The Life Sciences Law Review

Editor
Richard Kingham

Law Business Research

The Life Sciences Law Review

This article was first published in The Life Sciences Law Review, 1st edition (published in April 2013 – editor Richard Kingham).

The Life Sciences Law Review

Editor
Richard Kingham

Law Business Research Ltd

THE LAW REVIEWS

THE MERGERS AND ACQUISITIONS REVIEW

THE RESTRUCTURING REVIEW

THE PRIVATE COMPETITION ENFORCEMENT REVIEW

THE DISPUTE RESOLUTION REVIEW

THE EMPLOYMENT LAW REVIEW

THE PUBLIC COMPETITION ENFORCEMENT REVIEW

THE BANKING REGULATION REVIEW

THE INTERNATIONAL ARBITRATION REVIEW

THE MERGER CONTROL REVIEW

THE TECHNOLOGY, MEDIA AND

TELECOMMUNICATIONS REVIEW

THE INWARD INVESTMENT AND

INTERNATIONAL TAXATION REVIEW

THE CORPORATE GOVERNANCE REVIEW

THE CORPORATE IMMIGRATION REVIEW

THE INTERNATIONAL INVESTIGATIONS REVIEW

THE PROJECTS AND CONSTRUCTION REVIEW

THE INTERNATIONAL CAPITAL MARKETS REVIEW

THE REAL ESTATE LAW REVIEW

THE PRIVATE EQUITY REVIEW

THE ENERGY REGULATION AND MARKETS REVIEW

THE INTELLECTUAL PROPERTY REVIEW

THE ASSET MANAGEMENT REVIEW

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

THE TAX DISPUTES AND LITIGATION REVIEW

THE LIFE SCIENCES LAW REVIEW

www.TheLawReviews.co.uk

PUBLISHER
Gideon Roberton

BUSINESS DEVELOPMENT MANAGERS
Adam Sargent, Nick Barette

MARKETING MANAGERS
Katherine Jablonowska, Thomas Lee, James Spearing

PUBLISHING ASSISTANT
Lucy Brewer

PRODUCTION COORDINATOR
Lydia Gerges

HEAD OF EDITORIAL PRODUCTION
Adam Myers

CHIEF SUBEDITOR
Jonathan Allen

SUBEDITOR
Anna Andreoli

EDITOR-IN-CHIEF
Callum Campbell

MANAGING DIRECTOR
Richard Davey

Published in the United Kingdom
by Law Business Research Ltd, London
87 Lancaster Road, London, W11 1QQ, UK

www.TheLawReviews.co.uk

ISBN 978-1-907606-60-1

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following law firms for their learned assistance throughout the preparation of this book:

ADVOKATFIRMAET BA-HR DA

BAE, KIM & LEE LLC

BÄR & KARRER AG

CORPORATE LAW GROUP

COVINGTON & BURLING LLP

DIERKS + BOHLE

FAUS & MOLINER

FIEBINGER POLAK LEON & PARTNER RECHTSANWÄLTE

HOGAN LOVELLS

KHURSHEED KHAN & ASSOCIATES

LEE AND LI, ATTORNEYS-AT-LAW

MAPLES AND CALDER

MATTOS MURIEL KESTENER ADVOGADOS

NAGASHIMA OHNO & TSUNEMATSU

NORTON ROSE

NSN LAW FIRM

PLESNER LAW FIRM

ROSCHIER

SÁNCHEZ DEVANNY

CONTENTS

EDITOR'S PREFACE

It is a pleasure to serve as the editor of the first edition of *The Life Sciences Law Review*, which aims to provide an overview of legal issues of special interest to pharmaceutical, biotechnology and medical device companies in 27 jurisdictions. The life sciences sector is of vital importance to the health and well-being of persons around the world. Innovative manufacturers play a key role in the discovery and development of new therapies, while generic manufacturers serve an equally important function by ensuring availability of inexpensive products once patents and regulatory exclusivity periods expire. Throughout the lifespan of a drug or device – from the earliest discovery stage, through non-clinical tests and clinical trials, the governmental approval process, and after entry to the market – lawyers play a central role as advisers to the industry.

