THE LIFE SCIENCES LAW REVIEW

EIGHTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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PREFACE

The eighth edition of *The Life Sciences Law Review* covers a total of 33 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year has seen a number of significant developments. Shortly after the publication date for this edition, the European Union will begin enforcing significant changes in the regulatory regime for medical devices. The United States is considering measures to improve the transparency of pricing for prescription drugs. The United Kingdom is addressing changes to drug regulatory systems that must accompany the country's withdrawal from the EU, and drug and device manufacturers are actively planning for the effects of Brexit on their supply chains. The governments in India and China continue to consider changes in their regulatory systems for drugs and medical devices.

It is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems, which govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this annual publication will be helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
February 2020

Chapter 12

FRANCE

Cécile Théard-Jallu and Xavier Vuitton[1]

I INTRODUCTION

France has a rather high-quality, strongly regulated, healthcare system that offers universal coverage for citizens, regardless of age or economic situation. It consists of an integrated network of healthcare professionals and pharmaceutical professions, hospitals or health and social care facilities (which can be either private or public) as well as a multidisciplinary ecosystem of other actors, including industry, financing and innovation support players or associations of patients.

It is administered by public policy at a national and regional level:

a the state directly finances and organises the delivery of health and social services;

b regional health agencies (ARS) manage and animate the healthcare system at a regional level, including health security, observation, prevention and promotion or the anticipation and management of sanitary crisis. They also have broad inspection-verification powers in three areas: health safety, how facilities and services are run, and medical procedures and practices; and

c some agencies are also involved in the regulation, including medical-economic aspects, of the health system in their respective fields of competence, such as the High Authority for Health (HAS), the National Agency for the Security of Health Products (ANSM), the Biomedicine Agency and the Digital Health Agency.

In 2018,[2] health expenses in France represented €203.5 billion (i.e., 1.5 per cent more than in 2017), with an average expense value of €3,037 per inhabitant. Therefore, the pressure put by regulatory authorities on costs is high.

French healthcare regulation is broadly in line with the EU framework with some specificities, for example the notion of 'exploitant' or a price reimbursement regime, that are detailed further below.

1 Cécile Théard-Jallu is a partner and Xavier Vuitton is of counsel at De Gaulle Fleurance & Associés.

2 Health related expenses in 2018 – French Ministry of Health's report. https://drees.solidarites-sante.gouv.fr/etudes-et-statistiques/publications/panoramas-de-la-drees/article/les-depenses-de-sante-en-2018-resultats-des-comptes-de-la-sante-edition-2019.

II THE REGULATORY REGIME

Medicines and medical devices are highly regulated in France throughout their life cycle (including R&D, manufacturing, distribution, pharmacovigilance, and advertising activities): while products' security and the safety of patients is under the scrutiny of the ANSM, products' performances are observed by the Ministry of Health and Social Security.

Although historically under a lesser control than medicines, which are subject to a prior marketing authorisation, medical devices now tend to be more tightly controlled with the EU Medical Device Regulations 2017/745 and 2017/746 of 5 April 2017 becoming compulsory in May 2020 and May 2022 respectively.

Medicines' and medical devices' legal regimes, though separate, are showing a number of similarities, such as in the advertising or price reimbursement domains.

Eligibility of medical products' reimbursement by the French social security system is assessed by the HAS while the Economic Committee for Health Care Products (CEPS) is in charge of negotiating reimbursement prices with rights holders, with the final decision made by the Ministry of Health. Owing to budgetary constraints and with the impact of new innovative products arriving on the market, French authorities tend to the reduction of reimbursement eligibility cases and prices.

The development of digital health and artificial intelligence is also becoming significant. For instance, on 12 April 2019, a first digital app, Moovcare,[3] has been pre-admitted by the HAS on the social security reimbursement list while the HAS recently issued new evaluation guidelines dedicated to publishers of AI-based products, which shall become final during the first half of 2020. In anticipation of those guidelines, on 7 February 2020 the HAS released its first opinion on a medical device operating a learning AI tool, admitting its moderate but effective improving effect on rendered medical service (i.e., in French an 'ASA III' level, the same as the one recognised by the Moovcare app) and pre-eligibility to social security coverage as well.[4]

i Classification

The definitions of medicines and medical devices are common to all Member States of the EU. French law is aligned on those principles.

