ALLEN & OVERY

Life Sciences Regulatory

Pharmaceuticals | 2018

"Top ranked in Chambers and Legal 500 for Life Sciences, pharmaceuticals and biotechnology."

"Allen & Overy LLP provides 'a very high level of service'. The firm has 'great knowledge of the pharmaceuticals industry (patent and regulatory)."

Legal 500 2017 (Healthcare and Life Sciences, France)

"They are very creative, pragmatic and understand our business model."

Chambers 2018 (Life Sciences: UK)

"They are excellent; it was a proper partnership."

Chambers Global 2017 (Life Sciences)

An introduction to our Life Sciences regulatory practice

Life Sciences companies operate in a complex and highly regulated environment, where they must deliver ever faster cycles of innovation while also meeting stringent industry and product-specific requirements. They are under intense pressure to reduce costs and prices while complying with broad corporate regulation such as anti-gift and transparency frameworks.

Repercussions for failing to comply with regulation can be significant. Regulators have powers to interrupt business, demand extensive remediation programmes and levy significant fines. Moreover, regulatory failures may cause reputational damage and impact trust between companies and their stakeholders including patients, payers and healthcare providers.

On the other hand, regulation provides attractive opportunities for innovative companies such as market exclusivities and protection of commercially confidential data. Companies must take full advantage of all such incentives to maximise their competitive position in this fast-paced market.

Our multi-jurisdictional team assists companies in the Life Sciences sector deliver their regulatory strategies. We count on regulatory experts qualified in all of the main EU jurisdictions. Most of our lawyers have previous in-house or scientific expertise, which makes us perfectly placed to fully understand your sector.

We counsel companies on regulatory issues affecting the entire lifecycle of their products, from R&D to market access and promotion of authorised medicines. Our practice covers stand-alone regulatory matters, and extends to advising on the regulatory aspects of patent litigation and strategy, as well as M&A and other commercial transactions.

In a complex regulatory environment, we work with our clients to make regulatory compliance a core part of successful business strategy.

Pharmaceuticals

Research & Development

Clinical trials

We advise companies on the stringent regulatory obligations and procedures they need to comply with to sponsor clinical trials in different EU member states. We also help our clients put in place contracts with the different parties involved in clinical research which are subject to specific, often national, requirements. The new EU Clinical Trials Regulation will significantly change the conduct of clinical trials in the EU, and we assist our clients with respect to the upcoming legal challenges while keeping them abreast of the national implementation in the key EU member states.

Regulatory data protection

We assist clients in protecting their investment in innovation by safeguarding their key data exclusivity and market exclusivity rights. Alongside our top-notch patent practice, we help our clients take strategic decisions to maximise their RDP rights vis-à-vis generic competition.

Patent infringement exemptions

The 'Bolar' exemption and 'experimental use' exemption address the important questions of what studies, trials and other R&D acts a pharmaceutical company may engage in before the expiration of patents covering a medicinal product. Our regulatory team, in close cooperation with our patent practice, has deep experience advising on these patent infringement exemptions that are particular to the pharmaceutical field.

Have you started preparing for the implementation of the EU CTR and considered how to effectively manage the different clinical trial data disclosure obligations under the EMA policies and CTR?

Have you taken into account the different scope and application of the research and Bolar exemptions across Europe, the United States and Asia to determine your R&D and manufacturing strategy?

Promotion and Interactions with Healthcare Professionals

Interactions with healthcare professionals

We regularly counsel our clients on all aspects of their interactions with healthcare professionals including in relation to hospitality and transparency obligations under the EFPIA Disclosure Code and member state legislation and industry codes of conduct.

Advertising and promotion

We regularly advise on advertising regulations related to medicinal products, including reviewing promotional materials and websites, and assisting our clients with respect to notification and authorisation requirements for the sponsoring of promotional events.

Have you considered establishing a mechanism to facilitate compliance reviews centrally on the basis of a multi-jurisdictional review of advertising & hospitality regulations in your key markets?

Do you know how to implement the EFPIA Disclosure Code on an EU-wide basis while also complying with transparency requirements under national (e.g. French and Belgian) Sunshine Acts?

"One of the top city firms in the pharma area."