We have sought to organise the regulatory discussion in each national entry to correspond roughly to the key stages of product development: the regulatory classification of the product, which determines requirements for approval; non-clinical studies and clinical trials; compassionate use prior to approval; product pre-clearance; regulatory incentives for investment in drug development; post-approval controls; manufacturing; promotion; distribution; legal status; imports and exports; special rules on controlled substances; and enforcement.

In addition to product pre-clearance procedures, many jurisdictions impose requirements for approval of pricing or reimbursement of pharmaceuticals and, to a lesser extent, devices. These are addressed in the entry for each country. We also set out basic information on administrative and judicial remedies, controls on financial relationships with prescribers and payors, special liability systems, and transactional and competition issues that are specific to pharmaceuticals and medical devices.

Finally, each chapter identifies issues of current interest in the jurisdiction. These include, for example, plans to increase transparency in the regulatory process without undermining protection of intellectual and industry property; efforts to adapt traditional regulatory systems to new and emerging technologies, such as companion diagnostics, gene therapy and cell processing; and implementation of regulatory pathways for

'biosimilars' as patents expire for the first generation of biotechnology-derived medicinal properties. As these and other issues develop, we expect to devote additional attention to them in future editions.

I wish to thank all of the contributors who have made this publication possible. They are an impressive group, and it is a privilege to be associated with them in this enterprise.

Richard Kingham

Covington & Burling LLP
Washington, DC
March 2013

Chapter 10

FRANCE

Mikael Salmela, Cécile Derycke and Ombline Ancelin[1]

I INTRODUCTION

Medicines and medical devices are regulated mainly under the Public Health Code ('CSP'), which deals with a wide array of matters such as clinical trials, marketing authorisations and CE-marking, manufacturing and distribution, advertising, and relationships with health-care professionals. The Social Security Code ('CSS') also contains several provisions focusing on pricing and reimbursement. This legal framework is complemented by a variety of governmental decrees and decisions of the health authorities, as well as agreements between authorities and representatives of the industry (e.g., for reimbursement).

The main authorities involved in enforcing the medicines and medical device regulations are as described below.

The National Security Agency of Medicines and Health Products ('ANSM')[2] has a wide role that includes *inter alia* the following topics:

a clinical trial authorisations;
b marketing authorisations and pharmacovigilance and materiovigilance;
c analysing the risk-benefit balance of health products during their life cycle;
d authorisation and monitoring of pharmaceutical establishments; and
e advertising of medicines and medical devices.

The ANSM was created at the end of 2011 to replace the former health products safety agency, the AFSSAPS.

1 Mikael Salmela and Cécile Derycke are partners and Ombline Ancelin is counsel at Hogan Lovells.

2 www.ansm.sante.fr.

The National Authority for Health ('HAS')[3] is involved in many strategic activities such as the scientific evaluation of health products for the purpose of their reimbursement, promoting good practices, monitoring the quality of medical information and establishing rules for certain quality certifications.

The Economic Committee for Health Products ('CEPS'),[4] is in charge of setting the price of reimbursed products.

II THE REGULATORY REGIME

Both medicines and medical devices are regulated under the framework described in Section I above.

The content of the regulations varies to a great extent on several topics, with a stricter regime for pharmaceuticals. The key differences may be noted in relation to the following fields (among others): putting the products on the market (this is derived from the general EU regulatory framework), administrative control of entities participating to the life cycle of products (pharmaceutical establishment are more controlled and regulated), pricing, or advertising (medicines are more controlled).

i Classification

French law is consistent with EU legislation as regards the definition of pharmaceuticals, medical devices, cosmetics and nutritional products.

If medicinal claims are made with respect to a product or a product contains an active substance, whose principal mode of action is pharmacological, immunological or metabolic aimed at restoring, correcting or modifying physiological functions, then the product will be classified as a medicinal product. Borderline products, such as combined products, cosmeceuticals, food supplements or novel food, cannot be classified as medicinal products if they do not fulfil the above definition. The French authorities' position is consistent with the MEDDEV guidelines drafted by the EU Commission as regards the classification of medical devices compared to medicines.