In the same way, French law implements the EU principle under which a combination medicine/medical device product may either be regulated as a medicinal product or a medical device based on its primary mode of action. If the medicine and medical device do not form a single integral product, but rather are packaged together, then the two components will be regulated separately as a medicinal product and a medical device respectively.

The European Commission guidance on the borderline between medical devices and medicines (MEDDEV Guidance),[5] will be followed by French authorities: a medical device's function is typically achieved by physical means; medical devices may be assisted in their function by pharmacological, immunological or metabolic means, but if these means are not 'ancillary' with respect to the principal intended action of a product, the product no longer

3 Designed by the French oncologist Fabrice Denis. https://www.has-sante.fr/jcms/c_2964253/fr/moovcare-poumon.

4 About the Diabeloop Type I Diabetes automatic management tool: https://www.has-sante.fr/jcms/p_3150658/fr/dblg1-system.

5 MEDDEV 2. 1/3 rev 3, Guidance on 'Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative'.

fulfils the definition of a medical device and thereby will be classified as a medicine. Where a product is classified as a medical device and contains, as an integral part, a medicinal product, the notified body assessing the device must consult with the European Medicines Agency or the relevant national competent authority.

Where a product may satisfy the definition of a medicinal product and that of other product categories, the medicines regime takes precedence over less restrictive regimes, such as those for medical devices.

In France, there is a wide variety of products in the vicinity of health products that are not medicines or medical devices and which are the subject of specific legal regimes that are either purely national or derived from EU law, such as cosmetic or veterinary medicinal products, contraceptives, tattoo products, etc. A case-by-case analysis is made.

ii Non-clinical studies

Before being tested on humans, medicines and medical devices may be tested in vitro or on animals. These studies are called 'pre-clinical' studies in France.

Data collected from pre-clinical trials is used to predict health products' effects on humans, and to support further market access procedural steps.

Experimentation on animals shall only be carried out by entities having received an authorisation to handle animals from the Ministry of Agriculture. These animals shall be housed in conditions approved by the Directorate of Veterinary Services (DSV).

Pre-clinical trials on animals shall be carried out as part of a quality assurance programme certifying that their conditions are optimal in terms of reliability and reproducibility. The commonly accepted quality policy is based on the 'good laboratory practice' standard.

Article 18 of EU Regulation 1223/2009 provides that animal testing is prohibited for all finished cosmetic products placed on the European market. France is aligned with this regulation.

iii Clinical trials

Clinical trials are particularly regulated. France is the fourth-largest EU country in terms of the recruitment number of patients, with an average 13 per cent decrease per year. A 133-day term is necessary to obtain the necessary prior authorisation and contract with the clinical site, on average.[6]

EU Directive 2001/20/EC on clinical trials of medicinal products has been transposed into the French Public Health Code.

Decree No. 2016-1537 of 16 November 2016 implements Act No. 2012-300 of 5 March 2012 on research involving the human person (known as the Jardé Act, one of the major texts on clinical trials in France). It specifies the procedures for carrying out research involving humans (definitions applicable to the various categories of research falling within its scope, functioning of ethics committees, procedures for requesting an opinion from the ethics committees, as well as the rules applicable to vigilance). Decree No. 2016-1538 also imposes a unique convention template to be used by sponsors when contracting with clinical sites, under certain conditions.

6 https://www.leem.org/presse/les-chiffres-cles-de-la-recherche-clinique-en-france; https://fr.calameo.com/read/002049284c898e2c747b8?page=1&view=slide.

In France, clinical trials on humans that are not justified by their usual care require a prior authorisation of the ANSM, after having obtained a favourable opinion of the competent ethics committee. Clinical trials are also subject to compliance with ethical standards, must take place under specific material and technical conditions and are undertaken under the supervision of a medical practitioner with the necessary expertise. In the event of an incident, the sponsor is held to an obligation of compensation.

iv Named-patient and compassionate use procedures

In France, under exceptional circumstances, certain medicinal products may be used and prescribed without a marketing authorisation. These uses are subject to an authorisation through the 'temporary use authorisation' regime (ATU), which is issued by the ANSM.

