THE LIFE SCIENCES LAW REVIEW

TENTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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PREFACE

The tenth edition of *The Life Sciences Law Review* covers a total of 30 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, like its predecessor, was dominated by the covid-19 pandemic. Manufacturers of healthcare products continued to expedite the development and testing of drugs, biologics, diagnostics and personal protective equipment. Vaccines, many making use of novel technologies, have moved from the laboratory to the clinic and then to patients in record times; a matter of months rather than years or decades. Regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency. Manufacturers and international organisations have worked closely together in an effort to ensure equitable access to vaccines and other important healthcare products in low- and middle-income countries, but much work remains to be done. In the wake of the pandemic, it is to be hoped that governments learn from the lessons of covid-19, placing systems and structures in place for the next pandemic or other health emergency and expediting the development and approval of new healthcare products to deal with endemic health issues such as cancer, coronary heart disease and genetic disorders.

In times like these, 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 that 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 year's publication will be especially 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 2022

Chapter 9

FRANCE

Eveline Van Keymeulen and Jeanne Fabre[1]

I INTRODUCTION

France is generally known for its high quality and also highly regulated healthcare system. As an EU Member State, France has implemented the EU medicines and medical devices regimes. This chapter should therefore be read in conjunction with the EU chapter and will focus on the specifics of the French regulatory regime. France has codified the essential rules on medicines and medical devices in the French Public Health Code, which encompasses both statutory and regulatory provisions.

The French National Agency for Medicines and Health Products Safety (ANSM) is the national competent authority in charge of the regulation, assessment and monitoring of health products, including medicines and medical devices. The ANSM, among other things, authorises clinical trials and issues national marketing authorisations for medicines. The High Health Authority (HAS) is the French health technology assessment (HTA) body responsible for the evaluation of medicines and medical devices with a view to pricing and reimbursement decision-making. The Economic Committee for Medicinal Products (CEPS), which is part of the French Health Ministry, determines the prices of reimbursed medicinal products and medical devices on the basis of the outcome of the HAS assessment.

The oversight of the French healthcare system is mostly centralised, with the ANSM as the central administrative enforcement authority for medicines and medical devices. ANSM inspectors monitor compliance with applicable laws and regulations through audits and inspections and may issue a range of enforcement measures. The ANSM is supported in this task by the regional health agencies (ARS), which are responsible for the implementation and enforcement of many regional health policies.

II THE REGULATORY REGIME

The French Public Health Code implements and complements the rules set forth in Directive 2001/83/EC and European Regulation No. 726/2004 with respect to medicinal products.

At the time of writing, the French Public Health Code still includes the rules implementing and complementing the provisions of Directives 93/42/EEC, 90/385/EEC and 98/79/EC with respect to medical devices (including in vitro diagnostic medical devices), despite Regulation (EU) 2017/745[2] related to general medical devices and active implantable

1 Eveline Van Keymeulen is a partner and Jeanne Fabre is an associate at Latham & Watkins.

2 Regulation (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

devices having become applicable on 26 May 2021. Regulation (EU) 2017/746[3] related to in vitro diagnostic medical devices will become applicable as of 26 May 2022.[4] The French ordinance adapting French law to Regulations 2017/745 and 2017/746 is, at the time of writing, expected by end of July 2022.

Medicinal products and medical devices are governed by the first and second book of Part V of the French Public Health Code.

i Classification

French law has implemented the EU definitions of medicines and medical devices as well as other regulated products (e.g., cosmetics) in the French Public Health Code. The ANSM, when deciding on the regulatory classification of a product, in particular in the context of borderline decisions, applies the principles and EU case law set out in the relevant EU guidelines; for example, the European Commission guidance on the borderline between medical devices and medicines (MEDDEV Guidance)[5] and on the demarcation between cosmetic products and medicinal products.[6]

Borderline decisions are made by the ANSM on a case-by-case basis, taking into account all the characteristics of the product, including its composition, scientific properties, product claims and advertising, the manner in which it is used, etc. The ANSM has published further guidance on borderline issues on its website.[7]

Borderline determinations may also be made by the French commercial or criminal courts in cases where the classification of the product is being challenged.

ii Non-clinical studies

Non-clinical laboratory studies are in vitro or in vivo experiments on animals in which products are studied under laboratory conditions to determine their safety for further clinical testing on humans. In France, such studies are more commonly referred to as 'pre-clinical' studies.

Directive 2010/63/EU regarding the protection of animals used for scientific purposes has been transposed into French law since 2013, in particular by means of the Decree No. 2013-118 of 1 February 2013. Research involving animals is only permitted by entities having received an authorisation to handle animals from the French Ministry of Agriculture. Animals participating in non-clinical research must be housed in conditions approved by the regional Directorate of Veterinary Services (DSV).

Non-clinical studies must further be planned, performed, monitored, recorded, reported and archived in accordance with the principles of Good Laboratory Practice (GLP),

3 Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

4 Unlike directives, which must be implemented into the national laws of the EU Member States, regulations are directly applicable in all EU Member States.

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'.

6 Guidance document on the demarcation between the cosmetic products Directive 76/768 and the medicinal products Directive 2001/83 as agreed between the commission services and the competent authorities of Member States.

