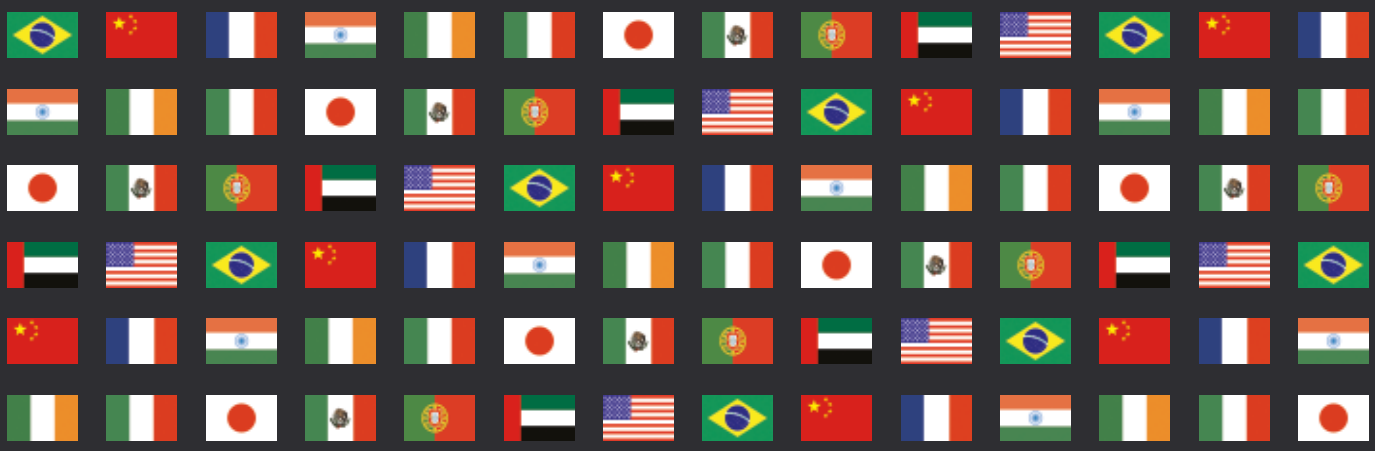
Healthcare Enforcement & Litigation 2021

Contributing editors
Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman



LEXOLOGY
Getting The Deal Through

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Skadden, Arps, Slate, Meagher & Flom LLP

Lexology Getting The Deal Through is delighted to publish the sixth edition of *Healthcare Enforcement & Litigation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on India.

Lexology Getting The Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.lexology.com/gtdt.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman of Skadden, Arps, Slate, Meagher & Flom LLP, the contributing editors, for their continued assistance with this volume.

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For further information please contact editorial@gettingthedealthrough.com

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France

Diane Bandon-Tourret and Victoire Storksen
LexCase

OVERVIEW

Healthcare funding

1 | 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 individuals.

Indirectly but significantly, private initiatives also play an indirect but significant role in healthcare funding, notably through finance of research, product innovation and 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 depend on the product's or act's therapeutic rating evaluated by the Commission of the High Health Authority (HAS).

Delivery

2 | 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 2015, there were around 3,089 facilities, including 1,389 that were state-owned, 691 run by private non-profits and 1,009 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 scope 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 monopoly over diagnosis, treatment and certain medical acts).

Key legislation

3 | 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 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 that entered into force in April 2019, as well as in commercial, civil and penal codes, respectively for behaviour in the market, contracts and liability, and criminal offences.

Key principles and legislation can result from European legislation, notably regulations and directives applying to clinical trials, medicinal products, medical devices and related good practices.

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

Responsible agencies

4 | 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 healthcare, and supervises the implementation of the national health policy through the French Health Directorate (DGS) and the French Directorate General for Health Services. Responsibility of enforcement is shared with administrative bodies, which are provided with powers of control and sanctions for this purpose, notably:

- regional health agencies: in charge of controlling hospitals as well as healthcare professionals' work;
- regional prefects: these officials oversee local applications of the national health policy;
- health insurance funds: these notably audit prescribers' activity if fraud is suspected;
- professional organisations (eg, 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 the above-mentioned stakeholders.

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

Scope of enforcement

5 | What is the scope of their enforcement and regulatory responsibilities?

These administrative bodies oversee and control the delivery of healthcare. 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 criminal offences related to public health and prosecuting.

Regulation of pharmaceutical products and medical devices

6 | 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 CSP, ANSM is notably responsible for regulation of medicines, contraception and abortion products, biomaterials and medical devices, in vitro diagnosis medical devices, cosmetics and tattoo produtcts, as well as software that are not medical devices but are used by biology laboratories and intented for helping to prescription or dispensation.

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

Scope of enforcement

7 | 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, 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 taking of decisions regarding cleanliness.

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. HCSP assists the Ministry of Health in its regulatory mission by providing its expertise.