There are two types of ATUs: cohort ATUs (request by pharmaceutical companies for a group of patients – the interested company is expected to have already filed or must file a marketing authorisation (MA) application), and individual ATUs (request by a physician for an individually named patient).

Medicines benefiting from an ATU are 100 per cent covered by the public health insurance system. They are provided to the healthcare facility by the pharmaceutical company holding the rights on the product. This provision is either free of charge or subject to payment of an amount freely determined by the company.

Under Article L. 5121-12-1 of the Public Health Code, it is also possible, on an exceptional basis, to distribute a medicinal product for an unapproved use on the basis of a 'temporary recommendation for use' (RTU). The ANSM may authorise an RTU for a period of three years for a medicinal product that has already been approved for different use, provided that the benefit-risk ratio of this use is considered to be favourable, and that a PUT (a therapeutic use and information collection protocol), is being elaborated and executed between the ANSM and the relevant pharmaceutical company.

v Pre-market clearance

Two MA procedures coexist: a national procedure and a European procedure (for medicines).

In France, the legislation provides for the requirements and procedures for obtaining an MA, as well as harmonised provisions for manufacturing, distribution, pharmacovigilance, and advertising of medicines, in line with EU law rules.

Similarly, French rules on market access of medical devices are in line with EU laws and the coming Medical Device Regulation (EU 2017/745) (MDR), including that they may only be placed on the market, put into service, or used if they have received a 'certificate of conformity' certifying the device complies with the essential requirements, which is confirmed by the affixing of the CE mark to the device. Companies manufacturing or marketing medical devices must register with the ANSM.

An MA for a medicine may only be granted to an applicant established in the European Union. Beginning with the MDR, medical devices' manufacturers must be established in the EEA or appoint a representative established in the EEA.

To allow faster access to innovative treatments for patients or faster development of existing products, the ANSM may implement a fast-track process for examining applications for authorisation of clinical trials on medicinal products, while respecting patient safety.

Since 18 February 2019, trials on complex design medicines and advanced therapy medicines have been additionally eligible for the fast track.

After having validly completed their market access procedures, medical product manufacturers must implement pharmaco- or materiovigilance procedures in order to monitor, evaluate, prevent and manage the risk of adverse reactions resulting from the use of medicines and medical devices.

Subject to some exceptions, herbal medicinal products, like all other medicinal products, are supplied by pharmacies, or on the websites of registered pharmacies. Medicinal plants can be used for the manufacture of medicines, but can also be supplied in bulk or in the form of pharmaceutical preparations by pharmacies.

The effectiveness and regime of homeopathic products are currently questioned, leading the French government to decide recently that they should no longer be reimbursed by social security as of 2021. For now, a specific registration procedure is provided by the Public Health Code to distribute homeopathic products.

vi Regulatory incentives

Pharmaceutical patents are granted, like all other patents, for a period of 20 years from filing, and are subject to the payment of annual fees. However, the MA is generally not issued for several years. To compensate for this period during which the patent cannot be exploited, a special title has been created: the Supplementary Protection Certificate (CPP), which extends the rights of the owner of a patent on a pharmaceutical product.

EU Regulation 1901/2006 of 12 December 2006 provides the possibility of obtaining a six-month extension from the CPP expiry data, for medicines that have been researched for a paediatric use.

Other national incentives or practices exist in particular at the pricing and reimbursement stage, for instance in princeps/generics positioning or for biosimilars on other innovative products.

vii Post-approval controls

The promotion, marketing, pharmacovigilance, batch tracking, withdrawal, storage and wholesale of medicinal products can only be performed in France by companies having an 'exploitant pharmaceutical establishment' title duly authorised by the ANSM (note that the exploitant may differ from the MA holder). Such exploitation shall be supervised by a responsible pharmacist (the equivalent of a qualified person). The MDR aligns medical devices with this rule, obliging medical devices manufacturers to appoint a qualified person.