7 Notice to applicants, Guidance for notified bodies and manufacturers on the procedure to be followed and the documentation necessary to consult the ANSM, version of 20 July 2021. ANSM webpage on 'Ancillary medicinal substance integrated in a medical device' (https://ansm.sante.fr/vos-demarches/industriel/demander-un-avis-scientifique-pour-un-dispositif-medical-incorporant-une-substance-medicamenteuse).

which define a set of rules and criteria for a quality system for the organisational process and the conditions for pre-clinical studies. These GLP standards have been implemented in France through an Order of 14 March 2000,[8] and reflect the OECD requirements.

iii Clinical trials

EU Directive 2001/20/EC on clinical trials of medicinal products has been transposed into the French Public Health Code. French clinical trials are mainly regulated by Decree No. 2016-1537 of 16 November 2016 which implements Act No. 2012-300 of 5 March 2012 on research involving the human person.[9] The Decree defines, among other things, the different types of research, the functioning of ethics committees, the rules applicable to vigilance, and consent by participants. France takes the third position in Europe, behind Spain and Germany, as far as participation in global clinical trials is concerned.[10]

Sponsors of interventional clinical trials must seek a prior authorisation from the ANSM, after having received a favourable opinion from the competent ethics committee, which assessment aims to ensure the safety of trial participants. By contrast, low-interventional and non-interventional trials only require a prior favourable opinion from an ethics committee. In 2016, a mandatory template (called a 'single agreement') for agreements between sponsors and healthcare institutions was put in place with the objective to simplify and accelerate the implementation of commercial clinical trials.[11] In addition, to provide faster access to innovative treatments for patients, the ANSM set up two fast-track programmes for trials for innovative treatments, new trials with known molecules, trials with a complex design and trials for advanced therapy medicinal products, which reduce the assessment timelines for such trials.[12] However, in general, a total of 253[13] days are required between the first administrative step and the inclusion of a first patient in a clinical trial in France, which is significantly longer than the average time frame on a European scale (139 days).[14]

Before a clinical trial can be initiated, participants must provide free and informed consent in writing. Direct or indirect compensation of trial subjects is prohibited except for the reimbursement of expenses and compensation for the constraints suffered (such as, for example, treatment, medical visits, follow-up examinations, hospitalisations).[15]

8 Order of 14 March 2020 related to good laboratory practices (www.legifrance.gouv.fr/jorf/id/JORFTEXT000000568998).

9 As amended by Ordinance No. 2016-800 of 16 June 2016 (www.legifrance.gouv.fr/loda/id/JORFTEXT000032719520/).

10 LEEM, 'Attractiveness of France for clinical research', 11th study, 13 December 2021 (https://www.leem.org/attractivite-de-la-france-pour-la-recherche-clinique-11eme-enquete-du-leem).

11 French Health Ministry, Single Agreement (https://solidarites-sante.gouv.fr/systeme-de-sante-et-medico-social/recherche-et-innovation/l-innovation-et-la-recherche-clinique/convention-unique).

12 ANSM, Medicines and biological products, fast-tracks clinical trials applications (https://ansm.sante.fr/page/essais-cliniques-procedure-fast-track-pour-les-medicaments).

13 Outside covid-19 impact. LEEM, 'Attractiveness of France for clinical research', 11th study, 13 December 2021 (https://www.leem.org/attractivite-de-la-france-pour-la-recherche-clinique-11eme-enquete-du-leem).

14 LEEM, '10th survey on clinical trials: Increasing France's leadership position - Leem's 10 proposals', 14 October 2020 (www.leem.org/presse/10eme-enquete-sur-les-essais-cliniques-accroitre-la-position-de-leader-de-la-france-les-10).

15 The total amount of compensation that a person may receive during a period of 12 consecutive months is limited to a maximum amount set by the French Health Minister (i.e., currently €4,500). See Order

For interventional trials, sponsors must subscribe to an insurance policy guaranteeing their civil responsibility, which allows for the compensation of trial participants in case of possible damage or harmful consequences (unless the damage does not result from the fault of the sponsor). The insurance cannot stipulate guarantees for an amount lower than the thresholds set by the relevant decrees.[16]

The EU Clinical Trial Regulation No. 536/2014 became applicable on 31 January 2022 and replaces some of the aforementioned French rules (subject to transitional provisions). However, the Regulation only governs interventional trials with medicinal products; other interventional trials and non-interventional trials remain subject to French law.

iv Early access and compassionate access programmes

In order to encourage timely patient access to innovative medicines, the use of unauthorised medicinal products intended to treat serious or rare diseases for which no appropriate treatment is available in France can be allowed under specific circumstances.[17] Over the years, France has developed a well-established system of named-patient and compassionate use programmes, which was significantly amended in 2021 further to the adoption of the 2021 Social Security Financing Act[18] (LFSS) to simplify applications, harmonise procedures, ensure immediate access to treatment for patients and rapid reimbursement, while ensuring financial sustainability for the health insurance system. The new system entered into force on 1 July 2021 further to the adoption of two decrees of 30 June 2021[19] and several orders of 1 July 2021.[20]

Under the former system, two specific programmes could be granted by the ANSM for a limited time period: (1) the 'temporary use authorisation' (ATU), which essentially

of 25 April 2006 relating to the maximum amount of compensation for constraints that a person may receive during the same year for participation in biomedical research (www.legifrance.gouv.fr/jorf/id/JORFTEXT000000240514#B).

16 That is €1 million per victim, €6 million per trial protocol and €10 million for all claims submitted during one insurance year under several research protocols. See Article R 1121-6 of the French Public Health Code.

17 Articles L 5121-12 and L 5121-12-1 of the French Public Health Code.

18 French Law No. 2020-1576 of 14 December 2020 on the financing of social security for 2021 (www.legifrance.gouv.fr/jorf/id/JORFTEXT000042665307).

19 Decree No. 2021-869 of 30 June 2021 on early access and compassionate authorisations for certain medicines (https://www.legifrance.gouv.fr/loda/id/JORFTEXT000043728288/2021-12-07/) and Decree No. 2021-870 of 30 June 2021 setting the deadlines mentioned in Articles L 5121-12 and L 5121-12-1 of the Public Health Code and in Article L 162-16-5-4 of the Social Security Code (https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043728411).

20 Order of 1 July 2021 issued for the application of Articles L 162-16-5-2 and R 163-52 of the Social Security Code and relating to the discounts applicable to a medicine covered in a given indication by a payment under Article L 162-16-5-2.
Order of 1 July 2021 issued for the application of Articles L 162-16-5-1-1 and R 163-33 of the Social Security Code and relating to the discounts applicable to a medicine covered in a given indication by a payment under Article L 162-16-5-1.
Order of 1 July 2021 issued for the application of E of IV of Article 78 of the Social Security Financing Act for 2021.
Order of 1 July 2021 on the gradual thresholds for compassionate access authorisations involving increases in discounts.

encompassed compassionate use programmes and named patient programmes[21]; and (2) the 'temporary use recommendation' (RTU)[22], an exceptional French-specific regime allowing the supply of certain medicines for a use that does not comply with their marketing authorisation (i.e., 'off label' use).[23]

Under the revised framework, these schemes have been integrated and replaced by 'early access' and 'compassionate access' programmes.

