

# 2019 Lex Mundi Healthcare and Life Sciences

## Global Trends Report

**LexMundi**  
World Ready

Lex Mundi is the world's leading network of independent law firms with in-depth experience in 100+ countries worldwide.



A background image showing laboratory glassware, including beakers and test tubes, with a pipette tip visible. The scene is lit with a cool, blue-green light, creating a professional and scientific atmosphere.

# Healthcare and Life Sciences Industry Group

## About Lex Mundi's Healthcare and Life Sciences Industry Group

Lex Mundi's Healthcare & Life Sciences (HCLS) industry group provides cross-border advice to a broad range of clients including private equity funds and portfolio companies, pharmaceuticals, biotechs, medical device companies, hospitals and health systems, senior living and nursing facilities, physician groups and ambulatory care centers, and other stakeholders. Through the Lex Mundi network of 160 leading law firms in more than 100 countries, our global team of HCLS lawyers offers you the in-depth knowledge and indigenous insight of full service independent firms, as well as the seamless cross-border service of the international business firm: the best of both worlds.

## Know-How and Market Trends

Members of the HCLS group hold meetings and run workshops with clients around the world on the latest developments in the healthcare and life sciences industry that are of cross-border importance. Through knowledge-sharing on trending issues, Lex Mundi firms help clients anticipate and proactively respond to complex regulatory challenges and key developments on the horizon in the jurisdictions where they operate. Recent discussions have focused on data privacy, antitrust and ethics in the healthcare industry, as well as the shift towards improved access to medicinal cannabis across the globe.

## A Unique Service Model

Through its Global Client Services Platform, Lex Mundi HCLS members seamlessly handle their clients' most challenging cross-border transactions and disputes. In addition to having common protocols for communication, timelines, deliverables and budgets, members of the HCLS group can work to uniform engagement terms. Joint fee quotes and coordinated invoicing are available on request. In addition, clients can benefit from Lex Mundi's secure and user-friendly digital platform to manage workstreams, budgets and billings. Each client and its advisers has access to a customized online dashboard on which to host its project. In addition to providing free of charge project management and tech support, Lex Mundi and its firms invest substantial time off the clock to understand their clients' particular needs and commercial drivers.

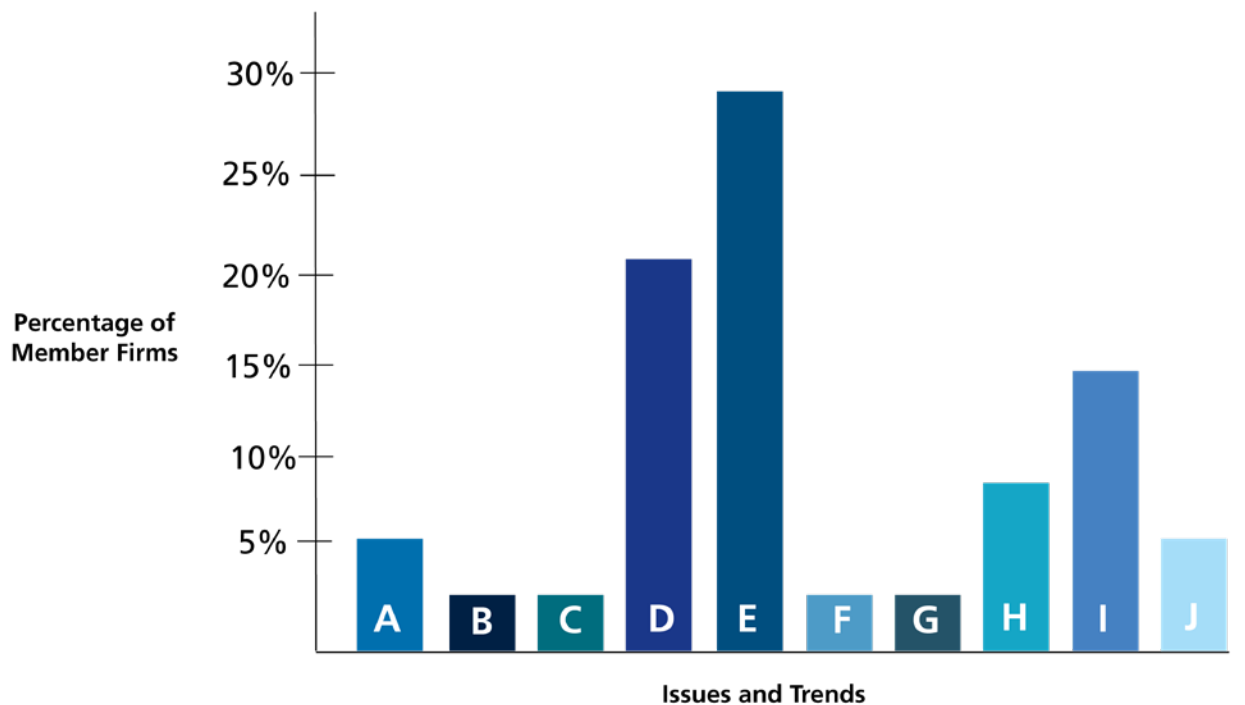
For more information on the Lex Mundi Healthcare and Life Sciences industry group, please contact [bd@lexmundi.com](mailto:bd@lexmundi.com)