Once marketed, the medicine remains under surveillance.

Thus, the benefit-risk ratio of the product is continuously evaluated to measure known or newly identified adverse effects. In the case of a health risk, a medicinal product may be subject to a health policy decision in the form of a restriction or change of indications. The medicine may also be withdrawn from the market.

The French Public Health Code expressly authorises the transfer of an MA from a given holder to another, for free or against a payment. Yet, transferring an MA still requires the prior approval of the ANSM. Such a transfer between seller and purchaser may be carried out by an agreement. The purpose of this agreement will not be the transfer of the MA in itself, but the transfer of the right to apply for an MA as well as of the file and information necessary to obtain it, such as the related regulatory documentation.

viii Manufacturing controls

Manufacturers and operators of medicinal products (branded and generic specialities) must be authorised as pharmaceutical establishments by the ANSM, meet the appropriate manufacturing and inspection requirements, and comply with applicable rules of good practice (manufacturing, distribution, etc.).

A pharmaceutical manufacturing site shall be supervised by a responsible pharmacist, whose statutory position is governed by the Public Health Code and who shares potential civil and criminal liability with the company's manager.

Transfers of the 'pharmaceutical exploitant' status shall be submitted to the ANSM for prior approval.

Again, the new MDR will bring the obligation of a qualified person in the medical device field, regarding manufacturing controls.

ix Advertising and promotion

In principle, advertising of a drug to the public is only allowed on the condition that it is not subject to medical prescription, none of its different presentations is reimbursable by compulsory health insurance schemes and the MA or registration does not prohibit or restrict advertising to the public because of a possible risk to public health.

Such advertising to the public, as well as advertising to healthcare professionals, is subject to the prior authorisation of the ANSM.

For the advertising of medicines and medical devices, the use of certain media is regulated or prohibited, while some statements are mandatory and others are prohibited. In addition, the broadcast of some of these advertisements is subject to an authorisation of the ANSM.

For instance, 'medical software' is not among the media commonly accepted by the ANSM for advertising medicines and medical devices. The ANSM also seems to accept advertising taking the form of 'pop-ups', under specific conditions.

Advertising may only cover medicines that have obtained MAs or parallel import authorisations. In addition, advertising for medicines undergoing a reassessment of their benefit-risk ratio is prohibited.

Advertising must also comply with the essential requirements concerning the safety and health of patients and must not include a list of information expressly prohibited by the Public Health Code.

Based on the ANSM's guidelines, advertising for a medical device must present it objectively, including in its performance or compliance with essential security requirements, and promote its proper use.

In the same sense, an advertisement cannot mention a position taken by an administrative authority or an advisory body with regard to a medical device in a manner likely to alter its meaning or objectivity.

Advertising must not be misleading or present a risk to health.

x Distributors and wholesalers

The distribution of medicines is carried out by distribution establishments that have obtained an authorisation from the ANSM. In these establishments, all activities are carried out in accordance with the wholesale distribution good practices.

The wholesale distribution good practices specify the fundamental principles that must be respected in the wholesale distribution of pharmaceutical products, particularly in terms of general organisation, including quality management, staff, premises, and equipment (including computerised systems).

The application of the regulations relating to the wholesale distribution of medicines (including good practices) is periodically controlled during inspections carried out by the ANSM or the regional health agencies, under the aegis of the ANSM.

The French model of a pharmacy is based on three main principles. The establishment of pharmacies on the territory depends on demographic thresholds, in order to enable the need of medicines to be optimally met. The ownership of pharmacies is exclusively reserved for pharmacists in order to ensure professional independence. Finally, the sales of medicines and other products over the counter is reserved exclusively for pharmacists, practising in pharmacies and registered with the Order of Pharmacists.

Online selling of medicines by pharmacies has to be authorised by the ANSM, and only concerns off-the-shelf medicines.

xi Classification of products

Medicines are listed in multiple categories. Each list is regulated by specific provisions covering distribution, dispensation or promotion for instance.

