Simmons & Simmons

Regulatory and market access in Life Sciences

Ranked First Tier for Pharmaceuticals and Biotechnology
The Legal500 UK 2015

European Law Firm of the Year for Life Sciences 2014
Managing IP Global Awards 2014

Core strengths

Life Sciences companies are operating in a rapidly changing and increasingly demanding regulatory environment. Innovation, safety and value for money are major challenges.

Regulatory frameworks evolve quickly to keep pace with innovation, with changes to legislation creating uncertainty. Transposition of European Directives into national legislation rarely leads to complete harmonisation, requiring companies to implement regulatory strategies adapted for each market.

We have put specialist regulatory expertise at the heart of our Life Sciences sector group, building a flexible, integrated team based locally in major markets to respond to our clients' needs at any stage of the product life cycle. Our European team is complemented by expert capability in the Middle East and China.

Our services

Our international regulatory and market access team works closely with our corporate, commercial and IP teams on:

- R&D contracts
- Clinical trials
- Manufacturing agreements
- Product classification
- Market access and CE marking
- Pricing & reimbursement
- Supply chain & distribution
- Advertising & promotional activities
- IP/Patents (life cycle strategies)
- Data and regulatory exclusivity
- Regulatory enforcement and (criminal) sanctions/compliance
- Industry codes of conduct/self-regulation
- Transparency – data and relationships with healthcare professionals
- Administrative/public law
- Public/private partnerships with healthcare institutions
- Product recall and liability
- Business development & partnerships

"Significant life sciences practice, characterised by the depth of its expertise".
Chambers UK 2015

" offers regulatory and transactional expertise alongside its superb patent practice and is proficient in co-ordinating pan-European mandates."
Chambers Europe 2015

Expertise in practice

- acting for a major Japanese pharmaceutical company on the regulatory, commercial and trade mark aspects of an agreement following the citation by the EMA's Invented Name Review Group of a marketed product with a similar name, as a cross-border team through our Tokyo, London and Milan offices
- advising a global healthcare conglomerate on clinical trials in 21 EU jurisdictions
- assisting a major pharmaceutical company on several collaboration agreements relating to the development of a drug and its companion diagnostic
- advising a US-based medical devices manufacturer on SOPs and contractual requirements for sponsorship, consultancy, grants and clinical trials in respect of medical devices in France, the UK, Germany and Italy
- advising a top 10 global pharmaceutical company on EU data exclusivity issues arising from the proposed clinical development strategy in relation to a vaccine, involving the UK, Germany, Italy, Netherlands and France
- advising a national medical device manufacturers' association on its contribution to law reform, including the revision of the EU Directives, draft national legislation on the maintenance and traceability of medical devices
- providing strategic advice to a global leader in nano-physical healthcare products in connection with the classification of its product in the UK (when classified differently in other European countries.) advising a speciality Scandinavian biotech in relation to regulatory compliance in the UK in respect of its interactions with healthcare professionals, including sponsorship and consultancy arrangements
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- advising the medical devices subsidiary of a global conglomerate in connection with the potential impact and risks associated with the introduction of brokering activities under the Falsified Medicines Directive
- advising a pharmaceutical company on the conditions for assigning distribution agreements and public tenders to a company
- assisting and advising a pharmaceutical company in proceedings relating to alleged breach of applicable regulations and GMP following an inspection by the French regulatory authorities
- representing a major pharmaceutical company within a criminal investigation launched on grounds including manslaughter, involuntary bodily harm, administration of toxic substances and misleading advertising
- advising the European management of an Asian pharmaceutical company on anti-corruption measures and liabilities in accordance with Italian law
- representing a pharmaceutical company in proceedings before the Council of State (France's highest administrative court) challenging a pricing and reimbursement decision
- representing numerous pharmaceutical clients with regard to marketing access approval proceedings before the Dutch Medicines Evaluation Board
- advising manufacturers and distributors on local laws relating to sell-out pricing changes for Rx and OTC products across the GCC states and applicable notification and approval requirements for price changes
- advising on market authorisation matters including continuing supply obligations in the UAE, Qatar, Bahrain, the Kingdom of Saudi Arabia, Kuwait, Yemen, Algeria, Oman and Tunisia
- advising a pharmaceutical company in connection with the legal risks surrounding the distribution of certain cosmetic products under a disputed mark in China
- advising numerous innovative drug companies on regulatory matters such as GCP, GMP, marketing authorisation, promotion and pharmacovigilance in the context of licensing and collaboration deals

Key international contacts

Key contact biographies can be viewed at simmons-simmons.com

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