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THE PRIVATE WEALTH AND PRIVATE CLIENT REVIEW
THE MINING LAW REVIEW
THE EXECUTIVE REMUNERATION REVIEW
THE ANTI-BRIBERY AND ANTI-CORRUPTION REVIEW
THE CARTELS AND LENIENCY REVIEW
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EDITOR’S PREFACE

The second edition of the Life Sciences Law Review provides an overview of legal issues of interest to pharmaceutical, biotechnology and medical device companies in 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.

This edition also includes a new 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 (ICH) 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 of 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 2014
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. The EU framework has developed significantly, however, 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’ (marketing company, 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. Pricing and reimbursement matters are covered by the Social Security Code. 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, the granting of marketing authorisations, the issuance of dear doctor

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1 Sophie Pelé is an associate at Norton Rose Fulbright LLP.
letters,4 the authorisation of advertising, and the 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 diseases, the assessment of the therapeutic benefits of medicines and medical devices for reimbursement purposes through its transparency committee, and the accreditation of sales representatives’ networks pursuant to ethics’ guidelines. 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 frameworks. 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.

Both categories of products are, however, treated similarly in some respects. France has recently provided that, just like medicines, advertising material for medical devices 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 Justice5 has recently recognised.

ii Non-clinical studies

A law adopted on 5 March 20126 significantly reshaped the framework for biomedical research in France; however, that law has not yet entered into force and might be delayed because of the expected implementation of a new regulation under discussion at EU level. Non-clinical studies would fall within the boundaries of regulated research and, as such, require the prior assessment of an ethics committee, to be carried out pursuant to good practice and, depending on the degree and nature of additional intervention on the human body as compared with usual therapies, the prior informed consent of all patients. Non-clinical trials, however, with minimal associated risks would merely require informed consent, in writing or otherwise, whereas observational non-interventional studies could be carried out as long as patients do not object.

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4 A direct health-care professional communication, defined as information aimed at ensuring safe and effective use of medicinal products which is delivered directly to individual health-care professionals by a marketing authorisation Holder, or by a competent authority.
5 ECJ, 3 October 2013, C-109/12, Laboratoires Lyocentre.
6 Law No. 2012-300 (Loi Jardé) relating to research involving human beings.
iii Clinical trials

Clinical trials for medicines and medical devices conducted in France must receive a prior opinion from an ethics committee (CPP) and prior approval from the ANSM. 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.

Once the law of 5 March 2012 comes into effect, sponsors will be required to make publicly available the results of the studies within a reasonable period of time. In addition, they will have to identify the country where the studies were carried out, if it is outside the European Union.

Interestingly, sponsors based in France will be allowed to submit their study plans to French ethics committees for prior opinion even if they plan to conduct the studies outside the European Union.7

The methodology of clinical trials is also subject to some guidance from the French health authorities. For instance, clinical studies on medical devices, which show some specificity as compared with trials of medicines, may not always be conducted in the form of double-blind randomised studies, which is usually requested by the authorities. Therefore, the HAS recently issued a notice on the quality criteria to which the methodology must adhere in such a case.8

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 2011.9 Temporary authorisations for use (ATUs) 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, the 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, ATUs 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 highly 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 a temporary recommendation for use. In the absence of any marketing authorisation or ATU, a product may be prescribed off-label, either because it is vital to the treatment of a patient, in light of the existing state of the art, or because it is permitted by a temporary recommendation for use (RTU) issued by the ANSM. The

7 Article L1123-7-1 of the French Public Health Code.
9 Law No. 2011-2012 of 29 December 2011 relating to strengthening safety of medicines and health products.
conditions for granting RTUs are rather similar to ATUs, except that they are imposed by the authorities upon pharmaceutical companies. In addition, the law for social security funding for 2013\textsuperscript{10} extended the possibility for the ANSM to issue RTUs although other treatments are already authorised. The objective of this is to allow the use of products more affordable than those already authorised. This position was adopted in response to the situation in which Avastin is used to treat age-related macular degeneration at a more affordable price than Lucentis.

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 the ‘exploitant’ of medicines. In addition to the requirement for a marketing authorisation, a medicine may only be marketed by an authorised marketing company, the premises and operations of which has been inspected and authorised in advance by the ANSM. A head pharmacist is responsible for the control of the main 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. In addition, however, 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 in 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).