Among the latter fall two categories: 'advice' medicines, which are prescribed by pharmacists to patients who seek advice from the pharmacist when a symptom occurs; and 'general public', which are medicines that are allowed to be promoted in the media (after having obtained an authorisation granted by the ANSM).

Some medicines are more strictly regulated, and classified as 'poisonous substances'. They present various types of risks (toxic, teratogenic, carcinogenic, mutagenic, etc.). Their manufacture, sale, possession and use require special authorisations. Only healthcare professionals are allowed to prescribe these substances, subject to time limit on use. Narcotic substances that could lead to addiction also are specifically regulated.

Non-listed medicines are available off-the-shelf.

xii Imports and exports

Any entity importing medicines, including bulk product, from countries outside the EEA must first obtain an import authorisation from the ANSM. However, if the medicine has obtained an MA (or an ATU) this will fulfil the import authorisation requirement. Where the product has an MA or an ATU, imports into the EEA may only be performed by an entity holding a manufacturer's import licence (authorisation) issued by the ANSM, which requires, among other things, the holder of the licence to appoint a responsible pharmacist.

Any entity importing medical devices from countries outside the EEA may only do so if the device has a certificate of conformity. Any entity importing medical devices must declare this activity with the ANSM and once the MDR comes into force, will need to be established in the EEA or appoint a representative established in the EEA.

Exports to non-EU countries of medicines that are not subject to MA in France are subject to a declaration to the ANSM. The export of medicines without an MA in France to an EU Member State is not subject to a prior export declaration.

For reasons of public health, the export of medicines without MA or of medicines likely to trigger risks not proportionate to the expected benefits may be prohibited by the ANSM.

Medical devices may not be exported if they give rise to a sanitary decision of the ANSM prohibiting the same. Free trade certificates can be issued by the Paris Île-de-France International Chamber of Commerce in order to facilitate exports outside the EU (this also applies to medicines).

xiii Controlled substances

In France, any operation relating to narcotics and psychotropic substances is expressly prohibited, unless an authorisation has been granted by the General Director of the ANSM. Those substances are closely observed and their use, transportation and flows are entered into a special register.

The ANSM endorsed the proposals of an expert group on a practical framework for the purpose of allowing access to cannabis for medical use, for an experiment in France in July 2019. On this basis, the Social Security Funding Act for 2020 launched a two-year experimental phase during which the practical conditions for experimentation and distribution of products, products to be used, training of health professionals, and conditions for patient care and follow-up will be studied with possible funding by social security.

Some medicines present a risk of addiction for patients. In addition to the usual monitoring of adverse reactions (pharmacovigilance), a specific monitoring has been created in cases of abuse, dependence and misuse, called 'addictovigilance'.

'Addictovigilance' is based on a network of regional centres responsible for collecting and evaluating these cases: the Centres for Assessment and Information on Drug Dependence (CEIP), led by the ANSM.

xiv Enforcement

The ANSM frequently conducts inspections on the manufacturing of medicinal products, clinical trials, and the implementation of pharmacovigilance by MA holders.

The General Director of the ANSM may pronounce injunctions and financial penalties against operators if they do not comply with the laws and regulations applicable to medicines.

Three types of enforcement procedures may be underlined:

a the ANSM may issue an injunction, following a contradictory procedure, to an operator to regularise the situation within a specified period;

b in the event of a risk to public health due to the placing on the market or use of a health product, the ANSM may take health policy measures such as a suspension of the MA, of the manufacture, of the distribution, or a restriction of use, etc.; and

c the ANSM may impose financial penalties on the operator. These financial penalties depend on the gross turnover of the operator, and the nature of the breaches noted by the ANSM.

The European Medicines Agency may also control and impose specific measures to operators in cases of violations of international regulations.

Medical devices, which used to be under less scrutiny on the field including because no central registration was available, will become more tightly controlled by the authorities, including the ANSM, thanks to the enforcement of the new MDR.

Other agencies or directorates may participate in this enforcement, for instance on fraud or competition law aspects.