Other agencies

8 | 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 does – among others – the Competition Authority, the nuclear safety authority, the union for the collection of social security contributions and family allowances, and prosecutors.

Simultaneous investigations

9 | 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 one on a matter falling under another's scope of competency. Collaboration may be organised by law (eg, new anti-kickback laws obliges 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's 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. Administrative proceedings do not prevent a prosecutor from investigating a case (article L5312-2 CSP expressly supports this).

Agencies are permitted to reach different conclusions from parallel investigations.

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

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

The Public Health Code (CSP) provides authorities with large powers to monitor regulatory compliance, notably health policing powers. Health products suppliers can be investigated, including on-site inspections (from 8am to 8pm). 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 CSP lists inspectors' prerogatives during an on-site inspection, which include:

- collecting, on-site or upon request, all information, justification and necessary documentation with regards to the inspectors' objectives;
- obtaining communications by seizing all documentation from anybody, as long 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 investigation authorities must comply with the principle of balancing these powers. The agency shall notably comply with the contradictory principle (ie, the obligation, prior

to any decision or pleading, to inform its opponent of its intention and to allow him or her to share its position, defences and evidence). In an emergency situation, the contradictory phase can be bypassed by an agency.

Investigation time frames

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

Investigations may result from new data communicated to the agency, such as vigilance events, deviations found during an inspection, or a request to investigate a matter 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, the National Agency for the Safety of Medicines and Health Products (ANSM) sets out an inspection programme that is 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.

Access to investigation materials

12 | 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, an appeal can be raised before the Commission of Access to Administrative Documents .

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.

Investigations abroad

13 | 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 investifations of foreing manufacturers.

The French authorities investigate foreign entities as well, including foreign sites manufacturing products intended for import 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 2085, ANSM inspected 677 sites, 6 per cent of which were abroad.

Authorities cooperate with foreign agencies to conduct on-site investigations.

Enforcement proceedings

14 | 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 that respect, an agency can conduct on-site inspections and require, if necessary, the assistance of the police to this end and 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 appealed before an administrative court.

Criminal proceedings are initiated and directed by the Office of the Prosecutor against individuals or companies, which 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 incriminated party may raise an appeal before the Court of Appeal.

Sanctions

15 | 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. 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 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) and can be appealed.

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

Actions against employees

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

Actions against employees are possible under French law, but are subject to restrictions. The employee must have intentionally committed an act of particular gravity that case law considers to be detached from their job functions. Case law generally considers crimes as detachable fault. This doctrine of parallel action is particularly sensitive, as it often requires an employee to build his or her own defence.

The company's directors (and the responsible pharmacist in pharmaceutical companies) and their delegates are usually the first to be affected by parallel action. Therefore, how power is delegated within the company is a key element to identify liability and qualify 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 be sanctioned by their professional organisations.

Defences and appeals

17 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 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 decision 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 the merit (ie, request a judge rule on the case).

Minimising exposure

18 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.

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.

Recent enforcement activities

19 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 recent scandal within the sector of implantable medical devices (called 'implant files'), authorities have reinforced their control, notably upon health products considered as a risk.

The latest sanctions were post-investigation injunctions issued to pharmaceutical companies to resolve discrepancies and suspensions of the marketing, distribution, importation and use of medical devices, including the recall of products. In 2020, ANSM notably suspended the opening authorisation of a pharmaceutical site on the ground that the responsible pharmacist was not granted with sufficient prerogatives and authority over the pharmaceutical activities, and suspended the marketing and distribution of a medical device that had lost its CE marking. ASNM also paid particular attention to cosmetics components and took a suspension decision in this sector as well.

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.

Self-governing bodies

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

In France, both the pharmaceutical and the medical devices sectors have active trade unions, as does dental and cosmetics industries. Major trade unions include LEEM for drug industrials, SNITEM for the medical devices sector, SIDIV for in vitro diagnostic medical devices, COMINENT for the dental sector, and FEBEA for cosmetics.

These groups all issue recommendations and police their members through charters and codes of conduct that industrials 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.

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

21 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, remunerations, gifts or other benefits) that might compromise their judgement in favour of a supplier of products and 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. The Public Health Code (CSP) penalises these companies and those offering such advantages. However, this principle has exceptions, which are detailed in the CSP and are strictly interpreted. For example, remuneration of a service is not considered an advantage and may thus be acceptable under certain circumstances detailed by 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 some information on these financial relationships and advantages granted.

Enforcement

22 | How are the rules enforced?

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

In breaches 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 – that fine may be five times higher for companies).

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

Reporting requirements

23 | 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 to be defined by the application decree that 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 a public website, Base Transparence Santé.

