to be prepared for such actions. This means that procedures and responsibilities at both the entity and group level must be clearly identified and documented. Training and simulations may help the company's readiness to face such actions. Based on our experience, lack of preparation can be detrimental to the company.

Once an action starts, the company should mandate a team – including staff responsible for regulatory, legal and business aspects of the company's operations – to internally investigate the case without delay. Involving attorneys at the very beginning of the internal investigation (especially where criminal proceedings may be, or have been, initiated), is advisable to assess and, if necessary, minimise risk and to benefit from legal privilege, as correspondence with in-house lawyers is not protected in France.

The preparation of the defence must also consider the risk of exposure in the media from the very beginning.

Within pharmaceutical companies, according to the pharmacist's ethical code, pharmacists must maintain trustful relationships with authorities and allow inspectors to complete their investigations. Violations of this obligation are punishable by sanctions. Experience of National Agency for the Safety of Medicines and Health Products investigations demonstrates that inspectors appreciate efforts to cooperate.

A strategy should also include the healthcare providers' insurers.

Law stated - 18 July 2023

Recent enforcement activities

What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Recently, most of the investigations conducted by authorities have concerned fraud in social security claims. Recent cases relate to private healthcare centres, especially in the optical and dental sectors.

Law stated - 18 July 2023

Self-governing bodies

Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Healthcare professionals (notably doctors, nurses, pharmacists and physical therapists) must be registered with a professional body or a competent authority. These organisations assess the compliance of their members'

professional practices with deontological rules. They can investigate complaints brought by patients or authorities and conduct administrative proceedings, potentially leading to sanctions such as blame (warning), suspension or withdrawal of the right to practice. Such decisions can be challenged before the competent courts.

Professional bodies can also bring complaints against healthcare professionals before a criminal court, in the case of criminal offences, and inform administrative authorities.

Law stated - 18 July 2023

Remedies for poor performance

What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Health authorities can request compliance with good practice and any other standard of certification. They can also request training, regular self-inspections and audits, and new inspections from their agents to verify compliance with applicable laws and regulations.

Regional health agencies and designated hospitals can also sign performance agreements relating to the improvement of patient care, attractiveness and operational effectiveness.

Law stated - 18 July 2023

PRIVATE ENFORCEMENT

Causes of action

What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Citizens can bring civil or administrative actions in cases of damage owing to a situation induced by non-compliance with healthcare regulations. Such damage can arise from the patient's medical care (eg, an error by a healthcare professional in the prescription of the treatment or the diagnosis – 'professional fault') or from the use of a medicinal product or a medical device. A citizen can also bring a claim before a Conciliation and Indemnification Commission (CCI) to get compensation from a designated person or, in cases of medical hazard, from a national compensation fund.

If a citizen suffers from an infringement of criminal law, he or she can also introduce a criminal action or become a party in a pending proceeding.

More informally, a citizen can inform administrative authorities of any violation of laws and regulations or alert the media.

Law stated - 18 July 2023

Framework for claims

What is the framework for claims of clinical negligence against healthcare providers?

According to article L1142–1 of the Public Health Code (CSP), the liability of healthcare providers, including professionals and the facility concerned, for activities involving diagnosis and care is fault based. Facilities are liable for damages due to nosocomial infections unless they prove the infection was caused by an external cause.

The CCI procedure was created to compensate patient's medical injuries should the patient's damages be serious enough. The patients only have to send a request form (Cerfa No. 12245*03) and provide supporting exhibits. An attorney is not mandatory for these proceedings. Expert investigations are then ordered and the case is heard by the CCI. If the CCI retains the liability of the healthcare professional, its insurer must offer the patient compensation for the damages within four months. Acceptance closes the case and the patient then loses his or her right to raise the claim before a court.

The patient can always bring his or her case before an administrative, civil or criminal court during CCI proceedings, or afterwards if they decline the compensation offer. The court in which a case is heard depends on the public or private status of the healthcare facility and the nature of the alleged fault. In most clinical negligence cases expert investigations are requested or ordered by a judge before a decision is made, to identify the circumstances of the incident and assess the patient's damages.

Law stated - 18 July 2023

Seeking recourse

How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Producers of pharmaceuticals and medical devices are responsible for damages caused by defective products or by a fault in a product.

A 'defective product' is one that does not provide the safety a user can legitimately expect when used as reasonably expected and following the information provided by the manufacturer (article 1245 et seq of the Civil Code). The manufacturer may be liable regardless of whether it complied with existing norms. However, if the default results from the imperative rule, then the producer cannot be held strictly liable.

Defective product liability does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as a fault or a warranty in respect of latent defects. Should regulatory and legal infringement not qualify as a defect, the claimant can always invoke a fault.

The burden of proof to show the product was defective, the producer was at fault, the injury, and the causal relationship between the product and damages, is on the patient. Expert investigations are usually ordered to provide the judge with details and explanations about the product and the causes of the damage, and to assess the damage.

Law stated - 18 July 2023

Compensation

Are there any compensation schemes in place?

There are no official compensation scales in place in France. However, this may change in the near future.

To date, some non-official scales are usually applied, such as that run by the National Office for Compensation of Medical Accidents, the Dinthillac Nomenclature, and a compensation scale based on the Courts of Appeal's case law. These do not bind judges, who remain free to go far beyond or below recommended compensation levels to fully compensate the prejudice, but as the scales reflect jurisprudence they provide defendants with relatively good estimations of legal risk.

Law stated - 18 July 2023

Class and collective actions

Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

The 2016 Touraine Law introduced class actions in the CSP with restrictive conditions (article L1143-1 et seq of the CSP). Class actions must be conducted by a patient association and must aim to exclusively compensate for physical injury, including mental injury. According to French tradition, no punitive damages can be ordered. To date, because of the specific requirements and the duration of proceedings, class actions have seen limited use in France. In 2022, for the first time in France, a class action was declared admissible (Tribunal judiciaire of Paris, 5 January 2022, Case No. 17/07001).