Legal 500 UK 2017 (Pharmaceuticals and Biotechnology)

Market Access

Marketing authorisations

We advise pharmaceutical companies on the complex set of obligations when placing a product on the market for the first time. We have extensive experience advising on product classification and borderline issues (medicinal product/ medical device/cosmetic) and provide assistance in relation to marketing authorisation procedures and related compliance issues.

Early access programmes

We work with our clients on a wide range of issues associated with developing strategies for market access, including in relation to early access programmes, which are becoming a crucial instrument in emerging areas such as gene therapy and innovative cancer treatments.

Pricing and reimbursement

Our pan-European regulatory team has extensive experience advising clients on highly strategic pricing and reimbursement questions in all key EU member states, including assistance on newer pricing models such as outcome based pricing, which are particularly relevant for costly orphan and gene therapy products.

How can you leverage a valid data exclusivity argument related to one of your key authorised products vis-à-vis the EMA in case of disagreement between national competent authorities?

How do you develop an effective early-market access strategy for a ground-breaking paediatric gene therapy treatment when faced with complex cross-border patient enrolment and pricing & reimbursement?

Manufacturing, Distribution and Reporting

Pharmacovigilance and reporting

We have hands-on experience of the pharmacovigilance regimes in place to ensure that all adverse events are registered with the appropriate authority and enable the continuous monitoring of the safety of any class of medicinal products authorised in the EU.

Distribution, supply and substitution

We regularly advise clients on issues relating to the distribution, supply and substitution of medicinal products, and in particular on the heightened restrictions applicable to the online sale of such products.

Manufacturing

We advise on all aspects of the Good Manufacturing Practice regimes which is at the heart of all aspects of the manufacture, import, quality management (including documentation) and labelling of medicinal products.

Are you involved in any legal or advocacy initiatives to ensure the enforcement of second medical use patents in key EU markets where the regulatory framework hinders effective patent protection?

Have you reflected on how recent national developments regarding interchangeability, substitution and pricing of biosimilars may affect your EU and worldwide strategy?

"They are one of the top firms for pharma and Life Sciences."

Chambers 2017 (Life Sciences: France)

Your key contacts

Belgium and France

Eveline Van Keymeulen
Counsel
Tel +33 1 40 06 55 66
Mob +33 6 46 43 14 42
eveline.vankeymeulen@allenovery.com

France

Laëtitia Bénard
Partner
Tel +33 1 40 06 50 33
Mob +33 6 22 74 75 84
laetitia.benard@allenovery.com

Germany

Eda Zhuleku
Senior Associate
Tel +49 89 71 043 3125
Mob +49 1 72 61 13 400
eda.zhuleku@allenovery.com

United Kingdom

Marjan Noor
Partner
Tel +44 20 3088 2554
Mob +44 7717 800 371
marjan.noor@allenovery.com

Rafi Allos
Senior Associate
Tel +44 20 3088 2164
Mob +44 7717 800 650
rafi.allos@allenovery.com

Dedicated senior PSL resource

Jacqueline Bore
Life Sciences PSL
Tel +44 20 3088 1379
jacqueline.bore@allenovery.com

A&O Life Sciences Hub

A dedicated Life Sciences blog where experts from Allen & Overy analyse the latest EU and national legal and regulatory developments in the sector.

Visit us at **www.aolifescienceshub.com**

Founded in **1930**

Approximately **5,400** staff

554 partners

3,000 attorneys

44 major centers worldwide

Global reach and local depth

Allen & Overy counts on a global network of lawyers spread across **44 offices in 31 countries** in Europe, Asia Pacific, the Americas, the Middle East and Africa. In addition, we have carefully selected a network of leading Life Sciences relationship law firms in jurisdictions where we do not currently have the specific regulatory expertise that our clients require. These networks mean we are well placed to provide our clients with the highest quality coordinated legal advice across the globe, using regulatory specialists on the ground with local knowledge and insight, thus enabling our clients to successfully implement their global strategies.

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* Associated offices
** Cooperation office

"Strong network of offices across Europe with highly regarded practices in France, Belgium and the UK."

Chambers 2016 (Life Sciences: Europe-wide)

GLOBAL PRESENCE

Allen & Overy is an international legal practice with approximately 5,400 people, including some 554 partners, working in 44 offices worldwide. Allen & Overy LLP or an affiliated undertaking has an office in each of:

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