The Life Sciences Law Review

Fourth Edition

Editor
Richard Kingham

Law Business Research

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EDITOR'S PREFACE

The fourth edition of *The Life Sciences Law Review* provides an overview of legal issues of interest to pharmaceutical, biotechnology and medical device companies in more than 30 jurisdictions. As before, each chapter contains information on legal requirements relating to the key stages in the life cycle of a regulated product, from discovery, through the clinical development process, registration, manufacturing and promotion, plus other issues of special interest, such as pricing and reimbursement, special liability regimes, competition and commercial transactions in the context of the medical products business. Each of the chapters has been prepared by a recognised expert in the relevant jurisdiction, and the resulting work product will assist industry lawyers, regulatory affairs staff and others who need to have an understanding of the issues in each major market.

There is also a chapter on international harmonisation, which plays an increasingly important role in the regulation of pharmaceuticals and medical devices. In particular, the guidelines adopted by the International Conference on Harmonisation have been incorporated into the national requirements for pharmaceuticals in the European Union, United States, Japan and most other developed countries, and are increasingly influential in developing countries. Readers may find it useful to review this chapter before consulting the national chapters, because it is often key to understanding many local requirements.

Once again, I wish to thank all of the lawyers who contributed to this reference work. It is a pleasure to be associated with them.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2016

Chapter 13

FRANCE

Sophie Pelé[1]

I INTRODUCTION

The French regulatory framework for life science products is regarded as one of the most sophisticated, and was one of the pillars for the creation of the EU regulatory framework. However, the EU framework has developed significantly, and now there is sometimes a mismatch between the French and EU regulations. By way of example, one could mention the French concept of *exploitant* (a licensed company authorised to market pharmaceutical products, which may differ from the marketing authorisation holder), which has no equivalent in the EU regulations.

Despite such discrepancies, the French regulations broadly reflect the EU regulations regarding the manufacture and marketing of pharmaceutical products and medical devices, with the exception of the pricing and reimbursement schemes, which remain national in nature. Manufacture and marketing are governed by the Public Health Code.[2] Pricing and reimbursement matters are covered by the Social Security Code.[3] In addition, 'soft law regulation' tends to play an important role, not only through good practices harmonised across Europe, but also from a medico-economic standpoint.

This dual system is also reflected in the organisation of competent national authorities. The French Agency for the Safety of Medicines (ANSM) is in charge of the health and safety aspects of both medicines and medical devices, including: the approval of clinical trials; granting of marketing authorisations; issuance of 'dear health-care professional' letters; authorisation of advertising; and inspections of manufacturing

1 Sophie Pelé is a senior associate at Dechert LLP.

2 www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665&dateTexte=20140107.

3 www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006073189&dateTexte=20140107.

premises. The National Authority for Health (HAS) is responsible for medico-economic aspects, notably the publication of guidelines recommending therapeutic strategies for the treatment of certain diseases, the assessment of the therapeutic and medico-economic benefit of medicines and medical devices for reimbursement purposes through its transparency committee, and the accreditation of softwares assisting dispensing physicians and sales representatives' networks. Finally, the Ministry of Health, which includes the Pricing Committee (CEPS), is in charge of the pricing of reimbursed products.

II THE REGULATORY REGIME

Despite their supervision by the same national health agencies, medicines and medical devices are subject to two separate legal regimes. Medicines are governed by the provisions transposing the EU code relating to medicinal products for human use and cannot be tested, marketed or promoted without prior approval. Medical devices are subject to the provisions transposing into French law the EC marking requirement regime applicable throughout Europe.

However, both categories of products are treated similarly in some respects. In France, advertising material for medical devices has been aligned with the medicines regime and must obtain prior approval in certain cases. In addition, medicines and medical devices are subject to very similar processes in terms of pricing and reimbursement.

i Classification

Rules and principles governing the classification of health products are broadly based on EU case law. However, differences in approach still persist between Member States, as the European Court of Justice has recently recognised.[4]

ii Non-clinical studies

The Law of 26 January 2016[5] modernising the health system (the Health Bill) introduces the concept of 'commercial studies' in order to clarify that the promoter must supply the products free of charge and refund the health-care centres for all extra costs incurred in conducting the study.

iii Clinical trials

Clinical trials for medicines and medical devices conducted in France must receive a prior opinion from an ethics committee and prior approval by the ANSM. It is worth noting that, in some cases, the ANSM can refuse to grant such authorisation. In a judgment dated 3 April 2015, an administrative court upheld one such refusal.[6]

4 ECJ, 3 October 2013, No. C-109/12, Laboratoires Lyocentre.

5 Law No. 2016-41.

6 Paris Administrative Tribunal, 3 March 2015, No. 1401975/6-1, AB Science.

Private sponsors must supply all the tested products free of charge to the health-care centres hosting the health-care professionals (HCPs) appointed as investigators and compensate for the extra costs incurred in conducting the trial.