# Current Trends in Healthcare and Life Sciences

## Executive Summary

In September 2019, Lex Mundi conducted a poll of its member firms to identify recent developments and current challenges faced by healthcare practitioners across the network. This Global Trends Report is a compilation of those results.

The below chart illustrates what issues are currently top of mind for healthcare practitioners around the globe.



- |  |  |
|--|--|
| <b>A</b> Anti-Bribery and Corruption                 | <b>F</b> Intellectual Property Protection                    |
| <b>B</b> Antitrust Considerations                    | <b>G</b> Licensing Arrangements                              |
| <b>C</b> Consumer Protection                         | <b>H</b> National Health Program                             |
| <b>D</b> Data Privacy                                | <b>I</b> Technology, Including Virtual Health and Telehealth |
| <b>E</b> Government Healthcare Regulatory Compliance | <b>J</b> Other   |



# The Americas



In the Americas, Lex Mundi healthcare lawyers agree that **data privacy** and **regulatory compliance** are both top of mind for practitioners.

In light of the patchwork of local, federal and international legislation applicable in North America, compliance with data privacy continues to pose several challenges for clients who are at the same time trying to determine how to share sensitive data with relevant stakeholders for the benefit of patients. In light of the recent Facebook settlement with the Federal Trade Commission, clients also want to understand how vendors or subcontractors may use protected health information. A number of jurisdictions across the Americas (such as California, Barbados and Brazil) are enacting new personal data privacy legislation in line with the GDPR and industry participants are closely watching the impact of such regulations on the healthcare industry. In countries such as Barbados, where there is a move towards digitization of government-held records, including health-related records for its hospitals and polyclinics, the intersection between digitization and data privacy is a matter of serious concern. One member firm lawyer also advised that **cybersecurity** is a key issue for those in operations, board members and patients across the United States.

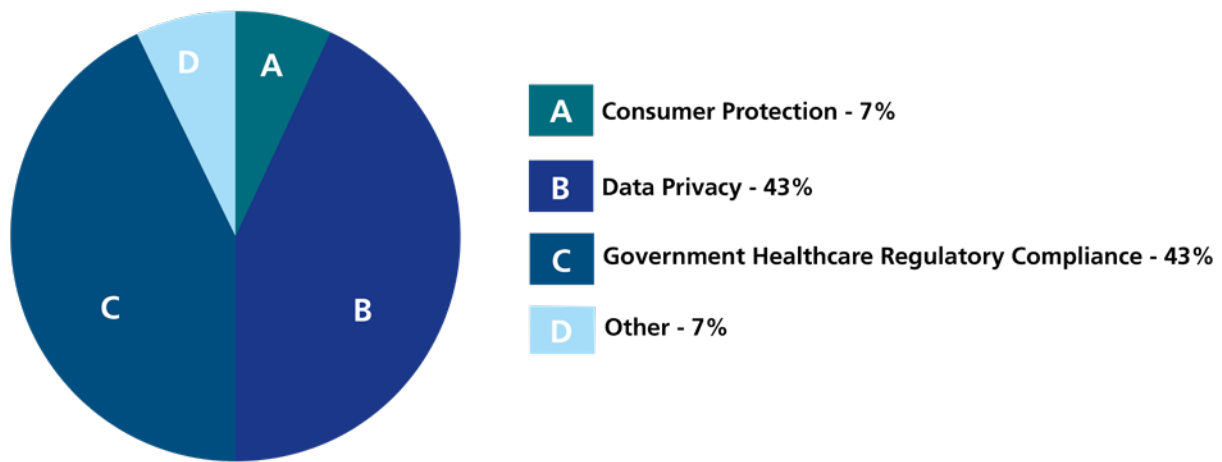
The healthcare industry in the United States has become one of the highest regulated industries in the country. It faces scrutiny from regulatory and enforcement agencies, as well as the whistleblowers that lurk around every corner. Compliance issues can lead to civil and criminal actions resulting in significant fines and penalties and the presence of a mandatory monitor.