In there is any doubt, classification as a medicine will prevail over any other classification, as provided for under EU legislation.

ii Non-clinical studies

The OECD principles on good laboratory practices ('GLP') have been implemented into French law, the applicable regulations being spread across various legal instruments depending on whether the studies relate to medicines for human use, for animal use or to cosmetics. Compliance with GLP is assessed by three authorities, ANSM being the one competent as regards studies on human medicines or cosmetics (the other authorities for other types of products are the ANSES and the GIPC).

3 www.has-sante.fr.

4 www.sante.gouv.fr/comite-economique-des-produits-de-sante-ceps.html.

As regards animal welfare, French law implements the EU regulatory framework. Key principles are that:

a animal testing must be necessary because it is not possible to find substitute methods;

b only authorised persons in authorised establishments can do such testing;

c the animals must come from authorised testing establishments, or from breeders or providers that have been subject to prior declaration;

d the choice of the animal is carefully justified; and

e pain and suffering for the animal is avoided.

iii Clinical trials

The same rules apply for clinical trials relating to medicines and medical devices as these are regulated under a specific chapter of the CSP relating to research involving human subjects. These regulations have been amended in 2012, though certain implementing decrees are still awaited for the new regulations to come into force. Under these regulations, three main subcategories of research types exist: interventional trials; interventional trials that do not involve medicines and only involve minimal risks and requirements; and non-interventional trials.

Interventional trials are subject to prior authorisation from the ANSM and a request to the relevant committee of public protection (an ethics committee – 'CPP'). If the sponsor is not based in the EU, it must appoint a representative in the EU. The sponsor must also seek an import authorisation for the trial product if it is not already authorised in France. Once the authorisation for the trial is granted by the ANSM, a declaration must be filed with the French Data Protection Authority ('CNIL'). In addition, if the sponsor markets reimbursed products in France, the applicable agreements with investigators must be submitted for prior consideration to the competent professional body (e.g., the French Medical Association), and this body must also be made aware of the practical implementation of the agreement.

The sponsor must hold specific insurance covering the damages resulting from the fault of the sponsor or any other participants in the trial. The sponsor is strictly liable for any damage arising from a clinical trial. The sponsor must prove that neither it nor any other participant of the clinical trial committed any fault. The trial must be carried out in accordance with good clinical practices ('GCP') and prior consent is required, except in specific circumstances (e.g., emergency inclusion). Specific vigilance obligations apply in relation to trials and adverse events must be reported within given time periods. The sponsor must also issue a specific periodic report on safety.

There is no specific legal regime in relation to investigator-initiated studies.

iv Named-patient and compassionate use procedures

As regards medicines, named-patient and compassionate use procedures are applicable either for a group of patients or on a named-patient basis. These procedures must be followed to obtain a 'specific temporary-use authorisation' ('ATU'). An ATU is granted for products that:

a do not have a marketing authorisation in France;

b are used for the treatment, prevention or diagnosis of a rare or serious disease where no satisfactory alternative method is available in France;
c the efficacy and safety of the product must be presumed and a benefit expected for the patient;
d the patient cannot be included in a clinical trial; and
e the authorisation is granted for a limited period of time.

The procedures for obtaining an ATU have become more stringent under new regulations enacted in December 2011.

As regards medical devices, as per EU regulations, the ANSM may authorise non-CE-marked medical devices on a named-patient basis where such devices present an 'interest for the protection of health' (i.e., when no alternative devices bearing a CE mark exist on the market, or the benefit expected for the patient is significant compared to other alternatives available). The authorisation request is made by the manufacturer before the ANSM, though the health-care professional ('HCP') treating the corresponding patient obviously bears the responsibility for recommending the use of the medical device.

v Pre-market clearance

French law implements the EU regulatory framework.

A medicine put on the French market must hold either an EU-wide centralised marketing authorisation administered by the EMA and issued by the European Commission, or a national marketing authorisation granted by the ANSM (under a national procedure, mutual-recognition procedure, or a decentralised procedure). A particularity exists in France as regards the concept of '*exploitant*'. The *exploitant* is the entity holding most of the responsibility for ongoing obligations relating to the use of a marketing authorisation in France. The *exploitant* can be the marketing authorisation holder ('MAH') or an entity to whom such holder licenses the marketing and sale of the medicine (or both the MAH and such entity, in case of co-marketing arrangements).