'Early access' programmes encompass the former cohort ATU, ATU extension of indication, post-ATU and post-marketing authorisation direct access programmes. Early access programmes are available for medicinal products with specific therapeutic indications intended to treat serious, rare or debilitating diseases that have not yet obtained a marketing authorisation or that have obtained a marketing authorisation but have not yet obtained a reimbursement decision. To be eligible, the applicant must justify that: (1) there is no therapeutic alternative; (2) the treatment cannot be deferred; (3) there is a presumption of innovation; and (4) the efficacy and safety of the medicine are strongly presumed based on clinical trial results.

An application for an early access programme must be submitted to the HAS, which is responsible for issuing the authorisation. When the medicinal product has not yet obtained a marketing authorisation, the HAS decision is taken after having received a favourable opinion from the ANSM. Within this programme, the applicant notably undertakes to finance the real-life data collection defined by the authorities, to ensure continuity of treatment and to apply for marketing authorisation a within maximum of two years following the early access authorisation or to submit an application for reimbursement within one month following the grant of the marketing authorisation.

Similarly to the former ATU, medicines that are supplied to patients in the context of an early access programme are fully covered by the public health insurance system. The pharmaceutical company that holds the authorisation may choose to provide the product free of charge or independently determine a 'free temporary price' (an 'indemnity') it charges for the medicine (except if a price has already been negotiated). Importantly, if the final price set by the CEPS is lower than the indemnity that was charged by the company during the early access programme, the company will have to pay back the difference between those two amounts to the health insurance (through the French Union for the Collection of Social Security Contributions and Family Allowances). In addition, the company must declare, on 15 February of each year, its turnover corresponding to the medicine under an early access programme as well as the number of units supplied during the previous calendar year. The company must then pay rebates calculated on the basis of the pre-tax turnover invoiced to health establishments (annual clawbacks).

21 Two types of ATU existed: (1) 'cohort ATU', which are compassionate use programmes as set forth in Regulation (EU) No. 726/2004 (i.e., a request made by a pharmaceutical company for a group of patients); and (2) 'nominative ATU', which correspond to named-patient programmes defined by Directive 2001/83 (i.e., a request made by a physician for an individually named patient).

22 RTUs were granted by the ANSM provided there was a therapeutic need and the benefit/risk ratio of the medicine was presumed to be favourable, in particular on the basis of published scientific data on efficacy and tolerance. RTU were granted for up to three years but could be renewed. The objective of the RTU was to ensure the safe use of medicines that would otherwise be used off label through the implementation of a patient monitoring programme organised by the relevant pharmaceutical companies.

23 Article L 5121-12-1 of the French Public Health Code.

An early access programme ends when the regulatory conditions are no longer met, when the pharmaceutical company does not comply with the commitment to file a marketing authorisation or a reimbursement registration, when the pharmaceutical company does not comply with the programme protocol, or in case of public health reasons.

'Compassionate access' programmes, on the other hand, encompass the former nominative ATU and RTU. This programme is available for medicinal products with specific therapeutic indications: (1) which are not subject to clinical research for commercial purposes; (2) for which there is no appropriate treatment; and (3) for which the efficacy and safety are presumed based on the available clinical data. A compassionate access authorisation can be requested either by a prescribing physician for medicinal products without marketing authorisation to treat a serious, rare or incapacitating disease for a renewable period of one year (granted by the ANSM), or at the ANSM's own initiative or at the request of the Ministers of Health or Social Security for a medicine that already has a marketing authorisation for other indications for a renewable period of three years.

A compassionate access authorisation automatically entails reimbursement by the public health insurance system. When the medicinal product benefiting from compassionate access is already reimbursed for one of its authorised indications, the indication benefiting from compassionate access is covered under the same reimbursement conditions. When the medicine is not yet reimbursed for any of the authorised indications, the indication benefiting from compassionate access will be reimbursed either on a fixed annual basis per patient or on the basis of an indemnity freely set by the pharmaceutical company and invoiced to health establishments. In this case, a mechanism of rebates to be paid by pharmaceutical companies also applies.

A compassionate access programme ends when the regulatory conditions are no longer met or in case of public health reasons.

v Pre-market clearance

Medicinal products

Medicinal products must obtain a marketing authorisation to be marketed in the EU. Only products falling within the mandatory scope of the centralised procedure, listed in Regulation (EC) No. 726/2004, must obtain an EU-wide authorisation by the European Commission following a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP). All other products can be authorised through either the national, decentralised or mutual recognition procedures in the relevant national territories. The French marketing authorisation procedures for medicinal products closely follow the EU rules set out in Directive 2001/83/EC. The ANSM is the French competent authority for granting national marketing authorisations that are valid in France, following either the national, mutual recognition or decentralised procedure. A national marketing authorisation for medicines is initially valid for a five-year period and may then be renewed without time limit.

Fees for marketing authorisations (as well as their renewal and modifications) are provided in the French General Tax Code and depend on the type of authorisation. In

2021, the fees for a decentralised or mutual recognition marketing authorisation application amounted to €55,000 and €35,700, respectively, depending on whether France acted as the reference member state (RMS) or not.[24]

Medical devices

Medical devices must obtain a CE conformity mark to be marketed in the EU. Depending on the risk class of the medical device, the conformity assessment procedures set forth by Regulation (EU) 2017/745 require either a self-assessment by the manufacturer or the assessment by a notified body appointed by an EU Member State (in France, the ANSM designates French notified bodies such as GMED). Consequently, the ANSM is not involved in conformity assessments for medical devices, but companies[25] manufacturing or marketing Class I or custom-made medical devices must register with the ANSM.[26] The putting into service in France of Class IIa, IIb, III and active implantable medical devices must also be communicated to the ANSM,[27] which publishes a list of these devices on its website.[28]