III PRICING AND REIMBURSEMENT

In France, prices and reimbursement issues are determined by two separate public bodies: the HAS, assessing the reimbursable status and level of reimbursement of the drug (based on its Rendered Medical Service (SMR) and the Improvement of the Rendered Medical Service (ASMR); and the CEPS for the determination of the price. Once the HAS Transparency Commission has issued its opinion on a proposed SMR and ASMR for the product, the CEPS (an inter-ministerial organisation placed under the joint authority of the Ministry of Health and Social Security and the Ministry of Economy) proposes and negotiates a reimbursement price with the holder of the rights on the product, giving rise to a specific agreement between the two.

The Ministry of Health and Social Security ultimately is the one setting the reimbursement rate and price of the product by a decree.

Only prices of reimbursed drug products are regulated by the law.

The rules governing prices of reimbursed drug products are contained in the French Social Security Code (SSC) and supplemented by an agreement called the Accord Cadre (Framework Agreement), between the CEPS and an organisation representing pharmaceutical manufacturers (the 'Leem'), as well as HAS and CEPS doctrine.

Additionally, French law provides a specific mechanism for funding drug products under an ATU, for which the pharmaceutical manufacturer may independently determine the sales price of the drug to hospitals. The manufacturer must inform the CEPS of this price, which is then published. Once the CEPS determines the price (as noted above) and the price is published, the pharmaceutical manufacturer must pay back to French social security the difference between the sales billed to the hospitals and those same sales calculated with the CEPS-determined price.

Further considerations apply for the prices of drugs purchased by hospitals. Because sales of drugs to hospitals are generally made through a public tender, the price proposed by the pharmaceutical manufacturer to the hospital is generally lower than the sales price agreed upon with the CEPS (as prices within public tenders are generally low due to competition).

This same mechanism applies for medical devices.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The ANSM is a public establishment; it is therefore subject to administrative law.

There are two types of administrative appeals: *ex gratia* and hierarchical appeals. An *ex gratia* appeal is lodged with the person who issued the administrative act. Hierarchical appeals are addressed to the administrative authority that is superior to the one having issued the administrative act (decision) in question.

The hierarchical appeal may follow an *ex gratia* appeal, or it may be brought without the latter. In the same way, both appeals may be lodged simultaneously.

If the petitioner's request is not granted, an appeal may be lodged to the administrative court (contentious appeal). Appeal of a decision of the administrative court has to be brought before the French Council of State, the Administrative Supreme Court. The court controls the legality of the decisions of the ANSM, the HAS and of its specialised commissions.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Owing to the increasing volume of care consumption, the social security fund has been largely indebted and healthcare professionals are under pressure regarding the quantity of medical care acts or medicines they prescribe if reimbursed by social security (for instance, sick leave).

For the same purposes of reducing social security debt (but not only), financial relationships between companies and healthcare professionals are under high scrutiny and susceptible to a variety of criminal offences in France.

For instance, the Public Health Code prohibits any form of advantages – direct or indirect – (e.g., cash and in-kind benefits) granted to a number of identified health-related actors including healthcare professionals, or a public entity (or a public servant), by a pharmaceutical company or a medical device manufacturer manufacturing or marketing products that are reimbursed by the French social security system or certain sanitary or cosmetic products, or a care services supplier.

Violating those anti-gift rules can be sanctioned by a one-year prison sentence and a €75,000 fine.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

French law provides special liability and compensation systems for injuries caused by medicines and medical devices.

For clinical trials, the Public Health Code provides that the sponsor of the trial must assume the compensation of patients in the case of harmful consequences, unless he or she can prove that the damage does not result from his or her fault. Research involving human beings requires prior subscription of an insurance policy guaranteeing the sponsor's civil liability.

In addition, the Public Health Code provides for two liability regimes: a fault-based liability regime and a no-fault liability regime.

The National Office for the Indemnisation of Medical Accidents (Oniam) has the mission of organising the amicable, rapid and free compensation scheme for victims of certain faulty medical accidents (in the event of insurance failure) and not at fault, without going through legal proceedings. It may compensate the patient if he or she is the victim of abnormal consequences of his or her state of health directly related to the medical act including: a medical accident or damage attributable to a biomedical research activity; an iatrogenic condition (or side effect linked to medical treatment), or a nosocomial infection (i.e., an infection contracted in a healthcare establishment).