A medical device put on the French market must hold the CE mark and follow related certification procedures. The manufacturer must prove that the device conforms to the essential requirements under the European regulatory framework. Any Class IIa, IIb or III medical device, or any active implantable medical device that is put on the market for the first time must be communicated to the ANSM.

As far as special categories of products are concerned, the French regulatory framework implements the EU framework in substance as regards applicable authorisations and registrations (e.g., homeopathic and traditional herbal medicinal products registration).

As regards generics and biosimilars, fast-track procedures, implementing EU regulations, apply.

vi Regulatory incentives

Data and market exclusivity rules in France follow EU regulations. Incentives set out for orphan medicines at the EU level also apply in France. In addition, limited incentives exist under French social security regulations, being mostly related to taxes on turnovers and wholesales that do not apply to sales of such products. Orphan medicines may be

put on the market following the ATU procedure described above, which may enable faster access to the product.

There are no specific regulatory incentives, such as linkage between the marketing authorisation procedure and patent rights expiry. However, a framework agreement has been entered into between the pharmaceutical industry association, the LEEM, and the CEPS. This agreement, which was renewed in December 2012 and will last until the end of 2015, deals with several matters relating to reimbursed products and provides some incentives.

vii Post-approval controls

Most post-approval controls relate to the marketing of medicines. The *exploitant* (see Section II, v *supra*) of a medicine is subject to a variety of obligations relating to the monitoring of the life cycle of the product. The activities of the *exploitant* include wholesale, promotion, medical information, pharmacovigilance, batch follow-up and possible recall operations and, if applicable, product-storage operations. The *exploitant* must maintain a pharmaceutical establishment that is subject to authorisation by the ANSM and the establishment must include qualified persons, especially a 'responsible pharmacist'. Further to new regulations enacted in late 2011, the *exploitant* is subject to new reporting obligations pursuant to which it must immediately inform the ANSM of any prohibition or restriction imposed by a foreign authority on the marketing of a medicine authorised in France and of all other new information that may influence the risk-benefit assessment of the medicine.

The MAH may also be bound to specific post-approval control duties (distinct from those of the *exploitant*). In particular, the MAH must immediately inform the ANSM (and provide explanations) if the holder no longer markets a medicine in another country but the medicine is still being marketed in France.

Variations or amendments to the marketing authorisations and transfers of ownership of such authorisations, as well as suspension or revocation of such authorisations substantially follow the EU regulatory framework.

As regards medical devices, the duties of the manufacturer (or its EU representative) are in line with EU regulatory framework principles, including duties relating to materiovigilance, maintaining the product file, and ensuring appropriate assessments are carried out in relation to the maintenance of the CE-marking.

viii Manufacturing controls

The manufacturing of medicines is subject to various controls. In particular, the import, distribution or use of raw materials used for medicines is subject to a declaration to the the ANSM. Any establishment manufacturing medicinal products must be subject to an authorisation from the ANSM, which will then supervise the site and verify its compliance notably with good manufacturing practices. Each establishment having manufacturing activities must employ a qualified person (both permanent and temporary).

The manufacturing of medical devices is part of the more general declaration requirements of the marketing of medical devices. Such requirements are substantially similar to the EU regulatory framework for medical devices.

ix Advertising and promotion

The definitions of advertising medicines and medical devices are similar: they include any form of information, for example, canvassing, that aims to promote the prescription, delivery, sale or use of the products.

For medicines, further to recent regulations, prior authorisation of the ANSM is required in order to advertise medicines to health-care professionals. The advertising must comply with the provisions of the marketing authorisation, the therapeutic strategies recommended by the HAS and the summary of product characteristics, it must present the medicine objectively, promote its appropriate use and not be misleading or undermine the protection of public health.

Medical representatives' visits with health institutions must be carried out with several health-care professionals in group meetings (this does not apply to pharmaceuticals reserved for hospital use, prescribed only in hospitals, or initially subject to prescription in a hospital). Such visits are subject to an agreement with the establishment.

Advertising to the public of medicine is also subject to the ANSM's prior authorisation. No advertising to the public is permitted as regards prescription or reimbursed medicines.