These requirements will be subject to change once the EU database (Eudamed) becomes fully operational as Regulation (EU) 2017/745 requires that the unique device identifier (device-related information) and information related to economic operators (e.g., manufacturers, authorised representatives and importers) is registered on this database. Until then, devices must be registered in accordance with the national requirements, but the ANSM encourages manufacturers to register their devices in Eudamed and it considers that these EU registration requirements are equivalent to the national requirements.[29]

vi Regulatory incentives

The French Public Health Code implements the periods of eight years of regulatory data exclusivity (during which generic and biosimilar applicants may not file a marketing authorisation) followed by two years of market protection (during which regulators may review generic or biosimilar applications, but generic or biosimilar manufacturers may not launch their product) under Directive 2001/83/EC for products for which qualifying national applications were submitted after 30 October 2005. This 10-year period can be extended for one year if the marketing authorisation holder of the originator medicine obtains, during the first eight years, an authorisation for a new therapeutic indication providing a significant clinical benefit. Regulatory exclusivity periods start running when the product is first approved in the European Economic Area, not necessarily in France.

24 Article 1635 *bis* AE of the French General Tax Code (www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000037947963/) and Article 344 *undecies* A of Annex 3 of the General Tax Code (www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006069574/LEGISCTA000006133760/#LEGISCTA000006133760).

25 This applies to companies whose headquarters are in France.

26 Articles R 5211-65 and R 5211-65-1 of the French Public Health Code.

27 Articles L 5211-4 and R 5211-66 of the French Public Health Code.

28 The list is available at https://ansm.sante.fr/documents/reference/declarations-des-dispositifs-medicaux/liste-des-communications.

29 ANSM, Eudamed database for medical devices: launch of the module for operator registration, national provisions for the registration of medical devices pending the availability of the Eudamed database (https://ansm.sante.fr/actualites/base-de-donnees-eudamed-pour-les-dispositifs-medicaux-lancement-du-module-destine-a-lenregistrement-des-operateurs).

The additional data and market exclusivity provisions for orphan medicinal products and for products with paediatric indications developed in accordance with an approved paediatric investigation plan under Regulation (EC) No. 141/2000 and Regulation (EC) No. 1901/2006 apply directly in France. Other rewards and incentives[30] provided at EU level also apply in France (such as scientific advice and protocol assistance).

Pharmaceutical patents are granted for a period of 20 years from filing. As in the EU, there is no patent linkage (i.e., a connection between the regulatory approval process and patent expiry) under French law. The French Office for Intellectual Property (INPI) is responsible for granting patents as well as supplementary protection certificates (SPC) for medicinal products that meet the criteria under Regulation (EC) No. 469/2009 and for the paediatric extensions thereof. SPCs have a maximum duration of five years.

The French Intellectual Property Code contains a 'Bolar' provision,[31] which allows the performance of trials that are necessary for marketing authorisation during the patent protection period. Unlike the 'EU' Bolar provision provided by Directive 2001/83/EC,[32] which only applies to the development of generic medicines, the French Bolar exemption applies to both innovative and generic medicinal products.

vii Post-approval controls

Post-approval controls with respect to medicinal products and medical devices in France mirror the requirements established at EU level, in particular in Directive 2001/83/EC and the relevant medical devices Regulation and Directive, as discussed in the EU chapter.

The respective procedures for pharmacovigilance (for medicinal products) and reactovigilance (for in vitro medical devices)[33] are determined at national level. The procedure for materiovigilance (for medical devices) is determined by Regulation 2017/745 and will be further complemented by national provisions in the course of 2022 once the French ordinance adapting French law to Regulations 2017/745 and 2017/746 is published.

viii Manufacturing controls

The substantive requirements governing the manufacture of medicinal products, including the need for a manufacturing or import authorisation, a qualified person, and compliance with good manufacturing practices (GMP) are determined at EU level and discussed in the EU chapter.

Companies manufacturing medicinal products must obtain a pharmaceutical establishment licence from the ANSM[34] and comply with the aforementioned substantive

30 Medicinal products developed for children that are already authorised but are not protected by a patent or supplementary protection certificate are eligible for a paediatric-use marketing authorisation (PUMA). If a PUMA is granted, the product will benefit from 10 years of market protection as an incentive.

31 Article L 613-5 (d) of the French Intellectual Property Code.

32 Article 10 Paragraph 6 of Directive 2001/83/EC.

33 As of 26 May 2022, the procedure for reactovigilance will be set forth by Regulation (EU) 2017/746 and will be further complemented by the French ordinance adapting French law to Regulations 2017/745 and 2017/746.

34 Transfers of pharmaceutical establishment licences, as well as several important modifications to such licences (e.g., change of manufacturing activities, change of headquarters) are subject to prior approval by the ANSM. Other modifications (e.g., appointment of a new responsible pharmacist, change in the legal form or corporate name of the company holding a licence) only require an a posteriori notification. A mere change of control is not subject to prior approval or notification.

requirements.[35] Each company that includes at least one pharmaceutical establishment must be owned by a pharmacist or by a company in which a pharmacist participates in the management or board of directors of the company. Pharmaceutical establishments must be supervised by a 'qualified person', in France referred to as the '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. If a company has more than one pharmaceutical site, the responsible pharmacist must appoint a 'delegated pharmacist' for each site.[36] Deputy pharmacists are appointed to assist and temporarily replace responsible pharmacists and delegated pharmacists.[37]

Pharmaceutical establishments are subject to on-site inspections by the ANSM for compliance with applicable legal and regulatory requirements (including GMP). The ANSM inspects around 200 pharmaceutical establishments each year. Since 2016, GMP certificates issued after such inspections are uploaded by the ANSM into the EudraGMDP database.

ix Advertising and promotion

The rules governing the advertising of medicinal products and medical devices are included in the French Public Health Code and complemented with guidelines issued by the ANSM, such as the Charter regarding internet and electronic media communication. Advertising of medicinal products and medical devices is only permitted for authorised or certified products and must comply with the terms of their marketing authorisation and certification, respectively, as well as the therapeutic strategy recommendations of the HAS. It must objectively present the products, promote their proper use and not be misleading or undermine the protection of public health.