Pharmaceutical product and medical devices manufacturers shall be responsible for defective products they distribute. Patients may obtain compensation directly from the company.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

The European Union and France face major competition issues in the healthcare sector and the French Competition Authority has not hesitated to sanction pharmaceutical companies. In 2017 for instance, the Authority imposed on Janssen-Cilag a €25 million fine for impeding

and then limiting the development of a competing medicine. In 2013, a €40.6 million fine was imposed on Sanofi-Aventis for denigrating a competitor medicine to health professionals in order to limit its entry into the French market.

Medicine prices and their reimbursement by the social security system is also one of the major issues of competition law. To ensure that medicines prices are not excessive, the French Competition Authority tends to regulate the market by, for instance, encouraging parallel importations through a European MA.

On 21 November 2017, the French Competition Authority announced the launch of a major sector inquiry into the functioning of competition in the pharmaceutical and medical biology sector.

ii Transactional issues

The healthcare sector is active in the French M&A market. 2018 has been a particularly dynamic year in terms of M&A deals with mega deals in the pharma sector and the multiplication of operations in the medical technology (medtech) and biotechnology sectors that contributed to the structuring of the market.[7]

Medtech is in a good position, in particular e-health companies. Investment funds are showing their appetite for a variety of players, for instance in the AI-based medical imaging, diabetes, orthopaedics and sterilisation markets.

VIII CURRENT DEVELOPMENTS

The French healthcare and life sciences market is dynamic and relatively performing with a high life expectancy and good access to care services.[8] Innovative technologies, including in the digital sphere, are on their way to trigger in-depth transformation of the sector and sustain the development of French investments and progresses on the international scene. However, budget constraints push the French government to reduce funding by the social security system, putting high pressure on products' pricing. Also, capital venture or private equity investments amounts are lower on average compared to financing available in other regions such as the US, leading a number of national entrepreneurs to develop and market their products outside the French territory. A new momentum has come to counter this phenomenon with a new digital health framework policy having been launched in 2019, with the creation of a new digital health space for every citizen and the creation of a national Health Data Hub to sustain research and innovation and the sharing of data, enhancing the use of digital tools and practices, including artificial intelligence, at all levels of the healthcare life cycle, while the new bioethics bill may soon introduce a new human warranty concept in French law for the use of AI in the medical practice in line with EU guidelines.

7 https://www.pwc.fr/fr/publications/fusions-acquisitions/m-and-a-explorer-industries-de-sante.html.

8 https://www.oecd.org/fr/sante/systemes-sante/Panorama-de-la-sant%C3%A9-2019-Comment-la-France-se-compare.pdf.

Appendix 1

ABOUT THE AUTHORS

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With a profile in IT, commercial contracts, innovation technologies, data privacy and intellectual property law, Cécile Théard-Jallu has developed a strong experience for international players in the private and public sectors, including major American and European structures, particularly in the fields of health, life sciences, insurance, energy, the environment, telecommunications, mobility and more generally digital technology.

She helps clients design and implement their digital strategy and technological innovation (connected devices, artificial intelligence, Big and Smart Data, blockchain, robotics, etc.).

She focuses on complex contractual transactions, including R&D and consortium, technology transfers, licensing deals or technology change related projects, with or without public funding. In addition, she advises clients on the engineering, design, negotiation and implementation of their commercial, IT, technological and industrial contracts.

She has carried out numerous missions related to the protection of personal data, including with the GDPR's arrival.

She worked for approximately one year in Washington, DC as a seconded lawyer within Covington & Burling LLP and as a seconded lawyer with one of the world's leading medical equipment companies. As a member of the 'Health/Life Sciences' and 'Technology' groups of the International Bar Association, she has been included for several years in the *Best Lawyers* ranking published in partnership with *Les Echos*, in the 'Biotechnologies' and 'Information Technologies' categories for France.

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