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 not to issue any reimbursement decisions for generic products more than six months prior to the expiration of the originators’ rights.

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.\textsuperscript{11}

In addition, the framework agreement between the CEPS and the pharmaceutical companies speeds up the process for the determination of the price for the most innovative products, and provides for the discharge of rebates to innovative, orphan and paediatric drugs. Also, various provisions favour innovative paediatric indications, which

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\textsuperscript{10} Law No. 2012-1404 of 17 December 2012 on social security funding for 2013.

are granted a one-year extension of guaranteed pricing (six years instead of five), as well as a guaranteed daily treatment cost no lower than for the adults’ dosage.

The framework agreement also encourages originators to authorise early entry of generic products, by allowing a reduction of rebates to be paid by originators companies to the CEPS on the volumes of products sold.

vii Post-approval controls
Following the French scandal concerning PIP breast prostheses, post-approval controls have been increased for medical devices. The ANSM can launch surprise 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.

viii Manufacturing controls
France has just implemented the changes made by Directive No. 2011/62/EC on good manufacturing practices and issued updated guidelines. They notably enhance traceability measures and safety features, as well as the control over active ingredients (such as audits to be carried out by the manufacturers of final products at the premises of manufacturers of active substances, or use of imported active substances produced pursuant to the highest standards).

France also recently implemented several provisions aimed at monitoring shortages of certain medicines of high therapeutic value, or without therapeutic equivalent.

Marketing companies must notify the ANSM of any suspected shortage and organise emergency call centres to dispatch the products in case of an effective shortage. Periodic reports of deliveries made through emergency call centres must also be notified to the ANSM.

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 type 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: each quarter for advertising to HCPs and one week per month for advertising to the public. Two months

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12 http://ansm.sante.fr/Activites/Elaboration-de-bonnes-pratiques/Bonnes-pratiques-de-fabrication-de-medicaments-a-usage-humain/(offset)/2.

following the expiry date of each period determined by the ANSM for the receipt of 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 after their launch, and only in reply to a written request placed by a health-care professional.

x DISTRIBUTORS AND WHOLESALERS
Wholesale activities have been affected by a Decree of 28 September 2012,\(^\text{14}\) in order to address shortages of some key products. Wholesalers who in France are entrusted with public service duties, must notify the ANSM of their geographical 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 geographical area prior to exporting them.

In parallel to the above, it is also specified that pharmaceutical companies must ensure an appropriate and continuous supply of products to any and all wholesalers to enable them to comply with these duties.

xi CLASSIFICATION OF PRODUCTS
The transposition into French law of the 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.\(^\text{15}\) The Administrative Supreme 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 (OTC) products.\(^\text{16}\) Consequently, all OTC products are now available online.

xii IMPORTS AND EXPORTS
Similar to the provisions described above relating to the regulated distribution of pharmaceutical products, new measures have been adopted to control the import and export of products that could lead to shortages of such products in some parts of the French territory. Wholesalers are required to notify pharmaceutical companies of the products and volumes they export outside of the French territory. This notification, however, only concerns a limited list of products to be decided by a ministerial decree which has not yet been adopted. Moreover, the technical details of the information to be included in the notification will be provided for in an agreement between the

\(^{14}\) See footnote 11, supra.


\(^{16}\) Administrative Supreme Court, 17 July 2013, No. 365317.
pharmaceutical companies, wholesalers and the Health Ministry, which is still to be negotiated.

xiii Controlled substances

Controlled substances are classified into four different categories (dangerous, narcotics, psychotropics, and drugs on lists I or II), depending on their level of danger. Registration is made by Ministerial Decree, following the opinion of the ANSM when such substances are medicines. Drugs can receive a categorisation different to that of their compounds, and in the event 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 List I or II of controlled substances 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 is empowered with significant inspection powers to control each step of the supply chain for drugs and medical devices. It has recently updated its framework for the conduct of inspections, in order to focus on a risk-based approach and enhance the adoption of remedial and preventive measures throughout the various activities of controlled entities.17

The Bertrand Law of 29 December 2011 also increased the variety of fines that may be imposed by the ANSM for breaches of applicable health regulations, such as the non-declaration of shortages, the failure of wholesalers to comply with their public service obligations, the failure to notify a suspected adverse event or put in place a pharmacovigilance scheme.