On 28 September 2015, the ANSM initiated a pilot phase during which, on a voluntary basis, 13 out of 39 ethics committees have accepted, subject to the promoter's acceptance, to implement the changes required by the future application of European Regulation on clinical trials No. 536/2014. France is a pioneer in this respect.

The Health Bill also anticipates the entry into force of this Regulation by terminating the national trials registry that was maintained by the ANSM.

In 2014, the French government issued template agreements aiming at accelerating the implementation of trials within French public hospitals.[7] When a trial involves several centres, the negotiation of financial aspects takes place between a single hospital and the sponsor, while other centres will be bound by the same financial provisions. The aim is to be able to negotiate with the coordinating centre within a 45-day period. Hospitals receive financial incentives from public funds if they successfully implement the template. Moreover, sponsors might also provide for financial incentives related to the inclusion of patients. The first year of implementation of the template was reasonably promising: 40 health-care centres have used the template, accounting for 87 agreements signed and 214 negotiated, resulting in up to €2 million of subsidies for some centres.

iv Named-patient and compassionate-use procedures

Named-patient and compassionate-use procedures were significantly updated and strengthened by the Bertrand Law of 29 December 2011.[8] Temporary authorisations of use (ATU) may be granted to treat severe or rare diseases for which no treatment has been authorised, if and when the treatment cannot be delayed.

When requested by the pharmaceutical company intending to market the product, ATU will be granted if safety and efficacy are presumed and if a marketing authorisation has or will be applied for within a given time frame. When requested by a physician on a named-patient basis, ATU will be granted if safety and efficacy are presumed, if the patient cannot be treated through a clinical trial, and if the product is either subject to a clinical trial or an application for marketing authorisation (even temporary), at least in a request form. The last condition may be bypassed in a few specific cases, such as where there is a high probability of severe consequences for the patient without treatment.

Alongside these ATUs, the Bertrand Law has created a regulated scheme for off-label use, called temporary recommendation for use (RTU). Absent any marketing authorisation and an ATU, a product may be prescribed off-label either because it is indispensable to the treatment of a patient, in light of the existing state of art, or because it is permitted by an RTU issued by the ANSM. The conditions for granting RTUs are rather similar to ATUs, except that they are imposed by the authorities upon

7 Instruction No. DGOS/PF4/2014/195 of 17 June 2014 relating to the implementation of a template agreement for biomedical research with a private sponsor in public hospitals.

8 Law No. 2011-2012 of 29 December 2011 relating to Increasing the Safety of Medicines and Heath Products.

pharmaceutical companies. In addition, the law amending social security funding for 2014[9] broadened the regime RTU to cases where therapeutic alternatives might be available, but not with the same active substance, dosage or pharmaceutical form.

The status of the RTUs, however, remains to be clarified and currently, among the 10 RTUs that have been adopted, only a couple of them allow for the use of a product outside of its therapeutic indication despite the existence and availability of therapeutic alternatives holding a marketing authorisation.

v Pre-market clearance

The procedures for the approval of commercial distribution of medicines and medical devices stem from EU regulation. There is a peculiarity in France arising from the concept of an exploitant of medicines. In addition to the requirement of a marketing authorisation, a medicine may only be marketed by an authorised marketing company, whose premises and operation have been inspected and authorised in advance by the ANSM. The exploitant must either be the marketing authorisation holder, a third party appointed by the latter, or both. It must carry out the pharmaceutical activities connected with the sale, promotion and monitoring of the products, and only pharmacovigilance activities can be sub-contracted as such. A head pharmacist is responsible for the control of all the pharmaceutical activities such as pharmacovigilance processes and the compliance of promotional material with relevant laws.