Practitioners in a number of countries in Latin America are also increasingly advising clients on regulatory compliance.

- In Argentina, for example, global players have started entering the market through duly licensed local affiliates. As a consequence of this business model, practitioners are focused on strengthening and tailoring the internal policies of those entities, such as anti-corruption, to the applicable local laws and industry standards.
- In Mexico, practitioners note an uptake in cases against healthcare professionals relating to informed patient consent and the transition to electronic records.
- In Venezuela, although the government has relaxed the enforcement of **consumer protections**, especially those relating to price controls, healthcare players still perceive the current regulations as a risk to their businesses.

In Colombia, **price control** on pharmaceutical products and the impact on healthcare systems is top of mind for practitioners.

## 2019 Healthcare Trends in the Americas



### Predictions for the Next 12 Months

As federal law continues to overlap with license and compliance issues that have traditionally been the purview of the States, healthcare practitioners in the United States fear that 2020 will bring further confusion to the industry. This confusion is likely to be compounded by the increased interplay across the Americas between data privacy, technology and cybersecurity. Despite this prediction, our Lex Mundi member firms in the U.S. expect to see increased industry consolidation during 2020.

Political and economic change across the Latin American region is likely to have a big impact on the healthcare industry in 2020. For example, if a new Venezuelan government takes power in 2020, the current legal framework will likely see reform to support free-market policies and the development of innovative new products. In Colombia, 2020 will see the government continue to implement measures to regularize the financial crisis of the sector and increase the budget for healthcare services, while at the same time continuing to undertake measures for control of overpricing of supplies. In Argentina, financing high-cost treatments will continue to be a hot topic during 2020, which will demand more sophisticated legal tools for implementing risk sharing agreements with HMOs and navigating through pooled procurement schemes at national and regional levels to reduce medicine prices. The creation of the Argentine Health Technology Agency is expected to have a significant impact on this matter.

A number of Latin American jurisdictions, including Argentina and Ecuador, expect to see further discussion around the regulatory framework for genetic medicines and gene therapy.

Unsurprisingly, across the Americas, jurisdictions are expected to continue to explore new regulatory regimes for medicinal cannabis. It remains to be seen, however, if any jurisdiction will decide to follow in the footsteps of Uruguay and Canada by legalizing recreational marijuana.

# Europe, Middle East and Africa

2019 sees healthcare practitioners across the region grappling with a very different set of priorities.

Several Lex Mundi member firms identified **anti-bribery** as a top priority within the healthcare sector in their countries. Germany has recently introduced new regulations increasing liability for corruption in the industry and Greek practitioners are focused on taking a more proactive approach to advising healthcare companies on applicable standards in response to recent public incidents of corruption.

