
CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences 2026

Definitive global law guides offering
comparative analysis from top-ranked lawyers

Contributing Editor
Lincoln Tsang
Ropes & Gray LLP



INTRODUCTION

Contributed by: Lincoln Tsang, Ropes & Gray LLP

Ropes & Gray LLP is home to one of the world's pre-eminent life sciences groups, with a global platform for innovators at every stage of the development life cycle. The firm's collaborative approach – spanning more than 25 practice areas and touching all offices around the world – offers one of the largest and most experienced industry-specific teams, comprising more

than 300 lawyers, subject-matter experts and technical advisers who deliver sophisticated transactional, regulatory, IP, and litigation and enforcement strategies to position industry innovators and investors for success. The Ropes & Gray team is sought after to lead clients in navigating the complex legal landscape in which the life sciences industry operates.

Contributing Editor



Lincoln Tsang heads Ropes & Gray LLP's European life sciences practice. A former senior regulator, he received postgraduate training in toxicology and cancer pharmacology. Lincoln concentrates his practice on UK, EU

and cross-border regulatory compliance and enforcement, including litigation, internal investigations and public policy matters affecting the life sciences industry. Lincoln advises clients on R&D strategies, product life cycle management, product acquisition, and risk and crisis management. He also regularly represents clients before various regulatory bodies in a wide range of matters concerning medicines and medical devices, including clinical trials, product approval, advertising and promotion, manufacturing, safety vigilance, and health technology appraisal related to pricing and reimbursement decision-making.

Ropes & Gray LLP

60 Ludgate Hill
London
EC4M 7AW
UK

Tel: +44 20 3201 1500
Fax: +44 0 3201 1501
Email: lincoln.tsang@ropesgray.com
Web: www.ropesgray.com

ROPES & GRAY

INTRODUCTION

Contributed by: Lincoln Tsang, Ropes & Gray LLP

Navigating the Ever-Changing Global Regulatory Landscape: Adapting to Disruption and Uncertainty

Welcome to the 2026 edition of Chambers & Partners' Life Sciences Global Practice Guide. I would like to express my sincere gratitude to my colleagues for their expert contributions to this Guide. Their collective efforts have ensured comprehensive coverage of the latest developments across a wide range of regulatory, legal and policy issues in their respective jurisdictions. I would also like to take this opportunity to offer a few opening remarks.

The global regulatory landscape for the life sciences sector is experiencing rapid and profound transformation, shaped by policy innovation, regional divergence and mounting geopolitical pressures. As a result, organisations in this sector are encountering a more complex environment – one that presents both new opportunities and considerable uncertainties.

Regulatory regimes around the world are evolving at an accelerated pace, with cross-border trends shaping innovation, compliance and enforcement. In 2026, we anticipate significant new developments that reflect the sector's need to adapt to emerging scientific advances, shifting public health priorities and evolving political agendas. The interplay between regional regulatory approaches and the globalisation of life sciences innovation is intensifying the need for harmonisation, particularly in the design of clinical trials and the generation of evidence for rare diseases and digital health products.

Leadership transitions at major regulatory agencies, especially in the United States, are influencing global priorities and creating a degree of uncertainty. Policy directions are shifting, with new initiatives focused on expedited approvals, increased transparency and alternative standards of evidence for products addressing unmet medical needs. These changes have direct implications for market access strategies, compliance expectations and enforcement risks.

While the United States, European Union, United Kingdom and Asia are each pursuing distinct policy directions, there is a growing call for greater global collaboration and harmonisation. Divergent approach-

es to data exclusivity, market access and post-market surveillance are emerging, even as stakeholders seek to align on standards for innovative therapies and digital health solutions. The need for harmonised regulatory frameworks is particularly acute in areas such as rare diseases, where efficient evidence generation and timely patient access are critical.