Medical devices can be marketed in France upon the delivery of an EC-marking. However, in addition, manufacturers located in France must notify the ANSM of the first marketing of their devices, and any commercialisation in France of Class II and Class III medical devices on French territory must be notified to the ANSM (pursuant to the classification of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices), together with a copy of the instruction leaflet.

vi Regulatory incentives

Data and market exclusivity rules in France follow EU regulations. However, there are some national peculiarities concerning the preservation of originators' rights. First, originator companies must notify their rights to the ANSM for publication purposes. Second, such rights can also be notified to the CEPS, which undertakes in principle not to issue any reimbursement decision for generic products more than six months before the expiration of the originators' rights. The CEPS cannot, however, prevent a launch at risk scenario.

9 Law No. 2014-892 of 8 August 2014 on Amendments to Social Security Funding for 2014.

Increasingly, regulatory incentives tend to be developed at the pricing and reimbursement stage. Indeed, framework agreements entered into by the CEPS and the pharmaceutical and medical devices companies provide for pricing incentives or conditional pricing, subject to the conduct of additional studies to monitor the safety and efficacy of their products.[10] The framework agreement between the CEPS and the pharmaceutical companies covering 2016–2018 also confirms the ability to agree on pay-for-performance schemes, but only in situations where the application of usual pricing provision is not adequate.

In addition, the framework agreement speeds up the process for the determination of the price for the most innovative products, and provides for the discharge of mandatory rebates to innovative, orphan and paediatric drugs. Also, various provisions favour innovative paediatric indications, which are granted a one-year extension of guaranteed pricing (six years instead of five), as well as a guaranteed daily treatment cost not lower than for the adults' dosage or the possibility to agree on a capped total turnover.

vii Post-approval controls

Following the French scandal concerning the breast prosthesis PIP, post-approval controls have been increased for medical devices. The ANSM can launch unannounced inspections to detect deviations from applicable technical standards, and impose fines or suspend the marketing of non-compliant products.

In the same way, post-approval controls over pharmaceutical products have improved quite significantly with the right of the ANSM to deliver marketing authorisations on a conditional basis, provided that the holder carries out safety or efficacy studies in real treatment conditions and in comparison with existing therapies within a given time frame.

In 2015, the ANSM recently displayed its willingness to use its post-approval control powers: further to the inspection of manufacturing premises in India, it ordered the suspension of 25 marketing authorisations granted to generic products.

Pharmacovigilance reporting obligations have also been broadened. By a decision of 20 March 2014, the French data protection authority[11] created a template agreement for the collection of personal information for pharmacovigilance purposes. The collection of personal data is simplified and the transfer of data outside of the EU is addressed. In the same manner, the processing of health data in the context of compassionate use (ATU and RTU) is subject to a simplified harmonised procedure since 11 December 2014.[12]

viii Manufacturing controls

France has significantly strengthened manufacturing controls which led, for instance, to the withdrawal of 25 generic products that were manufactured in India. The ANSM

10 See http://social-sante.gouv.fr/IMG/pdf/accord_cadre_11_janvier_2016.compressed.pdf for medicines, and www.sante.gouv.fr/IMG/pdf/accord_cadre_dispositifs_medicaux.pdf for medical devices.

11 Decision No. 2014-099 of 20 March 2014.

12 www.cnil.fr/documentation/deliberations/deliberation/delib/327/.

carried out unannounced inspections in the manufacturing premises and sanctioned the non-compliance with good manufacturing practices. France also actively addresses the recurrent issues relating to the shortage of certain medicines of high therapeutic value or without therapeutic equivalent.

Marketing companies must elaborate alternative plans and should notify the ANSM of any suspected shortage and organise emergency call centres to dispatch products in case of an actual shortage. In addition, pharmacists are now allowed to import alternative products in case of shortage.

ix Advertising and promotion

Following the Bertrand Law of 29 December 2011 relating to the strengthening of the safety of medicines and health products, any kind of advertising and promotion of medicines and certain medical devices now requires prior approval from the ANSM.

Advertising and promotional materials for medicines must be submitted to the ANSM following a specific calendar determined by the ANSM; quarterly for advertising to HCPs and one week per month for advertising to the public. Two months following the expiry date of each period determined by the ANSM for the receipt of the proposed advertising, in the absence of a negative answer from the ANSM, the proposed advertising is deemed approved and will be valid for two years.