**Regulatory compliance** is also top of mind across jurisdictions, but in very diverse ways. Certain states such as Denmark continue to see med device companies focused on compliance with the EU Medical Devices Regulation, in particular re-certification of medical devices with Notified Bodies. Other countries, such as the Slovak Republic, are focused on particular regulations relating to discrete matters such as reimbursement. On the other end of the spectrum however, 2019 has brought about a fundamental overhaul of the regulatory landscape for some countries. Ukraine is undergoing a major reform of its healthcare system aimed at transforming service delivery by state and municipal hospitals. Reforms include several major elements, including, among other things, transforming healthcare financing, introducing a guaranteed benefits package and implementing international standards of medical care. The reform involves significant changes in laws and regulations for healthcare facilities, requiring them to adjust to new requirements and change operational approaches.

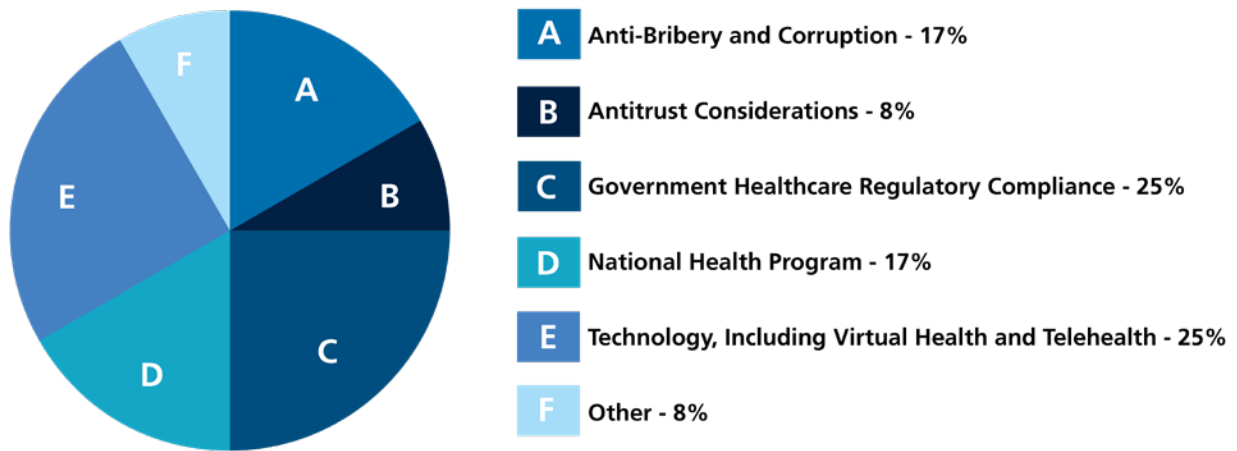
A number of countries in the region are in the process of introducing new **national health programs**.

- Cyprus has heralded in the new General Healthcare System (GHS) on June 1, 2019, the country's first full-coverage healthcare program for all citizens. However, many healthcare practitioners and private hospitals are reluctant to join the GHS due to disagreement on the way the system has been set up and how reimbursements will be made.
- South Africa is currently awaiting the introduction of its National Health Insurance, a financing system set to ensure that all citizens of South Africa (and legal long-term residents) are provided with essential healthcare. There are already however serious reservations about the government's ability to afford and manage these systems.

Overhaul is not, however, anticipated everywhere it should be. The UAE has struggled with very uneven quality of healthcare for a long time that sees many individuals (citizens and foreigners alike) travel overseas for healthcare. This is despite the fact that it has now become a requirement in the two largest Emirates (Abu Dhabi and Dubai) that employers provide all employees with major medical insurance coverage.

Much like recent developments in Asia, healthcare practitioners in Europe are focused on the interplay between **technology** (including virtual health and telehealth), data privacy and the speed of development of a number of products. For example, the Czech Republic's Ministry of Health is proposing regulatory changes to address the problem of digitalization in healthcare.

## 2019 Healthcare Trends in Europe, Middle East and Africa



### Predictions for the Next 12 Months

As major transformations in healthcare are set to play out in countries such as Ukraine, Cyprus and South Africa, national politics will continue to shape the industry across the region. The healthcare industry in Greece is expected to partly recover from the systemic and financial damages suffered after the last government (which was ousted after national elections that took place on July 7 this year) and the Slovak Republic expects an interruption to regulations due to 2020 spring elections and likely new leadership in the health-related authorities. Other Western European jurisdictions, such as Spain, expect to see a steady increase of M&A activity across the sector. In Spain, the pharma industry has recently been the target of dawn raids by the antitrust authorities for the first time in many years. Healthcare professionals will spend more time addressing the impact of technology, already a top priority for jurisdictions such as Ireland and Switzerland, on the healthcare industry. The Czech Republic is expecting to implement rules and standards for electronic communications between healthcare providers, in order to harmonize uncoordinated activities in this area and to create a uniform and secure state-guaranteed environment for all stakeholders involved in eHealth. Finally, certain countries like Ireland and South Africa look forwards to further regulation of, and improved access to, medicinal cannabis.