The advertising requirements further vary in function of, among other things, the target audience (i.e., the general public or healthcare professionals) and the prescription and reimbursement status of the relevant products. The rules restricting benefits to healthcare professionals and corresponding disclosure ('transparency') requirements are discussed in Section V.

Non-compliance with the relevant advertising requirements is subject to administrative or criminal penalties, which can be up to two years of imprisonment and up to €750,000 in fines for corporations.

Medicines

In France, the advertising of medicinal products to both healthcare professionals and the public requires a prior approval (or 'visa') from the ANSM, respectively called 'visa PM' and 'visa GP'. Advertising to the general public is only permitted for medicines that are not subject to compulsory medical prescription and not reimbursed by the mandatory health insurance. However, vaccines may be the subject of promotional campaigns to the public if they appear on a specific list issued by the Minister of Health.[38]

35 The licence application must, among other things, include information on the relevant manufacturing activities, the facilities in which these activities will be performed, and evidence that the facilities, equipment and procedures meet applicable GMP (set out in Directive 2003/94/EC).

36 Article L 5124-2 of the French Public Health Code.

37 Article L 5124-4 and Articles R 5124-23 et seq. and 5134-30 et seq. of the French Public Health Code.

38 Order of 28 September 2012 establishing the list of vaccines mentioned in Article L 5122-6 of the Public Health Code (www.legifrance.gouv.fr/jorf/id/JORFTEXT000026473702).

The ANSM provides general guidelines on medicines advertising on its website,[39] and has issued specific detailed recommendations regarding advertising to healthcare professionals[40] and the public,[41] respectively.

Medical devices

By contrast, the advertising of medical devices to healthcare professionals or the public is generally only subject to *a posteriori* control and does in principle not require a prior approval from the ANSM, unless for devices that are presenting a significant risk to health, as indicated on a specific list (e.g., diagnostic self-tests, specific implants, knee and hip prostheses).[42] Advertising to the general public is only permitted for non-reimbursable devices or reimbursable devices of Class I and IIa (advertising Class IIb or III devices to the public is prohibited). The ANSM provides general guidelines on medical devices advertising on its website,[43] and has issued specific recommendations[44] as well.

x Distributors and wholesalers

The substantive requirements governing the distribution of medicinal products, including the need for a wholesale authorisation and compliance with good distribution practices (GDP) are determined at EU level and discussed in the EU chapter.[45]

Similarly to companies manufacturing medicinal products, companies engaged in the distribution or wholesale of medicinal products must obtain a 'pharmaceutical establishment' licence by the ANSM, and comply with the aforementioned substantive requirements. Such establishments are periodically controlled during on-site inspections carried out by the ANSM or the ARS.

39 ANSM, Advertising control procedures (https://ansm.sante.fr/vos-demarches/industriel/modalites-encadrant-les-demandes-de-visa-de-publicite-pour-les-medicaments-gp-pm).

40 ANSM, Advertising for medicines, Recommendations for advertising to healthcare professionals (https://ansm.sante.fr/documents/reference/recommandations-pour-la-publicite-des-medicaments-aupres-des-professionnels-de-sante).

41 ANSM, Advertising for medicines, Recommendations for advertising to general public (https://ansm.sante.fr/documents/reference/recommandations-pour-la-publicite-des-medicaments-aupres-du-grand-public).

42 ANSM, Advertising for medical devices and in vitro diagnostic medical devices, General rules for the control of the advertising of MDs/IVD MDs (https://ansm.sante.fr/vos-demarches/industriel/modalites-encadrant-les-demandes-dautorisation-de-publicite-pour-les-dispositifs-medicaux-dm-dmdiv).

43 ANSM, Advertising for medical devices and in vitro diagnostic medical devices, General rules for the control of the advertising of MDs/IVD MDs (https://ansm.sante.fr/vos-demarches/industriel/modalites-encadrant-les-demandes-dautorisation-de-publicite-pour-les-dispositifs-medicaux-dm-dmdiv).

44 ANSM, Advertising for medical devices and in vitro diagnostic medical devices, Recommendations for the advertising of MDs/IVD MDs (https://ansm.sante.fr/documents/reference/recommandations-pour-la-publicite-des-dm-dmdiv).

45 Wholesale distribution covers all activities consisting of procuring, holding, supplying or exporting medicinal products (with the exception of supplying medicines to the public). Distributors must comply with the principles of GDP set out in Commission Guideline 2013/C 343/01. Distributors are, among other things, required to have adequate premises and equipment to ensure the proper conservation and distribution of the products, to operate a quality system and to have a plan for the effective implementation of recalls.

France has a specific concept, known as the 'operator'.[46] The 'operator' is the entity holding most of the regulatory responsibility for ongoing obligations relating to the use of a marketing authorisation in France (including wholesale distribution)[47] and can be the marketing authorisation holder or a company acting on its behalf (e.g., a subsidiary).[48]

xi Classification of products

Medicines

The French rules for classification of medicines are based on the EU provisions. In France, all medicines, regardless of their classification, fall within the scope of the pharmacy monopoly and can therefore only be dispensed by pharmacists.

Prescription-only medicines, which can only be obtained with a prescription from a physician, dentist or midwife, are either included in list I or II (by the Minister of Health further to the recommendation of the ANSM). List I medicines, which are identifiable by a red frame on the packaging, can only be dispensed for the duration of the treatment mentioned on the prescription. List II medicines, identifiable by a green box on the packaging, may be dispensed more than once from the same prescription for 12 months, unless otherwise specified by the prescriber. Another list includes narcotic medicines subject to specific restrictions.

Medicines that are not listed are subject to optional prescription and include over-the-counter (OTC) medicines. These are available without prescription and may be placed in front of the pharmacy counter to allow the patient to help himself or herself. These medications, which are included in a specific list issued by the ANSM,[49] are intended to treat common and mild symptoms, for a limited time, without the intervention of a physician for the diagnosis, initiation and monitoring of treatment, but with the advice of the pharmacist. They are packaged according to the dosage and duration of treatment and have an information leaflet specifically adapted to this use.