The approval process is the same for advertising and promotional materials for medical devices, except that submissions are not bound by the trimestral calendar.

In addition, distribution of samples is now restricted to new drugs or for new indications during the first two years from their launch, and only in reply to a written request placed by an HCP.

x Distributors and wholesalers

Wholesale activities have been affected by various measures aiming to address shortages of some key products. Wholesalers, who in France are entrusted with certain public service duties, must notify the ANSM of their geographic area of activity. In addition, the French Public Health Code now states that wholesalers must first distribute their products in order to meet the health needs in the notified geographic area before exporting them. As a result, pharmaceutical companies shall ensure an appropriate and continuous supply of products to any and all wholesalers, to enable them to comply with these duties.

In addition, the ANSM has audited the compliance with the wholesalers' requirements and has suspended several wholesale licences of distributors whose activity had deviated from the coverage of the French territory to the export of medicines.

Distribution in pharmacies has been significantly affected by recent changes, as outlined below.

First, medicines and medical devices fall within the pharmaceutical monopoly, namely, only a pharmacy that has been granted an authorisation from a regional health agency (ARS), based on the number of residents within its market area, can sell those products to the public. Law No. 2014-344 of 17 March 2014 has removed contact lens solutions, pregnancy tests and ovulation predictors from the monopoly, allowing their distribution in grocery stores.

The Ordinance No. 2012-1427 of 19 December 2012 regulates online sales of medicines. The burdens on online pharmacies are quite similar to those applying to brick-and-mortar ones. Indeed, an authorisation from the ARS is required, and only brick-and-mortar pharmacies are entitled to apply for such agreements.[13] However, the legal framework of online sales has been weakened by the cancellation of the principles of good online distribution decided by the Administrative Supreme Court on 16 March 2015.

xi Classification of products

The transposition into French law of European Directive No. 2011/62/EU on the sale of falsified medicines was rendered difficult by the classification of pharmaceutical products. Indeed, France first restricted online sales to a subcategory of non-prescription drugs, registered on the list of products available by direct access to the public.[14] The Supreme Administrative Court annulled this provision on the grounds of non-compliance with the EU directive that envisaged online sales of any and all over-the-counter products.[15] Consequently, all over-the-counter products are now available online.

xii Imports and exports

The Health Bill has introduced a prohibition for wholesalers exporting any medicine of high therapeutic value or without therapeutic equivalent and conditions the export of other medicines to national needs being first covered.

xiii Controlled substances

Controlled substances are classified into four different categories (dangerous substances, narcotics, psychotropics, and drugs on Controlled Substances Lists I or II), depending on their level of danger. Registration is made by a Ministerial Decree, following the opinion of the ANSM when such substances are medicines. Drugs can receive a categorisation different from that of one of their compounds, and in case of doubt or multiple categorisations, the stricter category will prevail.

Controlled substances in the form of active ingredients are subject to administrative requirements of traceability to track the precise volume used.

Drugs listed on Lists I or II will be subject to specific requirements in terms of storage in separate and secured premises, labelling with a symbol for death, limited volume of product delivered and, concerning narcotics, use of secured prescriptions.

13 Article L. 5125-36 of the French Public Health Code.

14 Article L. 5125-34 of the French Public Health Code, inserted by Article 7 of the Ordinance No. 2012-1427 of 19 December 2012.

15 Council of State, 17 July 2013, No. 365317.

xiv Enforcement

The Health Bill opens the door to significant revisions of the ANSM's powers and sanctions, together with a simplification of its scope of activity. These measures should be adopted by the government in the near future.

III PRICING AND REIMBURSEMENT

Pricing and reimbursement activities are governed by framework agreements entered into between the CEPS and the professional unions of medical devices on the one hand, and medicines on the other.[16]

The framework agreement concerning medical devices was signed for the first time on 16 December 2011. It aims principally at defining a template for each agreement on pricing of medical devices, applicable procedure and time limits.

