

Lex Mundi Global Trends in the Healthcare and Life Sciences Industry

North America

Healthcare and life sciences companies are facing unprecedented challenges due to many factors, including rapid advances in technology, increasing demands for privacy and data security, and sweeping regulatory changes, among others. An aging population demands more and different health services, as well as innovative life sciences products and services. Data management has become a key requirement across all business lines. As the business and regulatory environment becomes ever more complex, companies which have implemented flexible business models and efficient cost structures for R&D and regulatory and risk management will be best positioned to survive and thrive.

Latin America

The healthcare and life sciences markets are growing rapidly and companies are currently facing extraordinary challenges, such as the development of new complex treatments versus drug pricing (in particular high-cost treatments) and market access in asymmetric populations, with a lack of effective legal schemes in certain countries for assuring intellectual property protection. In addition, regulatory changes and significant advances in technology have impacted privacy, data security and the interconnectivity of the healthcare system (i.e. telemedicine, digital prescriptions and medical records). Attempting to balance the financing of the public and private healthcare system and satisfying unmet medical needs of the population is a common challenge in the world but particularly so in Latin America. Harmonizing and simplifying the sanitary regulatory requirements for companies and product registration is still a pending matter for many of Latin America's health authorities. Since the business and the regulatory landscape is becoming more complex and sophisticated, companies need to ensure a creative and innovative legal approach to succeed in this demanding context, for launching new product portfolios, landing investments and implementing cross-border transactions.

Europe

Key challenges to the life sciences industry include (i) the enforcement of the Medical Devices Regulation and related national legislation, in particular with regard to the amended certification process by the Notified Bodies and the traceability requirements, and (ii) the new legal framework on data protection (GDPR) which has a significant impact on pre- and post-grant market clinical research.

APAC

The overall market size for healthcare and life science products and services in APAC is growing fast. Digitization of healthcare information and the development of e-health bring new opportunities for businesses. However, the inequity in economic development and the various regulatory systems have caused big challenges for businesses. Medical expenditure is on the increase and a large portion of the population in the region still pay for their medical expenses themselves – therefore, most of the APAC markets are price-sensitive. We believe generic drugs have growth potential in this region but note that in some countries, there is still no adequate protection for intellectual property rights.

Africa

A surge in the demand for pharmaceutical products, coupled with an increased life expectancy, rapid urbanisation and the rise of the middle class, all support the assertion that Africa is the next frontier market for the healthcare and life sciences industry. As the African healthcare industry rapidly evolves, the importance of data management and privacy, along with the technological advancements and innovations in healthcare and life sciences have become major factors that have caused African companies to take a greater responsibility in ensuring that they conform with international best practices. The success of healthcare in Africa is dependent on the ability of consumers and investors to transact business on the internet without the fear of security breaches/lapses such as data theft. Growth in the industry has been hampered by challenges such as the uncertainty and insufficiency of comprehensive regulations, institutional corruption, poor infrastructure, a shortage of qualified healthcare workers and a substandard quality of service. These, along with the costs associated with developing the sector have contributed to the slow pace of technological advancement in many parts of the continent. A model that brings together the government, the private sector as well as academia, to focus on the effective and sustainable development of the healthcare industry, would be the best method for developing this industry in Africa. This would lead to the evolution of robust, innovative and qualitative healthcare systems across the continent and with the coming into force of the GDPR, empower companies to respond proactively with inventive and flexible business models that stimulate growth and promulgate data security in the healthcare and life sciences industry across Africa.