In France, only medicinal products that do not need a prescription can be sold online. An online pharmacy must be the immediate extension of a brick-and-mortar pharmacy. Only online pharmacies that have made a prior notification to the competent ARS and Order of Pharmacists and comply with strict 'good dispensing practices' can sell medicines online. In its judgment of 19 June 2019,[50] the Commercial Division of the French Supreme Court confirmed the pharmacy monopoly for online sales of medicines, thereby taking a different stance than the French competition authority (ADLC) which had argued for the liberalisation of such online sales.

46 Article R 5124-2 3° of the French Public Health Code.

47 This includes wholesale distribution, but also free of charge transfer, advertising, information, pharmacovigilance, batch monitoring as well as, where appropriate, the corresponding storage operations.

48 Or, both the marketing authorisation holder and such company, in case of co-marketing agreements.

49 ANSM, Over-the-counter medicines (https://ansm.sante.fr/documents/reference/medicaments-en-acces-direct).

50 Commercial Division of the French Supreme Court, Ruling No. 586 of 19 June 2019 (18-12.292) (www.courdecassation.fr/jurisprudence_2/arrets_publies_2986/chambre_commerciale_financiere_economique_3172/2019_9124/juin_9307/586_19_42873.html).

Medical devices

Most medical devices are available over the counter at specialty providers, distributors, or directly from manufacturers. However, the dispensing of certain categories of medical devices is restricted to specific supply channels. For example, some medical devices are included in the pharmacy monopoly such as in vitro diagnostic medical devices for self-use (except fertility and pregnancy tests). Corrective optical medical devices (glasses and contact lenses) may only be sold by opticians who hold a diploma or professional certificate. Hearing aids are subject to medical prescription and may only be sold by a certified hearing-care professional.

xii Imports and exports

The French regulations governing the import and export of medicinal products reflect those at the EU level, as discussed in the EU chapter.

The import of medicinal products into France is subject to a prior authorisation from the ANSM. Import authorisations are issued for a specific import to be carried out within three months or a series of imports envisaged for a maximum period of one year and for a given overall quantity. Such import authorisation is not necessary for products with a marketing authorisation or subject to an early access programme in France.

The export of medicines that do not have a marketing authorisation in France is subject to a declaration to the ANSM.

xiii Controlled substances

France implemented the UN Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971. As a general rule, any operation relating to narcotics and psychotropic substances is expressly prohibited unless specifically authorised by the Managing Director of the ANSM. Narcotic medicines are listed on the narcotics list, which triggers specific requirements for the prescription and dispensing of such medicines.

Addictovigilance is the monitoring of cases of abuse and dependence related to the use of any psychoactive substance, whether or not medicinal (with the exception of ethyl alcohol and tobacco). This surveillance is based on a national network of centres for assessment and information on drug dependence (CEIP), led by the ANSM, enabling health authorities to take appropriate measures to safeguard public health.

xiv Enforcement

Non-compliance with the French Public Health Code requirements for medicines and medical devices is generally investigated by the ANSM inspectors, sometimes supported by regional ARS inspectors. The Managing Director of the ANSM may pronounce administrative injunctions (following a contradictory procedure) and financial penalties, or order measures such as the recall of products or suspension of specific authorisations.

The ANSM may also refer severe instances of non-compliance to the public prosecutor, which could either propose a settlement or bring the case before the criminal courts. Non-compliance with many requirements of the Public Health Code, in particular when triggering a potential risk for public health, is punishable with criminal sanctions up to several years of imprisonment and fines of up to approximately €3.75 million.

In addition, the DGCCRF is a directorate of the Ministry of Economy in charge of enforcing compliance with consumer rules and rules applicable to some health products, including medical devices, cosmetics, etc. It regularly assists the ANSM in its enforcement

activities. The DGCCRF has a broad discretion with respect to the choice of administrative measures and sanctions, including injunctions and administrative fines, which are generally proportionate with the severity of the infringement.

III PRICING AND REIMBURSEMENT

The general principles related to the pricing and reimbursement of reimbursed medicinal products are set forth by the French Social Security Code. In addition, the more specific modalities of the pricing and reimbursement process are governed by a Framework Agreement entered into between the CEPS and the French pharmaceutical industry association (LEEM). Certain guidelines and principles related to the prices of medicinal products are also set forth by Ministerial 'Orientations'.

The price of a medicinal product is determined on the basis of a negotiation between the pharmaceutical company and the CEPS, which generally results in a 'pricing agreement' between the CEPS and the pharmaceutical company, entered into for a period of up to four years.[51] If no agreement can be reached between the CEPS and the pharmaceutical company, the CEPS can unilaterally determine the maximum price at which a product will be reimbursed.[52]

The price – more specifically the public sales price – is negotiated per medicinal product, resulting in the principle of 'one price per medicinal product'.[53] When determining the price of a medicinal product, the CEPS must in particular take into account (1) the improvement in medical benefit of the medicinal product (ASMR); (2) the results of the medico-economic evaluation; (3) the prices of the medicinal products with the same therapeutic purpose; (4) the anticipated or actual sales volumes; and (5) predictable and actual conditions of use of the medicinal product.[54]

The most important criterion in the price determination is the aforementioned ASMR of the medicinal product, that is, the therapeutic progress or the added value (in terms of efficacy and tolerance) of the new medicinal product in comparison with existing products on the market,[55] which is determined during the HTA by the HAS. Similarly, the medico-economic evaluation – the results of which are to be taken into account by the CEPS for highly innovative medicines with a possibly significant impact on the health insurance budget – is also part of this HTA.

51 See Article L 162-17-4 of the Social Security Code. This agreement not only determines the applicable price or prices, but usually also contains various provisions related to, for example, alternative payment schemes (pay for performance), rebates and financial penalties.

52 The Ministers of Health, Social Security and the Economy may oppose this decision within 15 days.

53 Even though the preliminary health technology assessment (see further) specifically takes into account the different indications (and their respective health benefits), the price set by the CEPS will apply to all indications covered by the same marketing authorisation.