The framework agreement concerning medicines (which entered into force on 31 December 2015 for the period of 2016 to 2018) provides a comprehensive framework for the determination and evolution of prices. In particular, it allows for an acceleration of the procedure applicable to determine the price of innovative products, by accepting a mechanism whereby the company declares its selling price and the CEPS accepts it within two to three weeks as long as it is consistent with prices in Germany, Italy, Spain and the UK, and provided that the company commits to compensate sales above its forecasts over four years. Outside of this specific scheme, the CEPS undertakes that products recognised as having an important therapeutic benefit (with an 'added clinical value' (ASMR) rating of I, II or III) will not be priced under the lowest of the above European prices, over a five-year period, extended by one additional year for paediatric indications. Other provisions concern paediatric and orphan drugs, including the possibility to agree on a provisional price, pending its confirmation following agreed studies. However, the parties did not manage to agree on rules to apply to biosimilars and their originators, and have created among themselves a committee to address this point that will be crucial for the future.

Health technology assessment procedures were implemented in France by a decree of 2 October 2012.[17] They concern the pricing and reimbursement of products (medical devices and medicines) claiming an important medical benefit (with an ASMR and 'added service value' rating of I, II, III) and that may have a significant impact on the social security budget. The latter criterion is deemed fulfilled if the turnover is above €20 million as from the second full marketing year.[18] However, the HAS may also produce a medico-economic opinion on other products it deems as having a significant impact on the organisation of the health-care system, according to the claims for the product.

16 See footnote 10, *supra*.

17 Ministerial Decree No. 2012-1116 of 2 October 2012 relating to the Medico-economic Functions of the Health Authority.

18 Letter from HAS and CEPS of 24 September 2013, DEMESP/SEESP/CRP/IBD/AT DIR 2013_45.

The procedure is similar to the one relating to opinions issued by the transparency committee for the eligibility for reimbursement by social security: the HAS first issues a draft opinion and then companies can request a hearing within eight days. However, the implementation of this new procedure has been quite difficult and needs clarification on the HAS expectations from the HTA studies.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The legality of decisions of health authorities that have a mandatory effect is reviewed by the Supreme Administrative Court. There have been discussions as to the nature of the control exercised in respect of the HAS's decisions, which simply provide recommendations to HCPs concerning prescription strategies. In 2011, the Supreme Administrative Court changed its case law and considered that such recommendations could be appealed as long as they were binding for the prescribers owing to their obligation to prescribe in compliance with the latest state of the art.[19]

However, the Supreme Administrative Court still considers that opinions from the HAS's transparency committee that are rendered before the decisions on the reimbursement and pricing of a drug cannot be appealed independently of the reimbursement or pricing decisions. This being said, a judgment by an administrative court of 9 October 2015 required the disclosure of the detailed votes of the transparency committee in order to enable companies to ensure the absence of any conflict of interest.[20]

Recent case law provides noteworthy guidance as to the CEPS's room for manoeuvre in setting prices. Indeed, although pricing decisions are rarely reversed, the Supreme Administrative Court has clarified the criteria for the calculation of the price. First, it stressed that the list of criteria provided by law is not exhaustive, but upheld a decision refusing to take into account the costs the company faces, to increase the price of its product.[21] The Supreme Administrative Court upheld another decision setting the price of an orphan drug, taking into consideration an existing treatment, albeit used off-label, as well as the objective of balancing the social security budget,[22] although the Supreme Administrative Court did appoint a judicial expert to provide more details concerning the research and development costs to be taken into account. Finally, the Supreme Administrative Court concluded that a differentiation can be made between different situations or for other reasons of public interest, provided that the difference remains proportionate and directly linked to its aim, thus validating a price decrease imposed by the CEPS in respect of a treatment for osteoarthritis following comparison of its risk profile with those of its competitors.[23]

19 Conseil d'État, 27 April 2011, No. 334396, Formindep.

20 Montreuil Administrative Tribunal, 23 October 2015, No.1411463, Laboratoires Genevrier.

21 Conseil d'État, 15 March 2013, No. 357112, Laboratoire Sciencex.

22 Conseil d'État, 20 March 2013, No. 356661, Laboratoire Addmedica.

23 Conseil d'État, 4 October 2013, No. 356687, Laboratoires Servier.

Moreover, the Administrative Supreme Court did not hesitate to cancel a decision decreasing the price of a drug treating osteoarthritis on the ground of the violation of rules relating to the composition of the CEPS, in particular as regards the level in the hierarchy of representatives from the health ministry.[24]

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

The Bertrand Law was amended by a decree and a governmental circular published respectively on 21 and 29 May 2013[25] (together the French Transparency Act). The reforms became effective as of 1 June 2013, and have been applicable to the relationships between HCPs and the health industry since 1 June 2012.