# Asia and the Pacific

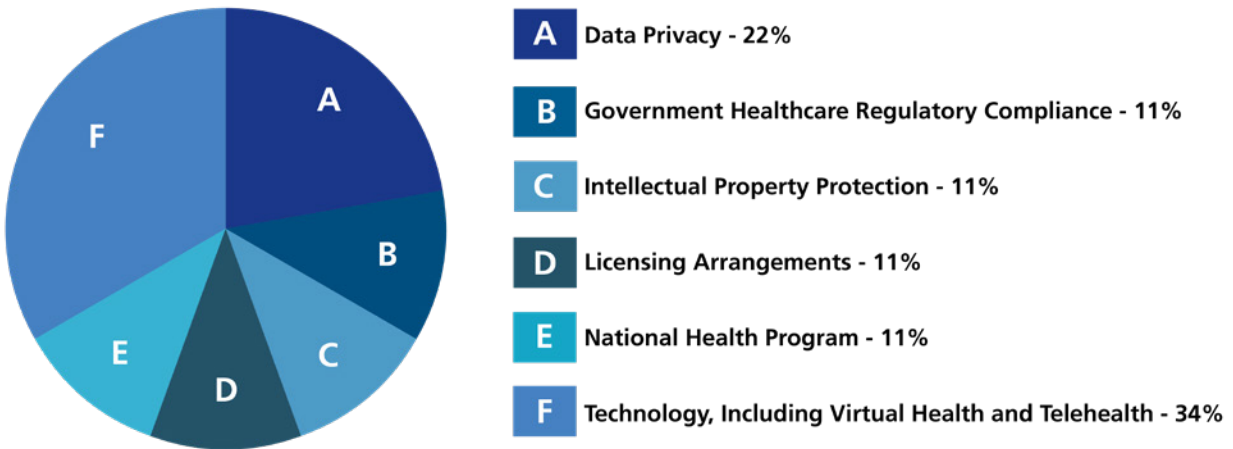
In Asia and the Pacific, many healthcare practitioners are focused on the impact of **technology** on the healthcare industry, including the growth of AI and big data fueling the entry of new players onto the market. Countries such as Thailand have recently seen the growth of innovative products including remote second opinions, mobile health apps and AI diagnostic services. Following the use of telemedicine in these countries, South Korea is getting ready to partially allow this product next year (currently prohibited under medical legislation). However, the use of new technology must be balanced against **data privacy** concerns around the collection of sensitive or personal data from patients, as any potential leaks expose the operator to legal and operational risks. In January 2019, Singapore saw the Personal Data Protection Commission (PDPC) issue its decision in the case concerning the largest breach of personal data in Singapore, holding that Singapore Health Services Pte Ltd failed to protect the personal data of individuals and imposing the two highest fines to date for failure to comply with the relevant legislation. In May, the PDPC published new guidelines on managing data breaches.

As in Europe, a couple of jurisdictions are seeing **major national transformations** that are impacting the healthcare industry. In China, the public procurement process of drugs is being overhauled. Four cities under central administration and seven other cities have been selected to participate in a trial scheme, under which 37 generic drugs are procured through centralized platforms that offer firm volume commitment to suppliers. It is widely predicted that eventually the trial scheme will be introduced to most cities in China covering most prescription drugs. Pharmaceutical companies, drug distributors and hospitals are all re-evaluating their business strategy to cope with such policy change. In Indonesia, an issue of great interest to healthcare practitioners is related to the implementation of a universal health coverage program called Badan Penyelenggaraan Jaminan Sosial (BPJS-Kesehatan), launched in 2014 and with the aim of covering all Indonesian citizens by 2019. This year has however seen the delay of reimbursement by the BPJS-Kesehatan to healthcare providers and healthcare facilities. This has been caused by a deficit in the BPJS-Kesehatan budget as a significant number of participants have not been paying their share of premiums.