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. It aims principally at defining a template for each agreement on the pricing of medical devices, applicable procedure and time limits.

The framework agreement concerning medicines (entering into force on 5 December 2012) provides a comprehensive framework for the determination and evolution of prices. In particular, it allows for an acceleration of the procedure

17 http://ansm.sante.fr/S-informer/Actualite/Nouveau-format-de-rapport-d-inspection-phase-pilote.

18 See footnote 9, supra.
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, the United Kingdom, Italy and Spain, 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 (ASMR19 I, II, III) will not be priced under the lowest of the above European prices, over a five-year period, extended by one year for paediatric indications. Other provisions concern paediatric and orphan drugs, including the possibility of agreeing on a provisional price, pending its confirmation following any agreed studies.

Health technology assessment procedures were implemented in France by a decree of 2 October 2012.20 They concern the pricing and reimbursement of products (medical devices and medicines) claiming an important medical benefit (ASMR/ASA21 I, II, III) and which 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.22 The HAS may, however, 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 one relating to opinions issued by the transparency committee for the eligibility to reimbursement from Social Security: the HAS first issues a draft opinion and companies can request a hearing within eight days.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The legality of decisions of health authorities that have a mandatory effect is reviewed by the Administrative Supreme 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 Administrative Supreme Court changed its case law and considered that such recommendations could be appealed as long as they were binding on the prescribers due to their obligation to prescribe in compliance with the latest state of the art.23

The Administrative Supreme Court still, however, considers that opinions from the transparency committee sitting within the HAS prior to the reimbursement and

19 Amélioration du service médical rendu is the scale between I (important) and V (absent) to rank the therapeutic benefit of medicines.
20 Ministerial Decree No. 2012-1116 of 2 October 2012 relating to medico-economic functions of the Health Authority.
21 Amélioration du service attendu is the scale between I (important) and V (absent) for ranking medical devices.
22 Letter from HAS and CEPS of 24 September 2013, DEMESP/SEESP/CRP/IBD/AT DIR 2013_45.
23 Administrative Supreme Court, 27 April 2011, No. 334396, Formindep.
pricing of a drug cannot be appealed independently of the reimbursement or pricing decisions.

In this respect, recent case law provides noteworthy guidance as to the CEPS’s margin of manoeuvre in price-setting decisions. Indeed, although pricing decisions are rarely reversed, the Administrative Supreme Court has clarified the criteria for the calculation of prices. 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 is facing, to increase the price of its product.24 The Administrative Supreme Court upheld another decision setting the price of an orphan disease drug taking into consideration a pre-existing treatment – albeit used off-label – as well as the objective of economic balancing of social security funding,25 although the Administrative Supreme Court did appoint a judicial expert to provide more details concerning research and development costs to be taken into account. Finally, the Administrative Supreme Court concluded that 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.26

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

The Bertrand Law of 29 December 2011 was amended by a decree and a governmental circular published respectively on 21 and 29 May 201327 (together, the French Transparency Act). The reforms became effective on 1 June 2013, and are applicable to the relationships between HCPs and the health industry dating from 1 June 2012.

The French Transparency Act aims to make public any kind of advantage, whether in cash or kind, amounting to €10 or more for each advantage granted directly or indirectly to HCPs and their professional associations, as well as students, patient associations, foundations, health-care centres, prescription software editors, 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. This only concerns situations in which HCPs receive payment or benefits 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. The governmental

24 Administrative Supreme Court, 15 March 2013, No. 357112, Laboratoire Sciencesx.
25 Administrative Supreme Court, 20 March 2013, No. 356661, Laboratoire Addmedica.
26 Administrative Supreme Court, 4 October 2013, No. 356687, Laboratoires Servier.
circular emphasises that fees to HCPs for advice provided in such agreements that are disproportionate compared with the value of the advice could be deemed an advantage, and should therefore be disclosed as such.

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 longer 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 with regard to reimbursement from Social Security), companies manufacturing or marketing cosmetic products (including personal care products) or contact lenses, when they enter into agreements with HCPs (or related associations) concerning research, vigilance and safety assessments of their products, and any company delivering services in connection with such products, including marketing, public relations and events agencies.

