Life Sciences France

Beginning our special focus on Life Sciences and taking a look at the legal implications that can arise, *Lawyer Monthly* speaks to François Vignaud, head of the Life Sciences Group in Europe, at global law firm, Dentons.

Please introduce yourself, your role and your firm.

I focus on commercial law, corporate law and Life Sciences laws and regulations at French and European levels. I advise my clients on mergers and acquisitions and joint ventures in France and abroad, mainly in the Life Sciences sector. I also play a major advisory role in regulatory matters in the Life Sciences sector (pharmaceuticals, medical devices, cosmetics, biotechnology products). I am regularly recommended and ranked, at French and international levels, as a leader in these activities. I also have vast experience in French and international commercial transactions, such as license and research agreements, distribution and unfair competition matters. I also coordinate the Life Sciences group in Europe which is particularly active in Germany, Poland, Romania and Russia.

Dentons is a global firm driven to provide its clients with the competitive edge in an increasingly complex and interconnected marketplace. We were formed by the March 2013 combination of international law firm Salans LLP, Canadian law firm Fraser Milner Casgrain LLP (FMC) and international law firm SNR Denton. Dentons' clients benefit from approximately 2,600 lawyers and professionals in more than 75 locations spanning 50-plus countries across Africa, Asia Pacific, Canada, Central Asia, Europe, the Middle East, Russia and the CIS, the UK and the US who are committed to challenging the status quo to offer creative, actionable business and legal solutions. Dentons provides access to top tier legal talents with experience in 24 sectors and 36 practices. Life Sciences and Healthcare are key and highly recognized sector groups within Dentons.

What are the most common types of case you deal with within the Life Sciences sector?

The most common types of case we have dealt with in the last couple of years are notably:

- acquisition/divestiture of manufacturing plants and of medical products (pharmaceutical, medical devices);
- pharmaceutical and medical device price regulations;
- issues raised by the recently enacted French Sunshine equivalent laws and regulations.

What are the common challenges faced by your clients when involved in Life Sciences?

Our clients, like the other actors in Life Sciences, have been facing an evolving environment in France concerning:

- the impact of the financial crisis in the state budget and deficit having an immediate impact on the financing of the social security system and consequently severe pressure on prices of reimbursed pharmaceutical and medical device products;
- the increasing level of new regulations (such as the French Sunshine equivalent laws and the reinforcement of the French FCPA equivalent laws) affecting directly the marketing and distribution tools of the players in the Life Sciences market.
- The substantial increase of litigations in product liability and related cases; following two recent major so-called "Mediator (a pharmaceutical product) and PIP (medical device) Scandals", laws and regulations dedicated to the life sciences sector have been enacted to increase the level of control on the sector and give additional rights to patients and related parties: this context has triggered an overwhelming number of product liability cases.

How has/can your firm assist the client when such challenges arise?

Our firm is particularly active and well-positioned to advise and help clients to face these new challenges through a dedicated Life Sciences team in France networked with the other dedicated Life Sciences teams of the Dentons firm throughout the world.

Have there been any recent legislative changes regarding this sector?

The law of December 21, 2011 followed by a number of implementing regulations, have introduced several modifications in the legal Life Sciences environment, including:

- transparency regulations on relations between the industry and healthcare professionals;
- reinforcement of the powers of the regulatory authorities (French ANSM);
- restrictions concerning the marketing and advertisement of medical products.

How can clients avoid the potential pitfalls of the laws which surround this industry?

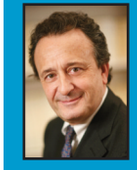
The Life Sciences industry in France will be able to face these new challenges by a mix of:

- development of innovation not only in new products but also through a new vision of health market access;
- a better understanding and willingness to adapt past organization and tools to the new economic and legal environment. This is where specialized and dedicated Life Sciences lawyers such as Dentons will be able to assist and advise the Life Sciences actors.

Do you foresee the need for legislative in the next 12-24 months, if so why?

French laws and regulations have been substantially modified these last two years and it is not expected that substantial new texts will be adopted. However the French Parliament is presently examining a draft bill concerning class actions (to date class actions are not available under French law). For the time being, this new legislation would not be open to product liability cases in the life sciences sector but we cannot exclude that the trend will be to open such type of action also to the life sciences sector, even with limitations. **LM**

Contact:



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