No advertising of a medicine is permitted if the risk-benefit ratio of a medicine is re-evaluated by the authorities due to a safety signal.

As regards medical devices:

a advertising to health-care professionals is subject to the prior authorisation of the ANSM where such advertising relates to high-risk products; and

b advertising to the public of reimbursed medical devices is prohibited, except as regards low-risk medical devices (Class I and IIa).

x Distributors and wholesalers

As regards medicines, when appointing a distributor in France, an MAH will usually appoint the distributor as an *exploitant* (see Section II, v *supra*), whose key functions include wholesale of medicines. Apart from exploitants, the wholesalers operate on the market. Each site of such wholesalers is subject to a prior authorisation and control by the ANSM, to make sure the relevant site complies with good distribution practices. Wholesalers are also subject to specific requirements as regards product portfolio and public service obligations on distributing products to pharmacies (which have monopoly over retail sales of medicines).

The distribution of medical devices follows a more standard distribution regime, where various distribution channels are used by manufacturers: direct sales, use of commercial agents, or appointment of authorised distributors. There are no specific regulatory constraints in this respect.

xi Classification of products

Medicines are classified mainly in the following categories:

a over-the-counter medicines; and

b prescription medicines, subdivided further when the medicines are subject to restricted prescription:

- medicines reserved for hospital use (can be dispensed only in hospitals and administered as part of hospital care, subject to exceptions);
- medicines prescribed only in hospitals;
- medicines prescribed initially only in hospitals (follow-up prescription can be made as part of outpatient care);
- medicines prescribed only by specialist physicians; and
- medicines requiring specific monitoring during the treatment (prescription is subject to periodic examination of the patient).

There are other specific categories that take into account the particular safety issues relating to the applicable medicines.

Medical device classification follows EU regulatory framework. Medical devices may also be subject to prescription or restricted dispensation. Applicable rules in this respect are found under the CSP and are product-specific (i.e., there is no general classification of prescription-only medical devices).

xii Imports and exports

Medicines from countries outside the European Economic Area ('EEA') can be imported only by pharmaceutical establishments that hold an authorisation. Such authorisation is also required where the imported products are manufactured by entities within the EEA not holding appropriate administrative authorisations. Such establishments must employ a qualified person. The export of medicines is also subject to a similar authorisation regime. In addition, the exporting entity must hold a 'certificate of a free sale' corresponding to the 'certificate of medicinal product'.

The import and export of medical devices follows the general rules of free movement of goods within the EU, requiring them to hold a valid CE mark to freely circulate within the EU. French rules on the import and export of medical devices from or to countries outside the EEA implement the EU regulatory framework. French authorities also issue a 'certificate of free sale' for medical devices holding CE marks to facilitate export procedures to countries outside the EU.

xiii Controlled substances

Controlled substances (such as narcotics and psychotropics) are subject to the general rules on medicines, as well as specific rules implementing international conventions (e.g., on the illicit traffic of drugs or on psychotropics). The import and export of such products is subject to prior authorisation. Special labelling rules apply depending on the products (e.g., packaging used for the transport of narcotics cannot identify the content of the packaging). Entities importing or exporting and selling controlled substances may be subject to other different obligations depending on the substances.

xiv Enforcement

The ANSM can monitor compliance with health-product regulations. The ANSM may also perform specific controls (e.g., technical controls, controls on manufacturing, packaging). The ANSM may also investigate offences relating to pharmacists and other health-care professionals. ANSM inspectors may be assisted by civil servants from other authorities (the Directorate General for Competition, Consumer Affairs and Repression of Fraud, tax services, customs services, etc.). ANSM inspectors have wide prerogatives in terms of premises that may be inspected (all professional premises and vehicles) and documents that may be examined or copied (they have access to all information related to their assignments and to most data, including medical data).

Further to an inspection, a report is drafted by the ANSM and the inspected company must provide answers. This report may be communicated to other EU health authorities. In case of non-compliance, administrative sanctions may be enforced against the company such as warning letters and suspension of activities. If inspectors discover criminal offences, the ANSM informs the Public Prosecutor, the Ministry of Health and the Ministry of the Economy.

Other French health authorities such as the Regional Health Agency also have inspection powers.