Regulators worldwide are placing greater emphasis on advertising, promotion and digital compliance, with stricter enforcement and higher expectations for organisational conduct becoming increasingly evident. Developments such as enhanced transparency, real-time publication of regulatory decisions and more robust enforcement of direct-to-consumer advertising rules are reshaping the compliance landscape. In this context, life sciences companies are finding it necessary to adapt their approaches to enforcement risk and strengthen post-market oversight.

Geopolitical tensions, trade investigations and shifting tariff threats are prompting a renewed emphasis on domestic production and localised supply models. The United States and the European Union are prioritising domestic manufacturing, while China is advancing local supply chains to enhance resilience. These trends are influencing long-term investment planning, pricing strategies and the management of supply chain risks.

Recent regional conflicts have further exacerbated these challenges, with direct consequences for the cost of goods and the stability of supply chains. Disruptions to critical raw materials, increased transportation costs and heightened border controls have resulted in greater volatility and unpredictability in sourcing and distribution. Life sciences companies are experiencing increased costs for both inputs and finished products, as well as delays in manufacturing and delivery timelines. These pressures are compelling organisations to reassess their supply chain strategies, diversify sourcing, and invest in greater resilience to mitigate the impact of ongoing and future disruptions.

Heightened geopolitical volatility is contributing to considerable uncertainty in global drug pricing. The risk of international price compression is rising, as countries

INTRODUCTION

Contributed by: Lincoln Tsang, Ropes & Gray LLP

adopt more assertive healthcare cost containment measures and regulatory divergence becomes more pronounced. In this environment, life sciences leaders and policymakers are having to reconsider their strategies to address these evolving challenges and maintain sustainable access to innovative therapies.

Regionally, leadership changes at the FDA and HHS in the United States are driving policy innovation, expedited approval pathways and more aggressive enforcement, particularly in the areas of advertising and off-label promotion. There is a concerted push for more US-based clinical trials and increased transparency in regulatory decision-making. In the European Union, comprehensive legislative reforms are modernising pharmaceutical laws, balancing the promotion of innovation with improved patient access. New exclusivity frameworks, incentives for antibiotics and the proposed EU Biotech Act are reshaping the regulatory environment. The United Kingdom's MHRA is implementing agile approval pathways, international reliance mechanisms and modernised regulations for medical devices and digital health, positioning the UK as a competitive first-launch market. Meanwhile, China and Japan are accelerating regulatory modernisation, streamlining approvals for innovative therapies and adapting frameworks to support domestic priorities and supply chain resilience.

Across all major regions, regulators are modernising and streamlining medical device regulations to foster innovation, improve patient access, and enhance regulatory efficiency. There is a concerted effort to support digital health, AI-driven solutions and electronic documentation, while maintaining robust safety and oversight.

Success in this dynamic and uncertain environment will depend on the ability of life sciences companies to remain agile and forward-looking. Careful monitoring of regulatory changes and global trends, thoughtful investment in risk management and the ongoing adaptation of compliance programmes will all play an important role. Embracing digital transformation and strengthening supply chain resilience are becoming increasingly important, particularly in light of recent disruptions. Constructive engagement with regulators and stakeholders can help shape policy and ensure organisations are well positioned for future developments.

In conclusion, the evolving global regulatory landscape – shaped by geopolitical tensions, regional conflicts and policy divergence – continues to present both challenges and opportunities. Successfully navigating this environment calls for a considered approach, with an emphasis on agility, informed decision-making and strategic foresight. For life sciences organisations, remaining responsive to change and attentive to emerging trends will be key to addressing complexity and making the most of new developments.

CHAMBERS GLOBAL PRACTICE GUIDES

Chambers Global Practice Guides bring you up-to-date, expert legal commentary on the main practice areas from around the globe. Focusing on the practical legal issues affecting businesses, the guides enable readers to compare legislation and procedure and read trend forecasts from legal experts from across key jurisdictions.

To find out more information about how we select contributors, email Rob.Thomson@chambers.com