54 Article L 162-16-4 of the Social Security Code.

55 The ASMR is determined on the basis of a comparative assessment of the safety and efficacy of the medicinal product (including level of proof, quantity of effect, and extrapolation to clinical practice), as well as its therapeutic need and its impact on patients' quality of life in comparison with existing medicines or therapies.

Importantly, during the HTA, the HAS also assesses the medical service rendered by the medicinal product (SMR); that is, whether the medicine makes any progress in relation to the available treatments, which makes it eligible to reimbursement. The National Union of Health Insurance Funds (UNCAM) sets the reimbursement rate depending on the SMR level.

In France, pricing and reimbursement procedures often take much longer than the time frames set forth by the Transparency Directive.[56]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The ANSM, the HAS and the CEPS are public bodies and thus subject to administrative law. In France, public authority decisions may be challenged either before the authority itself (*ex gratia* appeal) or before that authority's supervisory authority (hierarchical appeal). An *ex gratia* appeal can be followed by a hierarchical appeal.

If the applicant's request is dismissed, the applicant may appeal this decision before the French administrative courts. Appeal of a decision of the administrative courts would have to be brought before the French Administrative Supreme Court which can, however, only perform a legality control of the challenged decision.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

France is known for its strict regulation of the relationships between healthcare professionals or organisations and pharmaceutical or medical device companies by 'anti-gift' rules. In addition, following a number of scandals, France followed the US Sunshine Act example and implemented specific 'transparency' rules.

The anti-gift regulations were amended several times in the past and were recently, considerably broadened.[57] The French regime includes a general prohibition for companies manufacturing or marketing health products (regardless of their reimbursement status) to promise or to grant benefits, in kind or in cash, directly or indirectly, to healthcare professionals, students or organisations, and it is equally prohibited for these persons to accept such benefits. While some operations are not considered as benefits,[58] some others[59] are exempted subject to specific conditions, in particular a prior authorisation from or declaration to the competent professional orders.

56 In accordance with the Transparency Directive 89/105/CEE, the legal maximum time frame for a pricing and reimbursement procedure is 180 days from receipt of the application (90 days for the setting of the price, and 90 days for the determination of the reimbursement rate).

57 The Ordinance of 19 January 2017 had broadened the scope of the companies and beneficiaries subject to French anti-gift rules, pursuant to Act No. 2016-41 of 26 January 2016 on the organisation and transformation of the healthcare system. The scope of the anti-gift framework has been further extended by Act No. 2019-774 of 24 July 2019. The Ordinance was (mainly) implemented by Decree No. 2020-730 of 15 June 2020, followed by two orders of 7 August 2020 and two orders of 24 September 2020.

58 For example, remuneration for activities provided for in an employment contract or contract practice, benefits from the exploitation or transfer of intellectual property rights and commercial advantages offered under the agreements.

59 Exemptions concern (1) remuneration, compensation and expenses for specific activities, provided that the remuneration is proportionate to the service rendered and that the compensation or expenses do not exceed the costs actually incurred by the persons concerned; (2) donations and gifts, in cash or in kind, intended exclusively to finance research activities, the valorisation of research or scientific evaluation;

In parallel, companies producing or marketing health products (and companies providing services associated with health products) must comply with transparency requirements.[60] They must disclose and publish, on a single public website, information on benefits, remunerations and agreements they entered into with notably healthcare professionals, students, healthcare professional organisations, health institutions, media and social medias influencers, patients associations and editors of medical prescription and dispensing assistance software.

Non-compliance with the relevant anti-gift and transparency requirements is subject to criminal penalties, which can be up to two years of imprisonment and up to €750,000 in fines for corporations.

VI TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

The EU and France face major competition issues in the life sciences and healthcare sector and the French Competition Authority (FCA) does not hesitate to sanction pharmaceutical companies. For instance, in 2020, the FCA imposed fines worth a total of €444 million on three pharmaceutical companies for abusive practices designed to sustain the sales of a medicinal product to the detriment of a competitive medicinal product (which was 30 times cheaper). This is the first time that the FCA has found anticompetitive practices solely on the basis of a collective abuse of dominance under Article 102 of the Treaty on the Functioning of the European Union (TFEU). In earlier decisions, practices giving rise to a collective abuse of dominance also involved an anticompetitive agreement under Article 101 TFEU.

ii Transactional issues

Despite the ongoing covid-19 pandemic, the French mergers and acquisitions market has remained particularly active in the life sciences sector in 2021.

Investment funds also remain eager to invest in a variety of life sciences companies such as e-health companies (in the area of telemedicine and telehealth) and companies engaged in artificial intelligence, and covid-19 has sparked a specific interest in medical biology laboratories investments.

(3) donations and gifts intended for the persons concerned by the ban on receiving benefits, with the exception of associations whose purpose is unrelated to their professional activity; (4) hospitality offered, directly or indirectly, at events of an exclusively professional or scientific nature, or at events promoting products or services, provided that such hospitality is of a reasonable standard, strictly limited to the main purpose of the event and is not extended to persons other than the invited professionals; and (5) financing or participating in the financing of vocational training or continuing professional development actions.

60 The French Transparency Framework was extended by the Health Law of 26 January 2016 and in particular by Decree No. 2019-1530 of 30 December 2019 (the provisions of which entered into force on 1 January 2021) as recently amended by Decree No. 2020-730 of 15 June 2020.

VII CURRENT DEVELOPMENTS

i Launch and first findings of the medical cannabis pilot programme

The French medical cannabis pilot programme officially started on 26 March 2021 for a two-year period to determine the feasibility and relevance of making medical cannabis available in France.[61] During the programme, patients are supplied with medical cannabis (free of charge) for a number of predefined conditions. As at 22 November 2021, 1,000 patients were included in the pilot programme and more than 1,000 healthcare professionals, established in 200 selected hospitals, participated despite the pandemic context. Among the five conditions retained for the pilot programme,[62] medical cannabis is most commonly prescribed for refractory neuropathic pain, painful spasticity in multiple sclerosis and certain forms of medicine-resistant epilepsy. On 8 June 2021, the ANSM set up a new Temporary Scientific Committee[63] to monitor and ensure the operational implementation of the pilot programme.