III PRICING AND REIMBURSEMENT

Pricing for medicines depends on the market for which they are intended.

Regarding medicines for outpatient care, only pricing for reimbursed medicines is regulated. A specific procedure must be followed to set the price of a reimbursed medicine: the company proposes a price to CEPS; this is then subject to negotiations, which lead to a contract entered into for a period of up to four years. The contract sets out the company's commitments in terms of volume of sales, the control of its promotional practices and its participation in the Ministry of Health's global policies.

At the same time as following the pricing procedure, the applicant requests admission of the medicine on the list of reimbursed medicines. To this end, the medicine is subject to a scientific review by the HAS's Transparency Committee to verify whether the pharmaceutical provides a medical benefit ('SMR') that makes it eligible for reimbursement. The absence of SMR, or the lack of improvement in the SMR ('ASMR') compared to other existing medicines, or the lack of savings in the cost of treatment, prevents the medicine from being reimbursed. If there is SMR, then an SMR rating is granted to the medicine (major, moderate or low) together with a rating in terms of ASMR. This takes into account various factors (for example, the risk-benefit ratio of the medicine or positioning in the treatment strategy). The registration of the medicine on the list of reimbursed medicines is valid for five years, which is renewable subject to reassessment of the SMR.

The usual reimbursement rates applicable are 65 per cent (major SMR), 30 per cent (moderate SMR) and 15 per cent (low SMR). Full reimbursement rates may exceptionally apply. Specific rules apply for medicines subject to generic groups that are based on a reference price ('TFR'), and for medicines subject to a temporary-use authorisation ('ATU'). A variety of measures have been implemented under French

law aiming to limit medical expenses, such as out-of-pocket payments for patients, restrictions regarding the industry's promotional expenses, clawback mechanisms under agreements with the CEPS and incentives to use generics. Under recent regulations, a new medicine must show that it is at least as good as the therapeutic alternatives before it can be reimbursed.

Regarding medicines sold to hospitals, these must first be admitted onto a list of medicines agreed for use in hospitals. The prices are then freely negotiated subject to public procurement rules (where applicable).

The pricing for medical devices sold for outpatient care is only regulated for reimbursed medical devices. Medical device companies must follow a procedure before the CEPS to set the price that will serve as reference to the reimbursement. The main criteria taken into account in the context of these negotiations are the improvement to medical benefit compared to other medical devices, the improvement in the costs of treatment, the price of the device compared to other medical devices, the volume of projected sales and the foreseeable or actual conditions of use of the medical device. CEPS may also enter into agreements with medical device companies that may provide for sales volumes, relevant prices and specific discounts on the turnover made in France.

As regards medical devices sold to hospitals, these must also be admitted onto the list of reimbursed medical devices. Recent regulations have limited the purchase and use by hospitals of medical devices funded through the GHS (i.e., funded by the French health insurance as part of the medical services provided to the patients by health institutions), and which belong to certain homogeneous categories of products. Hospitals are only allowed to purchase medical devices that are among a selection of medical devices for which requirements in terms of efficacy have been proven.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Authorities such as the ANSM, the HAS and the CEPS hand down 'administrative decisions' in relation to health products and public health. Some of these decisions may be challenged, either before the authority itself or before the authority supervising the authority that took the decision. Moreover, claims may be brought before administrative courts, which are specialised in litigation involving public entities and in claims against administrative decisions.

In both cases, administrative decisions must be challenged within a two-month period. This period is calculated from the date of the notice or publication of the applicable written decision being challenged, or from the expiry of the period allocated to the authority to take a decision on the applicable subject matter (in such case, in the absence of a written decision, the authority is deemed to have taken an implicit dismissal decision). Where the decision is being challenged before public authorities, the two-month period is extended for two additional months to bring the case before the administrative courts.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Since the recent publicised cases in France involving both medicines and medical devices, the general public's focus has been drawn to the financial relationships between the industry and prescribers or public officials. As a result, regulations have been enacted or strengthened with a focus on transparency.

The key provisions governing financial relationships between the industry and prescribers or public officials can be summarised as follows.

