The Life Sciences Law Review

Fifth Edition

Editor
Richard Kingham

Law Business Research

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EDITOR'S PREFACE

The fifth edition of *The Life Sciences Law Review* covers a total of 37 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged 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.

Now, more than ever, it is important for leaders in the pharmaceutical and medical device industries and their advisers to be knowledgeable about the laws and regulations in major jurisdictions around the world. In the past year, there have been significant developments in the regulation of drugs and medical devices, especially in the United States, where a new law – the 21st Century Cures Act – was passed at the end of 2016. There are prospects for further developments in the coming year. The new president and the Republican-controlled Congress will consider legislative measures affecting the pharmaceutical and medical device sectors, including proposed repeal of the Affordable Care Act, continuing inquiries into pricing of medical products and reauthorisation of user fee laws that fund a substantial part of the drug and device approval processes. The United Kingdom will initiate formal proceedings to begin the process of withdrawing from the European Union, with potential consequences for the medical products sectors. Other jurisdictions, including China and India, are considering reforms to their regulatory systems for medicinal products.

Each of the chapters has 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 annual publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2017

Chapter 11

FRANCE

Sophie Pelé[1]

I INTRODUCTION

The French regulatory framework for life sciences products is regarded as highly sophisticated, and was one of the pillars for the creation of the EU regulatory framework. However, the EU framework has developed significantly, and now the French and EU regulations do not always correspond to each other. An example of this is 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 healthcare professional' letters; authorisation of advertising; and inspections of manufacturing 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

1 Sophie Pelé is a partner 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.

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 software that assists 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, French case law continues to broaden the scope of products falling within the definition of pharmaceutical products. This is the case for food supplements claiming to have therapeutic effects[4] and tiger balsam, the status of which is still not settled.[5]

ii Non-clinical studies

The status of non-interventional studies conducted on human beings has been aligned with rules applicable to clinical trials, with some specificities. For instance, the ethics committee can give its opinion with only two members present, and the approval from the ANSM is not required.

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. 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]

Decree No. 2016-1537 of 16 November 2016 significantly amended the regime applicable to clinical trials. Private sponsors must supply all the tested products free of charge to the healthcare centres hosting the healthcare professionals (HCPs) appointed as investigators and compensate for the costs and extra costs incurred in conducting the trial. For transparency reasons, the competent ethics committee will now be designated based on

4 Criminal supreme court, 24 November 2015, 14-87.689, Unpublished.

5 Criminal supreme court, 8 July 2015, 14-83.624.

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

a lottery. The Decree has notably been adopted in response to the deaths that occurred in the Biotrial research in 2015. Consequently, the reporting of adverse or unexpected events is significantly strengthened, and must lead to the provisionally suspending the administration of the tested product in Phase I.

The ANSM initiated a pilot phase during which, on a voluntary basis, ethics committees, subject to the promoter's acceptance, can implement the Regulation on clinical trials No. 536/2014. After one year of implementation, the time frame to review the applications is, on average, 64 days.

In 2014, the French government issued harmonised template agreements with the aim of accelerating the implementation of trials within French public hospitals.[7] Decree No. 2016-1538 dated 16 November 2016 broadens their application to any type of privately sponsored trial. The harmonised agreement is exclusive of any other agreement entered into in the framework of the same trial. It must therefore include the negotiations with the investigators, associations participating to the trial, etc. Moreover, 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 counterparts in return for the quality of the data collected, which correspond to former financial incentives related to the inclusion of patients.

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] A temporary authorisation 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, an 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, an 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 the art, or because it is permitted by an RTU issued by the ANSM. The conditions for granting RTUs are similar to ATUs, except that they are imposed by the authorities upon pharmaceutical companies. In addition, the

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.

law amending social security funding for 2014[9] broadened the regime of RTU to cases where therapeutic alternatives might be available, but not with the same active substance, dosage or pharmaceutical form. On 29 June 2016, the Administrative Supreme Court upheld this broadening of the RTU regime to cases where therapeutic alternatives are available, which had been challenged, among others, on the basis of violation of Article 5 of Directive 2001/83/EC.

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 subcontracted 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 CE 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 implantable 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 an at-risk launch scenario.

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 to 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. Moreover,

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

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.

the Ministries supervising the CEPS stated that they intended such pay-for-performance agreements to be limited to cases where the social security would not bear any risk, which will probably reduce the number of such innovative agreements.[11]

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 Poly Implant Prothèse (a company that produced breast prostheses), 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.

Pharmacovigilance reporting obligations have also been broadened. By a decision of 20 March 2014, the French data protection authority[12] 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.[13]

viii Manufacturing controls

The recurrent issues relating to the shortage of certain medicines, including those of high therapeutic value or without therapeutic equivalent, have given rise to multiple changes into the regulation.

Decree No. 2016-993 of 20 July 2016 obliges companies themselves to identify the medicines with high therapeutic value, for which they must elaborate detailed alternative plans and organise emergency call centres to dispatch products in case of an actual shortage. Any suspected shortage must be notified to the ANSM. In addition, pharmacists are 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.

11 Ministerial Orientation, 17 August 2016.

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

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

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.