Rather, patients sue jointly but in their own name, which allows them to obtain compensation for all the prejudices they may have endured due to the use of drugs, devices or provision of care. In practice, joints actions may be coordinated by associations, and tend to look very similar to class actions.

Law stated - 18 July 2023

Review

Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

French law offers persons affected by a decision taken by a public institution, or a private institution invested with a public service mission, an administrative recourse if certain conditions are met. Depending on the nature of the initial procedure, an administrative judge can withdraw the institution's decision, modify its contents, and grant damages. There are no dedicated procedures concerning other decisions from private institutions.

Interested parties must demonstrate that the decision is vitiated by form or content, causes damages, or qualifies as a criminal offence to substantiate a claim.

Law stated - 18 July 2023

Whistleblowers

Are there any legal protections for whistleblowers?

The 2016 Sapin II Law introduced legal protection for whistleblowers into French law, subject to conditions related to their status, the procedure to be respected and the divulging of information being necessary and proportionate to the goal of protecting concerned interests.

If these conditions are respected, the whistleblower can benefit from:

- protection of his or her identity, which remains confidential;
- enhanced protection against sanctions his or her employer might take because of the alert; and
- penal irresponsibility (ie, immunity from prosecution) for disclosing information protected by law (this does not apply if the information relates to national defence, confidential medical information or privileged legal information).

Within pharmaceutical companies, responsible pharmacists have a legal obligation to alert the National Agency for the Safety of Medicines and Health Products, notably in the case of persistent disagreements with the company's management board on the application of legal and regulatory requirements aiming at protecting public health.

The trend is to enhance the protection of whistleblowers. The legal provisions have been completed in this sense by Law No. 2022-401 of 21 March 2022 , and its application Decree No. 2022-1284 dated 3 October 2022 .

Law stated - 18 July 2023

Does the country have a reward mechanism for whistleblowers?

The legal definition of 'whistleblower' implies that the person concerned must act with goodwill and without any interest other than protecting the public interest. Consequently, the French state and legal system does not financially reward whistleblowers. However, they can benefit from protection. Should they have been involved in a criminal act, they may also benefit from clemency (eg, a discharge or a reduction of a sentence).

Law stated - 18 July 2023

Are mechanisms allowing whistleblowers to report infringements required?

Under applicable law, reports of infringements must follow three steps:

1. The employee must make an internal report. Since January 2018, companies with more than 50 employees have a legal obligation to set up a dedicated whistleblowing procedure.
2. If the company does not respond, the whistleblower may alert the appropriate authority.
3. If the authority does not take any action or respond, a whistleblower may alert the public by any means.

In cases of serious and imminent risk, a whistleblower can go directly to steps (2) or (3).

Support in carrying out this process can be requested from an independent administrative authority, the Defender of Rights.

Prior consultation with an attorney is, of course, recommended.

Law stated - 18 July 2023

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Prosecutors and agencies do cooperate with their foreign counterparts, most strongly within the European Union where cooperation results from regulation. With other countries, bilateral treaties guarantee mutual recognition and assistance.

Law stated - 18 July 2023

Triggering investigations

In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

Enforcement activities by foreign authorities may require the participation of French authorities within the context of cooperation.

They may also lead to the opening of an investigation in France should the facts fall under the scope of French law, but, according to the principle of non bis in idem , the investigated party must not yet have been definitively sanctioned for the alleged act (article 113-9 of the Penal Code).

Legal pursuits are initiated by prosecutors who have the power to evaluate and decide whether to investigate, after receiving a complaint by a victim or an official denunciation from a foreign authority (article 113-8 of the Penal Code).

Law stated - 18 July 2023

Pursuing foreign entities for infringement

In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

French criminal law applies to acts committed totally or partially in French territory (including complicity) as well as acts committed by French nationals or on French subjects abroad. Some provisions expressly address the extraterritoriality of French healthcare law (eg, the rules of good practice of distribution). Therefore, foreign nationals' and companies' acts may fall under French healthcare law and they may consequently be fined.

Law stated - 18 July 2023

UPDATE AND TRENDS

Key developments of the past year

What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

Several texts recently entered into force in France, especially in the sector of medical devices.

A new charter governs the presentation, promotion and information relating to products that may be reimbursed for under the list of medical devices, products and services qualifying for reimbursement (the LPP list), similar to what already exists for medicines. Application texts and repositories are awaited.

The conditions for reimbursement of products of the LLP list have been revised, bringing major reforms in areas such as framing of the distribution margins, and reinforcement of controls on product requirements. Application texts are due before 2025.

One of the priorities of French authorities remains the enforcement of the new anti-kickback legislation passed in 2017 (Ordinance No. 2017-49), as the application texts, which were long-awaited by the sector, have been enacted. Investigations have started and the first important sanction has been made public (€6.6 million).

Another priority is the implementation of the new medical devices regulation (MDR), in the context of the particular attention that has been paid to the medical devices sector in France due to recent major scandals involving

manufacturers and the French authorities. Thanks to the recent revision of French law in that regard, the National Agency for the Safety of Medicines and Health Products has new powers to police deviations from the MDR and shall reinforce controls. Complementary application texts are expected to align the regulatory provisions with the new legal provisions.

Finally, the focus on supply disruption and SARS-CoV-2-related products remains a significant issue.

Law stated - 18 July 2023

Jurisdictions

France	LexCase
Japan	Mori Hamada & Matsumoto
Malaysia	Raja, Darryl & Loh
Mexico	OLIVARES
USA	Mintz