Healthcare practitioners in other countries have seen very distinct trends during 2019. In Malaysia, attorneys have experienced a recent uptake in surveillance, inspection and enforcement by a number of regulatory agencies under the Ministry of Health. Licensing is also a focus point for practitioners in Malaysia, in particular with respect to government use compulsory licensing of patents. This is particularly so ever since one such compulsory license was issued late 2017, with implementation now in its early stage by the Malaysian Ministry of Health. In India, healthcare practitioners are focused on building an effective patent regime, and it is notable that there has been an increase of 33% in patents granted in the pharmaceutical sector and 54% in the biotechnological sector over the last two years. Orders have been passed in favor of the patentee in many cases, most notable being *Monsanto v. Nuziveedu* (biotechnology), *Roche v. Cipla* (pharmaceuticals), and *Merck v. Glenmark* (pharmaceuticals).



## 2019 Healthcare Trends in Asia and the Pacific



### Predictions for the Next 12 Months

Overall outlook for the healthcare industry in 2020 is positive, with reports of growth across many countries including Malaysia. The significant increase in the processing of pharmaceutical patent applications over the last year in India is very likely to attract major investments in the R&D sector. As the market share in China is further consolidated by big pharma and distributors, further investments and M&A is likely to occur. In Indonesia, it is rumored that the government is set to allow 100% foreign ownership of pharmaceutical manufacturing companies (currently restricted to a maximum of 85%). If these rumors are true, attorneys predict a significant increase in foreign direct investment in this sector.

With Hong Kong's telecommunication authorities determined to launch 5G for commercial use, it is predicted that the healthcare industry in 2020 will see a rapid emergence of tech-based companies offering on-the-spot services using mobile apps and wearables.

Since legalizing medicinal cannabis, Thailand is looking forwards to harnessing this burgeoning industry as the government identified the creation of a homegrown marijuana industry as a top priority. Stakeholders hope to see further moves towards legalization in this region during 2020. Malaysia and Laos are considering legalizing medical cannabis use, and the Philippines' lower legislature has passed a medical cannabis measure. Late last year, South Korea approved the Amendment to the Narcotics Control Act to allow for the import of medicinal cannabis treatments that have already been approved by health agencies in certain countries.

# LexMundi

## World Ready

### **About Lex Mundi**

Lex Mundi is the world's leading network of independent law firms with in-depth experience in 100+ countries. Lex Mundi member firms offer clients preferred access to more than 21,000 lawyers worldwide – a global resource of unmatched breadth and depth.

Each member firm is selected on the basis of its leadership in – and continued commitment to – its local market, and each brings comprehensive knowledge and understanding of the business climate, laws, culture, politics and economy of its respective jurisdiction. Working with Lex Mundi member firms you can be assured that you will be connected to:

- Premier member firms vetted for their leadership, expertise and capabilities for handling complex matters and disputes
- Global reach of unmatched breadth and depth
- Market- and industry-specific knowledge and strong connections to decision makers and influencers at the local, national and global levels
- Seamless client service for cross-border matters
- Legal resources to effectively and confidently deal with legal issues virtually anywhere in the world

Through close collaboration, information-sharing, training and inter-firm initiatives, the Lex Mundi network is an assurance of connected, on-the-ground expertise in every market in which a client needs to operate. Through our global client services platform, Lex Mundi members are able to seamlessly handle their clients' most challenging cross-border transactions and disputes.

Member law firms are located throughout Europe, the Middle East, Africa, Asia and the Pacific, Latin America and the Caribbean and North America.

Through our non-profit affiliate, the Lex Mundi Pro Bono Foundation, members also provide pro bono legal assistance to social entrepreneurs around the globe. For more information, please visit [www.lexmundi.com](http://www.lexmundi.com) and [www.lexmundiprobono.org](http://www.lexmundiprobono.org).

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