Ordinance No. 2012-1427 of 19 December 2012 regulates online sales of medicines. The obligations for online pharmacies are quite similar to those for brick-and-mortar pharmacies. Indeed, an authorisation from the ARS is required, and only brick-and-mortar pharmacies are entitled to apply for such agreements.[14] 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, which must be substituted by a ministerial order still to be issued.

xi Classification of products

The transposition into French law of Directive 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

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

products available by direct access to the public.[15] 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.[16] Consequently, all over-the-counter products are now available online.[17]

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 cover national needs first. Moreover, an experimentation will be carried out whereby wholesalers will notify an independent third party of the volumes sold outside of the French territory.

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 included 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.

xiv Enforcement

The ANSM's powers and sanctions have been strengthened by Ordinance No. 2016-966 of 15 July 2016, together with a simplification of its scope of activity.

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.[18]

The framework agreement concerning medical devices was signed for the first time on 16 December 2011. Its principle aim is to define a template for each agreement on pricing of medical devices, applicable procedure and time limits. Its duration was initially envisaged to be three years but it has not been amended since then.

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

16 Administrative Supreme Court, 17 July 2013, No. 365317.

17 Ordinance No. 2016-966 of 15 July 2016.

18 See footnote 10, *supra*.

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 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.[19] 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.[20] 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 healthcare system, according to the claims for the product.

The procedure is similar to the procedure 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. In guidelines issued in November 2016, the HAS clarified the methodology of HTA studies, notably the fact that the financial expectations should cover a three- to five-year term.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The legality of decisions of health authorities that have a mandatory effect is reviewed by the Supreme Administrative Court.

Recent case law has significantly increased the monitoring of the CEPS's room for manoeuvre in setting prices. The Administrative Supreme Court does not hesitate, even in summary proceedings, to request from the CEPS detailed economic justifications explaining the level of price decrease imposed. The CEPS cannot impose a price decrease for the mere reason that the global increase of spending authorised by the parliament must be maintained; objective and transparent criteria must be adhered to.[21] In addition, on the basis of the Transparency Directive, the CEPS has been sanctioned for not having published the criteria

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

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

21 Administrative Supreme Court, 18 April 2016, No. 397909, Advanced Technical Fabrication.

followed for the refusal to reimburse a product.[22] As a consequence of such judgment, the Social Security Bill for 2017 significantly amended the circumstances in which price decreases can be imposed.[23] The Court also stressed that the CEPS should adhere to the criteria set forth for the determination of the price. In cases where the cost of goods is taken into account, the CEPS cannot keep only 50 per cent of the value of trademark rights.[24]

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

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

The 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 by any company that manufactures or markets pharmaceutical products or medical devices in France (regardless of their status in relation to reimbursement by social security), and any company delivering services in connection with such products, including marketing, public relations and events agencies, directly or indirectly to HCPs and their professional associations, as well as students, patient associations, foundations, healthcare 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, as amended by Ordinance No. 2017-49 of 19 January 2017, 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 of €10.

Publication will occur on a biannual 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 Ordinance of 19 January 2017 also significantly reshaped the French anti-kickback rules. The scope is broadened regardless of the status of the products with regards to reimbursement. Any type of advantage proposed or procured is prohibited. However, it is now specified that royalties paid in connection to IP rights are not deemed an advantage. Fees paid for research or consultancy, grants, professional trainings, hospitality, are subject to a written agreement and a prior authorisation from the physicians' professional board. The maximum criminal fines have been increased to up to €150,000 for natural persons and €750,000 for legal persons.

22 Administrative Supreme Court, 27 June 2016, No. 386332, *GSK*.

23 Social Security Bill for 2017, No. 2016-1827, 23 December 2016.

24 Administrative Supreme Court, 13 May 2016, No. 381148, *Teofarma*.

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

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 healthcare 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 into 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.

The class action regime has been effective since the publication of Order No. 2016-1249 of 26 September 2016.

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.[26] In the pharmaceutical sector, this may apply to price-fixing, co-marketing or co-promotion 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.[27] 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 behaviour can reach 10 per cent of the group's worldwide turnover[28] 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. On 18 October 2016, the Supreme Court validated the fine imposed in the *Plavix* case.

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

26 Article L420-1 of the French Commercial Code.

27 Article L420-2 of the French Commercial Code.

28 Article L464-2 of the French Commercial Code.

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.

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 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[29] 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.[30]

VIII CURRENT DEVELOPMENTS

The Social Security Bill for 2017 has introduced various mechanisms to contain the increase of high prices of innovative therapies. Among others, the ATUs, whose price was, by way of principle, set freely by the companies, is now bound by two sets of rules: first, the companies will have to pay the difference between the ATU price and the net price negotiated with the CEPS; and second, unless the final price is set higher, the payment shall include the difference between the ATU price and a threshold of €10,000 per patient and per year, unless the overall turnover of the product is less than €30 million.

Competition on prices will also play an important role in the penetration of biosimilars, in the context of a changing scientific and regulatory environment. In May 2016, the ANSM issued guidelines stating that interchangeability during the treatment could be envisaged, subject to proper information delivered to the patient, agreement and monitoring of the patient, and strict traceability of the product. The Social Security Bill transposes these principles of information and monitoring at the level of the substitution by pharmacists. It remains to be seen how these rules will be understood and combined, especially in a context where biosimilars are mostly used in hospitals and purchased through public tenders.

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

30 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 is a national partner at Dechert LLP. She 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 healthcare 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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