REGULATION OF HEALTHCARE DELIVERY

Authority powers

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

By law, the opening of healthcare facilities is subject to specific authorisation from the territorially competent regional health agencies (ARS), which has powers of control upon the facility's operation (article L6122-1 and seq Public Health Code (CSP)). 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).

Investigation time frames

25 | 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 of 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.

Access to investigation materials

26 | 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.

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With regard 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.

Enforcement agencies

27 | 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 CSP). The ARS director can deliver an injunction on a hospital requiring them to comply with legal requirements or even suspend its authorisation to perform patients' care.

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

Sanctions

28 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 identifies that there are no more compliance issues, he or she can decide to end his or her measures. Otherwise, the 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) that can be appealed.

Regarding healthcare professionals, professional bodies, following administrative proceedings, can make judicial decisions ordering blame, or a suspension or the withdrawal of the right to practise.

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

Defences and appeals

29 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 decision 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 the merit (ie, request a judge rule on the case).

Minimising exposure

30 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.

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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.

Recent enforcement activities

31 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. These investigations are mostly directed against healthcare professionals and do not concern healthcare facilities.

Self-governing bodies

32 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 professional bodies 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, or a suspension or the 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.

Remedies for poor performance

33 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 (ARS) and designated hospitals can also sign performance agreements relating to the improvement of patient care, attractiveness and operational effectiveness.

PRIVATE ENFORCEMENT

Causes of action

34 | 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 regulation. 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.

Framework for claims

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

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

The CCI's 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 administrative, civil or criminal courts during CCI proceedings, or afterwards if they did not accept the compensation offered. The court where the case is heard by 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.

Seeking recourse

36 | 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.

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. Civil Code). The manufacturer may be liable regardless of whether it complied with existing norms. However, if the default results from imperative rule, then the producer cannot be held strictly liable.

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

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

Compensation

37 | Are there any compensation schemes in place?

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

Class and collective actions

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

2016 Loi Touraine introduced class actions in the CSP with restrictive conditions (article L1143-1 CSP). Class actions must be conducted by a patient association and must aim to exclusively compensate 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.

Rather, patients sue jointly but through individual procedures, which allows them to obtain compensation of all the prejudices they may have endured due to use of drugs, devices or provision or care.

Review

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

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

Whistle-blowers

40 | Are there any legal protections for whistle-blowers?

2016 Loi Sapin II introduced legal protection for whistle-blowers into French law, subject to conditions related to their status, a 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 whistle-blower 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 and privileged legal information).

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

41 Does the country have a reward mechanism for whistle-blowers?

The legal definition of 'whistle-blower' implies that they must act from goodwill and without any interest other than protecting the public interest. Consequently, the French state and legal system does not financially reward whistle-blowers. 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).

42 Are mechanisms allowing whistle-blowers 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 whistle-blowing procedure.
2 If the company does not respond, the whistle-blower may alert the appropriate authority.
3 If the authority does not take any action nor respond, a whistle-blower may alert the public by any means.

In cases of serious and imminent risk, a whistle-blower can go directly to step (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.

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

43 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.

Triggering investigations

44 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 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 the foreign authority (article 113-8 Penal Code).

Pursuing foreign entities for infringement

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

French criminal law applies to the 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.

UPDATE AND TRENDS

Key developments of the past year

46 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?

New legislation was passed in July 2019 (Law No. 2019-774), reforming the organisation of healthcare delivery and supporting digital offering.

Furthermore, enforcement of the new anti-kickback legislation passed in 2017 (Order No. 2017-49) is one of the priorities, subject to publication of the application texts, which were expected early in 2020. The first application text regarding new proceedings was published in June 2020 (Decree No. 2020-730) and will be enforceable as of 1 October 2020. The healthcare sector continues to wait for the publication of the other application texts, notably those that will clarify the thresholds for authorisation of the advantages granted.

Another priority in 2020 was to be the implementation of the medical devices regulation (EU 2017/745), however it has been postponed to 2021 because of the covid-19 crisis.

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Due to recent major scandals and pending cases, the authorities are paying particular attention to the medical devices sector, especially in the matter of implants, and to vigilance systems. A focus on supply disruption has been observed as well.

Coronavirus

47 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

A specific and exceptional legal framework has been enacted in France (Law No. 2020-290) to allow for the management of the coronavirus crisis. Both administrative and judicial procedural timelines have been extended because of the shutdown of non-essential activities.

Medical devices, equipment and medicines were requisitioned or reserved to certain patients by law. Regarding market access, the Public Health Code allows, under specific conditions and upon authorisation of the National Agency for the Safety of Medicines and Health Products (ANSM), the marketing of medical devices without CE markings (R. 5211-19 CSP). Applications on this ground have been instructed by ANSM, which mostly preferred the path of clinical trial extensions.

In general, the agencies' activities have been affected (eg, ANSM has notably suspended part of its routine inspection programme and adapted its usual processes).

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