The French Transparency Act aims to make public any kind of advantages, whether in cash or in kind amounting to €10 or more for each advantage granted directly or indirectly to HCPs, their professional associations, as well as students, patient associations, foundations, health-care centres, prescription software editors, the media and professional training institutions. In addition, pharmaceutical and medical device companies (as defined below) must also disclose the existence of any agreement entered into with HCPs. The Health Bill broadened the disclosure obligations to the detailed object of the agreement, its date, the identification of the direct and final beneficiaries and the remuneration paid to HCPs above a threshold to be determined by a decree. This only concerns situations in which HCPs receive payment or advantages from these companies. In contrast, purchase agreements under which a pharmaceutical or medical device company sells products or services to HCPs, rebates or other advantages linked to such commercial arrangements, are not required to be publicised.

Publication will occur on a bi-annual basis: on 1 October for the first half of the year; and on 1 April of the following year for the second half of the year. All data will remain available for five years, or longer if an agreement is entered into for more than five years.

The French Transparency Act applies to any company that manufactures or markets pharmaceutical products or medical devices in France (regardless of their status in relation to reimbursement by social security), when they enter into agreements with HCPs (or related associations) concerning research, vigilance and safety assessment of their products, and any company delivering services in connection with such products, including marketing, public relations and events agencies.

24 Conseil d'Etat, 3 December 2015, No. 373948-383513, SA Groupe Lepine.

25 Ministerial Decree No. 2013-414 of 21 May 2013 relating to Transparency of Advantages Granted by Companies Manufacturing or Marketing Health or Cosmetic Products for Human Use; Ministerial Notice for Guidance No. DGS/PP2/2013/224 of 29 May 2013 for the Application of Article 2 of Law No. 2011–2012 of 29 December 2011 relating to Increasing the Safety of Medicines and Health Products.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

France has developed a vast range of special compensation systems aimed at providing compensation without the need for the victim to prove a fault. Compensation is usually paid out of public funds, unless fault by the life sciences company is proven. In any case, compensation is governed by the general patterns of liability under French law, which are notably governed by the full compensation of direct damages (physical, financial and moral), but excluding any compensation for consequential damages, and the individual assessment of claims.

Moreover, the Health Bill introduced into French law, for the first time, a class action that aims for compensation for corporate damages caused by health products. The action will be opened retroactively as well for damages caused by products that are no longer on the market. Actions may be brought by approved associations of health-care system users and will be opened by a single judgment on liability. Expert evidence may, however, be necessary at this early stage to establish the defect and the causality with corporate damages. The judgment will list the damages open for indemnification as well as publicity measures. Victims will have between six months and three years to opt in to the action. The judgment may also appoint a mediator for the determination of the indemnification level.

Importantly, the first phase of the class action procedure will suspend the time-bar period for individual actions.

This being said, a court recently granted indemnification to patients treated with Mediator (a weight loss drug), not because they suffered from an adverse effect, but to compensate for the anxiety created by the possibility of being faced with the adverse effect associated with this product.[26] In addition, victims have invoked the responsibility of the French state for having failed to withdraw defective products from the market. While the responsibility of the state has been recognised concerning the *Mediator* case,[27] an administrative court decided that proof was not established of the fact that the ANSM benefited from all necessary information and failed to withdraw the PIP breast implants from the market in due time.[28]

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

EU and French competition laws prohibit anticompetitive agreements and abuse of a dominant position. In this respect, at the national level, agreements between companies that have as their object or effect the prevention, restriction or distortion of competition within the French market are forbidden by French competition rules.[29] In the pharmaceutical sector, this may apply to price-fixing, co-marketing or co-promotion

26 Nanterre Tribunal of First Instance, 28 January 2016.

27 Paris Administrative Court of Appeal, 31 July 2015, No. 14PA04083.

28 Toulon Administrative Tribunal, 22 October 2015, No. 1302231.

29 Article L420-1 of the French Commercial Code.

agreements, which may also give rise to illegal exchanges of sensitive information insofar as they lead to a restriction of competition among the concerned companies. In addition, unilateral conduct of a dominant undertaking that acts in an abusive manner is also prohibited.[30] When there is a suspicion of such a practice – which may be brought through a claim by the victim of such conduct – the French Competition Authority (FCA) is empowered to conduct an investigation at the undertaking's premises (in practice, extensive investigative powers apply) or to send a request for information. Fines for such anticompetitive behaviours can reach 10 per cent of the group's worldwide turnover[31] and, in the meantime, the FCA may order interim measures in urgent and extreme cases.