Declaration of interests

Governmental officials and certain experts must make public the existence of any interests (direct or indirect) they received from any figures in the health industry for the last five years before assuming the role of a governmental official. Such declaration covers any links or benefits held by the declaring party or even by a member of their family that may affect their independence. The decree lists a variety of situations, such as exercising any principal or ancillary activity, paid or not, in any health administration, authority, establishment or public interest group, holding shares in such health institutions or holding a patent on a product subject to the relevant institution's activities.

The French Sunshine Act

Companies producing or marketing health products, or providing services associated with such products, must make public the existence of agreements and benefits (direct or indirect) they provide to various figures in the health industry (HCPs, HCP and patient associations, HCP students, health institutions, media organisations, etc.). The regulations have a very wide scope and have required the industry to adapt in order to find and report data in a manner compliant with these regulations.

French anti-benefits regulations

French regulations prohibit the granting of benefits to HCPs (and HCP students) by the industry. This includes the prohibition of any sort of gift or incentive, except if they are of negligible value and related to the HCPs' professional practice. Companies selling reimbursed products or services must submit all contracts and benefits with the HCP to professional bodies for their prior opinion. The professional bodies assess the fair market value of the payment made or the limited amount of the benefit granted. The professional bodies must also be made aware of the implementation of applicable agreements.

On top of these key regulations, general anti-bribery regulations apply. The industry has also adopted its own tools to monitor ethical practices. For instance, the LEEM has established the CODEEM, an organisation that issues recommendations on ethical practices and may sanction breaches of ethical rules.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Patients' claims related to health products are mostly based on Directive 85/374/EEC of 25 July 1985 on liability for defective products. This Directive was implemented

by Article 1386-1 and the following of the French Civil Code and introduced a strict liability system, under which the plaintiff must prove the defect of the product, the damage incurred and the causal link between the defect and the damage.

Patients may seek compensation from manufacturers, health-care institutions, health-care professionals or from the State Fund for Compensation of Medical Accidents ('ONIAM') by resorting to proceedings organised by Regional Commissions for Conciliation and Compensation ('CRCI'). CRCI proceedings are out-of-court amicable proceedings applicable to certain health disputes. These proceedings include investigations on the medical aspects of the case led by appointed experts and a meeting from the CRCI deciding what the root cause of the patient's injuries is, based on the experts' findings. CRCIs may dismiss the compensation claims, determine liabilities or find that injuries were caused by a therapeutic hazard, in which case ONIAM compensates the patient. Patients may file claims with courts should they not be satisfied with the outcome of the CRCI proceedings.

Moreover, a few special compensation systems have been implemented by the state for compensation related to specific products or pathologies (post-transfusion HIV and HCV, specific pharmaceuticals).

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

In the field of pharmaceuticals, there has not been any major decision of the French Competition Authority ('FCA') in 2012. However, certain practices are currently under investigation in particular regarding pharmaceutical companies' attempts to block or delay generic drug entry on the market. For example, in 2010, Teva Santé brought a complaint before the FCA against Sanofi for an alleged abusive smear campaign by Sanofi against Teva's generic of Plavix, one of Sanofi's bestselling drugs (Decision No. 10-D-16, 17 May 2010). Interim measures requested were rejected but investigation on the merits is ongoing.

This case and other pending investigations have been publicly revealed by the FCA indicating that this sector, and in particular the conditions of the introduction on the market of generic drugs, will be a priority in 2013.

In more general terms, blocking generics has been one of the FCA's main concerns in the pharmaceutical sector in recent years.

The FCA has focused on the following practices:

a progressive loyalty rebates applied by a pharmaceutical company on its clients' global orders on the condition that they purchased a pharmaceutical owned by this company exclusively from it;

b securing the loyalty of hospitals by offering rebates on the condition that the hospitals purchase from a particular pharmaceutical company both key pharmaceutical specialities for which it was the sole owner of IP rights and other pharmaceuticals for which there were competing products on the market; and

c predatory prices imposed by a pharmaceutical company on a related market thus harming a competitor that distributed generic drugs.