After an interim period during which each company must disclose the above information on its corporate website, publication will be made on a dedicated website administered by the French authorities.

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:

a the full compensation of direct damages (physical, financial and moral), to the exclusion of any compensation for consequential damages, and

b the individual assessment of any claim, excluding class actions.28

France recently brought into effect a unique regime aimed at facilitating the indemnification of victims of benfluorex. An independent indemnification body (ONIAM) can be requested by victims to facilitate amicable settlement of an indemnification claim or, alternatively, grant indemnification in the absence of any reasonable offer from the manufacturer. ONIAM will then sue the manufacturer, who will refund the indemnity payment, increased by a 30 per cent penalty, if judges confirm the manufacturer’s liability. If they chose the indemnification fund route, victims can also appeal before civil courts if the proposal is highly insufficient (the magnitude of which should be decided upon by the judges on a case-by-case basis). If liability is confirmed, the judge will apply the 30 per cent penalty to the indemnification.

28 It is worth noting in this respect that health and physical damages have intentionally been excluded from the law under consideration by the French legislator to introduce class actions for the first time under French law.
VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

EU and French competition laws prohibit anti-competitive agreements and abuse of a dominant position. In this respect, at French 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 the French competition rules.29 In the pharmaceutical sector, this may apply to price fixing, co-marketing or co-promotion agreements that may also give rise to illegal exchanges of sensitive information insofar as they lead to a restriction of competition among the companies concerned. 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, broad investigative powers apply) or to send a request for information (or both). Fines for such anti-competitive behaviour can go up to 10 per cent of the group’s worldwide turnover31 and, in the meantime, the FCA may order interim measures in urgent and extreme cases.

Within this framework, the FCA adopted two decisions in 2013 fining Sanofi and Merck (respectively €40 million and €16 million) for having abused their dominant positions against generics.

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 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 prevent or limit the entry of the generic medication on to the market.

In addition, the FCA issued a report on its pharmaceutical sector inquiry, which 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 and 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 market participants.

29 Article L420-1 of the French Commercial Code.
31 Article L464-2 of the French Commercial Code.
ii Transactional issues

Given the size of the potential combined turnover in question, mergers in the health area often give rise to 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 classification\(^ {32}\) 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 molecule level, albeit this tends to be more the case in antitrust cases rather than in merger cases.

VIII CURRENT DEVELOPMENTS

The new law for the funding of the social security for 2014\(^ {33}\) has two provisions that directly affect pharmaceutical companies.

First, the existing tax imposed on sales to pharmacists, which affects direct sales by pharmaceutical companies (i.e., those made without going through wholesalers), has been significantly increased: in addition to the existing first two thresholds, an additional 20 per cent has been imposed on the level of rebate granted by companies to the pharmacists, compared with the prices at which the products are sold by the wholesalers.

Second, the provisions allowing pharmacists to substitute a generic for a prescribed original has been transposed and adapted for biosimilar products. Substitution of biologic products by their biosimilars will be allowed for the first initiation of a treatment or continuing a treatment with the same large molecule.

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32 The World Health Organisation’s Anatomical Therapeutic Chemical Classification System with Defined Daily Doses.

Appendix 1

ABOUT THE AUTHORS

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Sophie Pelé is a lawyer in the antitrust, competition and regulatory department of Norton Rose Fulbright LLP in Paris office. Before joining Norton Rose Fulbright LLP in Paris, she spent six years in an international law firm of very first ranking in the life sciences field. Ms Pelé started specialising in public law and regulatory law eight years ago, focusing on the interplay between regulatory and competition law in regulated fields.

She focuses on highly regulated industry, notably life sciences, advising in various fields: clinical trial agreements, manufacturing agreements, marketing authorisations, import-export and parallel trade, pricing and reimbursement with governmental authorities, distribution schemes, public procurement at hospitals, compliance and interaction with health-care professionals, advertising and substitution of generic products.

Ms Pelé advises actors in regulated industries in their relations with independent regulators and administrative authorities.

She mainly assists clients of the pharmaceutical, medical devices, cosmetic, agro and food supplement industries, advising on regulatory aspects, including litigation before French administrative jurisdictions.

She also advises on consumer law, from the control of beneficial claims for health and the granting of commercial advantages to unfair and misleading advertising.
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