In this framework, the FCA adopted two decisions in 2013, fining Sanofi and Merck (respectively €40 million and €16 million) for having abused their dominant position in relation to generics. These decisions have been upheld by the Court of Appeal,[32] but are subject to pending final validation by the Supreme Court.

The FCA made a specific case with respect to these pharmaceutical companies, because of the context in which they operated. Moreover, it considered that a communication with respect to a pharmaceutical product confronted with a competing generic product may constitute a quasi 'automatic' abuse as soon as it is capable of having a negative impact on the generic product. This could happen if the originator does not limit itself to pointing out the objective qualities of its own product and does not refrain from emphasising the differences between the originator product and the generic drug. Such communication is analysed in detail and within the general context. As such, isolated elements, in themselves not illegal, may be punished by the FCA as a global, coherent and structured communication strategy, the goal of which is considered to be preventing or limiting the entry of the generic medication on the market.

In addition, the FCA issued a report on its pharmaceutical sector inquiry that was launched at the beginning of 2013, pointing out several potential competition law issues at each stage of the drugs life cycle. Among its recommendations, the FCA pushed for more regulatory incentives to encourage more competition from generic products, increase online sales and parallel trade, but also for the exchange of information between the FCA and pricing and health authorities to detect possible collusions in the calculation of the costs to be taken into account. This may trigger new investigations in the sector, as the inquiry may have been an opportunity for collecting information on the conduct of various actors in the market.

ii Transactional issues

Given the size of the potential combined turnover in question, mergers in the health area often give rise to an analysis from a competition law standpoint. A key element in this respect is the determination of the relevant market in respect of which the potential effects

30 Article L420-2 of the French Commercial Code.

31 Article L464-2 of the French Commercial Code.

32 Paris Administrative Court of Appeal, 18 December 2014, No. 2013/12370 and 26 March 2015, No. 2014/03330.

of the contemplated merger will be assessed. The case law is not fully settled in this field. Indeed, although the competition authorities consider the ATC/DDD[33] classification, at Level 3, as a starting point, the FCA may then combine various classes in light of the products' therapeutic indications or galenic form. In addition, the analysis may narrow to Level 4 or even Level 5, at the molecular level. Indeed, this was the approach taken by the FCA in a recent case, where it cleared a concentration by analysing the market shares of two companies from ATC/DDD Levels 3 to 5.[34]

VIII CURRENT DEVELOPMENTS

Health data becomes increasingly valuable.

On 24 September 2015, the Paris Court of Appeal upheld a decision by the FCA sanctioning Cegedim for having refused to sell its OneKey database to clients using competing CRM softwares.

More surprisingly, the Health Bill opened access to the publicly held health data for any research project of public interest.

33 The World Health Organization's Anatomical Therapeutic Chemical Classification System with Defined Daily Doses (ATC/DDD).

34 Decision No. 13-DCC-106 of 6 August 2013 related to acquisition of sole control of Warner Chilcott Company by Actavis Inc.

Appendix 1

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Sophie Pelé focuses her practice on life sciences regulatory matters and has experience with competition, litigation and public law matters in a wide variety of regulated industries. Her 'strong regulatory expertise' has been noted in *The Legal 500* and *EMEA Guide* 2015. Ms Pelé has substantial experience in clinical trial agreements, manufacturing or promotion agreements, marketing authorisations, pricing and reimbursement with governmental authorities, distribution schemes, import-export and parallel trade, public procurement at hospitals, compliance and interaction with health-care professionals, advertising, and substitution of generic and biosimilar products. Ms Pelé regularly represents multinational companies before French administrative jurisdictions.

Prior to joining Dechert, Ms Pelé served as a senior associate in the competition and regulatory department of another international law firm. Her previous experience also includes working at another leading law firm in life sciences in Paris.

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