In addition, on 28 June 2021, the Information Mission on the regulation and impact of the various uses of cannabis set up by the French Parliament in 2020 presented its final report on the regulation and impact of different uses of cannabis.[64] With regard to medical cannabis, the Information Mission formulated several proposals to ensure that, once the pilot programme is completed, the system can be made permanent to provide security for patients and allow the development of a French medical cannabis industry. Consequently, if the pilot programme is successful, medical cannabis may be officially legalised in France, but such development is not expected before the end of 2023.

ii New Framework Agreement between the LEEM and the CEPS

As a result of the covid-19 pandemic, the LEEM and the CEPS had agreed to another extension of their Framework Agreement dated 31 December 2015. However, a new Framework Agreement was signed on 5 March 2021 for a duration of three years. In accordance with the joint Mission Letter of the Ministry of Economy and the Ministry of Health issued on 19 February 2021, the Agreement significantly revises the rules for the price-setting of medicinal products to shorten timelines, favour innovation, stimulate investment and reinforce transparency. The key changes include, among other things:

a increased transparency of public investment in research and development (Article 2): companies have to declare to the CEPS the public investment in research and development from which they have benefited, as well as the contributions they have made to public bodies, and these amounts will be published in aggregate form in the CEPS activity report;

61 ANSM, Dossier regarding medical cannabis (https://ansm.sante.fr/dossiers-thematiques/cannabis-a-usage-medical).

62 The five conditions being: neuropathic pain refractory to accessible treatments, certain forms of severe and medicine-resistant epilepsy, certain intractable symptoms in oncology, certain palliative situations and painful spasticity accompanying certain central nervous system diseases.

63 The ANSM set up two others Temporary Scientific Committees for the implementation of the pilot programme and for the evaluation of the relevance and feasibility of making therapeutic cannabis available in France.

64 Information Report submitted by the joint information mission on the regulation and impact of the various uses of cannabis (https://www2.assemblee-nationale.fr/content/download/349566/3439035/version/1/file/Rapport+Cannabis+FINAL+v4.pdf).

b submission of five-year forward-looking data (Article 4): companies have to provide forward-looking elements to enable a stronger understanding of upcoming therapeutic innovations that are likely to have a significant impact on the financial plan or the organisation of care, by means of a declaration model (covering aspects such as expected indication, planned derogatory early access, claimed improvement in the medical service rendered (SMR) and so on);

c anchoring of the CEPS' price-setting practice for generic medicines in a specific article (Article 24); and

d new modalities for setting and regulating prices of biosimilars (Article 25): the obligatory price reduction (based on the price of the reference medicine) following biosimilar approval can be summarised as follows:

- for the pharmacy market, 40 per cent for the biosimilar and 20 per cent for the reference product from the date of commercialisation of the biosimilar; and
- for the hospital market, an identical rate of 30 per cent for both the biosimilar and the reference product upon registration of the biosimilar on the relevant reimbursement lists.

iii New implications of the 2022 Social Security Financing Law for pharmaceutical and medical devices companies

The 2022 Social Security Financing Law (2022 LFSS), enacted on 23 December 2021, introduces the following key measures:

a the implementation of an anticipated access to reimbursement for innovative digital solutions (e.g., digital medical devices with a therapeutic purpose, medical remote monitoring activities using a medical device);

b the launch of a pilot programme for early and direct access to medicines not yet listed as reimbursed products in hospitals to avoid pricing negotiation delays;

c the reintroduction of the possibility for pharmacists to deliver biosimilars to patients by way of substitution to a prescribed biological reference medicine; and

d the implementation of industrial criteria (i.e., security of supply of the French market guaranteed by the presence of production sites) in price-setting for some medicines, medical devices and services.

Appendix 1

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Eveline Van Keymeulen is a partner in Latham & Watkins' Brussels and Paris offices and a member of the firm's healthcare and life sciences practice.

Ms Van Keymeulen advises multinational companies and start-ups in the pharmaceutical, biotech, medical devices, cosmetics, and food and beverage sectors on a broad variety of complex European, domestic and cross-border regulatory matters, including clinical trials, product approvals, regulatory incentives, market access, promotion and advertising, post-market obligations, and general compliance matters.

In addition, Ms Van Keymeulen has extensive experience advising on medical cannabis and hemp-based product regulations. She successfully challenged the legality of French hemp regulations in the first landmark case related to cannabidiol (CBD) products before the Court of Justice of the European Union (Case C-663/18, *Kanavape*) resulting in a modification of French and EU regulations.

Ms Van Keymeulen is ranked in Chambers for Life Sciences Regulatory (since 2020) and recognised as a *Legal 500* Rising Star / Next Generation Lawyer in Healthcare and Life Sciences (since 2018). She is considered a National and Global Leader by *Who's Who Legal Life Sciences* (since 2016) and is further recognised as one of the leading life sciences practitioners in France by Legal Media Group 2021, *Best Lawyers 2021* and Euromoney's *Women in Business Law Expert Guide 2021*. Ms Van Keymeulen was also recognised as European Advisory Lawyer of the Year by, and won Impact Deal of the Year at, the prestigious Europe LMG Life Sciences Awards 2021.

Ms Van Keymeulen has authored numerous articles and has been a featured speaker on EU regulatory matters at prominent conferences such as the Pharmaceutical Law Academy in Cambridge. Ms Van Keymeulen also serves on the editorial board of the *European Pharmaceutical Law Review*.

In addition, Ms Van Keymeulen has been quoted in BBC Business Daily, Bloomberg, *The Times*, *Les Echos* and other leading international business journals on life sciences regulatory and policy matters.

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Ms Fabre has significant experience working in pharmaceutical companies. Since her Master's in Life Sciences Law, she has worked for more than three years for several companies, both for local affiliates and parent companies. She was seconded for 18 months part-time to a pharmaceutical company specialising in rare diseases, and a further three months for another pharmaceutical company. During that time she advised on a wide range of day-to-day regulatory topics (such as observational, ATU and post-ATU studies, contractual relationships with service providers, consultancy and pay for performance agreements and pricing and reimbursement topics).

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