The FCA also used the commitment procedure to deal with quota systems implemented by pharmaceutical companies for wholesaler's supplies. The reason was to plan the correct levels of production and rationalise the distribution network. The FCA validated the mechanism of a quota system provided that it is limited to what is strictly necessary for a reliable and optimal supply of the national market. In particular, the system must be transparent and flexible enough to be adapted to the wholesaler's need and for a new wholesaler to be able to enter the market. In September 2012, Decree No. 2012-1096 introduced some uncertainty as it provides that a pharmaceutical company must ensure appropriate and continued supply to all wholesalers in France in order to enable them to fulfil their public service obligations.

ii Transactional issues

Few merger transactions involving pharmaceutical companies are reviewed at state level, due to the turnover thresholds that are usually met by these companies at EU level.

Moreover, among those recently cleared by the FCA, none raised competition issues.

VIII CURRENT DEVELOPMENTS

Even though health products are heavily regulated, they have recently been at the heart of several public health matters attracting significant media coverage. As a result, new regulations and decisions from the authorities aiming to improve the safety of medicines or medical devices have been created. Civil courts have also been paying close attention to the situation of patients.

The most prominent statute is the 'Bertrand Law' dated 29 December 2011, which created many new duties for life sciences companies.

With respect to medical devices, the ANSM recently implemented a strengthened surveillance programme for some medical devices. The ANSM also issued proposals for the development of European materiovigilance and campaigns for the implementation of a processing procedure between national competent authorities.

The safety of medicines and medical devices is also scrutinised by the French courts: both civil and criminal. Decisions of the civil courts address, for example, causality (with presumptions sometimes allowed in the absence of a scientifically proven link), apportionment of liability between companies (with the recent exclusion of the concept of market share liability) or new type of damages (e.g., anxiety damage).

Appendix 1

ABOUT THE AUTHORS

MIKAEL SALMELA

Hogan Lovells

Mikael Salmela is a partner of the corporate team at Hogan Lovells Paris and leads the regulatory and commercial practice.

Mikael works for clients active in the life sciences industry, including medical device suppliers, pharmaceutical companies and research organisations. He has assisted clients on the preparation, negotiation and development of strategic partnerships or alliances to create scientific or industrial synergies and strengthen their position in the sector.

He has broad regulatory experience in the industry dealing with matters relating to R&D and clinical trials, operations (manufacture, supply chains and distribution channels, and outsourcing), promotional practices, compliance under new sunshine rules and anti-benefits regulations, as well as pricing and reimbursement. Mikael also has significant experience in the contracting practices and standards used in the health industry.

CÉCILE DERYCKE

Hogan Lovells

Cécile Derycke is a partner in Hogan Lovells Paris office. She heads the Paris life sciences group and is the co-head of the global life sciences litigation team.

Cécile specialises in product liability and litigation focusing on pharmaceuticals, biotechnologies and medical devices. She appears before French civil, commercial and administrative courts to defend product liability claims or in the context of commercial disputes (enforcement and termination of contracts, unfair competition, etc.) for clients from the life sciences sectors.

She has particular experience in multi-jurisdiction bodily injury cases and cross-border coordination of such cases.

In addition, Cécile assists our life sciences clients in the context of criminal investigations and proceedings pertaining to alleged product liability and she advises on relationships with the French health authorities.

Cécile also handles litigation matters involving regulatory issues (pricing and reimbursement, promotion, etc.).

OMBLINE ANCELIN

Hogan Lovells

Ombline Ancelin is a counsel in Hogan Lovells' antitrust, competition and economic regulation practice in Paris where she is the key contact in the life sciences sector.

She advises clients in particular in the life sciences sector during on-site investigations ('dawn raids') conducted by competition authorities. She assists them in developing and implementing effective compliance programmes (including related training) as well as performing compliance audits. Ombline also represents clients in antitrust investigations and litigation brought before the competition authorities and assists them in merger filings before the French Competition Authority and in various other jurisdictions. Moreover, she advises pharmaceutical and medical devices companies on a regular basis on their commercial policies and the drafting of their distributorships in compliance with the strict applicable French legal framework.

HOGAN LOVELLS
17 avenue Matignon
75008 Paris
France
Tel: +33 1 53 67 47 47
Fax: +33 1 53 67 47 48
mikael.salmela@hoganlovells.com
cecile.derycke@hoganlovells.com
ombline.ancelin@hoganlovells.com

www.hoganlovells.com