

10 Global Challenges For Life Sciences Cos. In 2016

Law360, New York (January 27, 2016, 10:45 AM ET) -- Life sciences companies face many challenges for 2016, including the demand to develop innovative products at reduced cost. More and more, this means that companies must assess opportunities in major markets across the globe and seek value-maximizing partnerships at all phases of the product life cycle, from development to manufacturing to marketing. The increasingly global and increasingly interconnected nature of the life sciences industry also means that companies must track litigation, policy, regulatory and enforcement developments in the U.S., EU, Asia and other major markets, and must also anticipate the ways in which these developments will impact business opportunities.

The following identifies ten key developments poised to shape the industry and 2016, and recommends steps that law and policy departments should consider taking to manage risks and take advantage of opportunities in the year ahead.

1. Embrace New Models for Drug Pricing and Accelerate Efforts to Demonstrate Value

New pricing regimes in the EU and China are heavily focused on comparative effectiveness, while the U.S. will also see new cost-constraining initiatives integrated with ongoing health reform activities and possible pricing legislation. Companies should respond by being transparent regarding pricing of new and existing products, preparing for aggressive negotiation over discounts and utilization management, and engaging patients and providers early in drug value and pricing discussions.

2. Implement Privacy Safeguards for Clinical Trial and Other Personal Data Transferred from the EU

The EU has overhauled its data protection system with a new General Data Protection Regulation that applies anywhere in the world to the processing of personal data about Europeans, now with fines up to four percent of global revenue. Companies should get ready for data protection impact assessments, mandatory data protection officers and a new European Data Protection Board as the two year implementation clock starts to tick.

3. Invest in Crossover Financing Rounds of Potential Acquisition Targets

These rounds are dominated by institutional investors looking to dollar cost average and enhance their allocation for future initial public offerings. By investing at this early stage, companies can get a toehold and insight on technology that they may want to see further derisked before acquiring in full while also securing a potential inside track to an acquisition.

4. Reevaluate Product Acquisition and Manufacturing Strategies in China

Ongoing reform of the drug review and approval regime will result in different regulatory pathways for locally made innovative products versus products manufactured outside China. The new regime is not yet finalized but will likely provide new opportunities for global companies doing business in China to benefit by acquiring local companies, rearranging product filing strategies and optimizing local manufacturing capacities.

5. Prepare for Unannounced Device Audits and Stricter Vigilance Scrutiny in the EU

Notified bodies remain under pressure to apply strict requirements for device certification and audits; member states are also heavily scrutinizing device vigilance. Device manufacturers should prepare for surprise audits, including of critical subcontractors and suppliers. They should also review vigilance reporting practices, focusing on reportability thresholds and the robustness of trend reporting.

6. Audit Data Integrity in Manufacturing and Clinical Trial Operations

Scrutiny of data integrity will be a global focus for 2016 and beyond, as demonstrated by international good manufacturing practice (GMP) inspections focused on data integrity and the first-ever active enforcement by the China [Food and Drug Administration](#) to ensure data integrity in clinical trials. Companies should get ahead by identifying and remediating systemic gaps, including software deficiencies, that could permit intentional or unintentional breaches of data integrity.

7. Assess Product Liability Risks Arising from Biosimilar Labeling

Following approval of the first U.S. biosimilar in early 2015, unanswered questions about naming and labeling present product liability issues. One of these issues is the lack of a clear regulatory requirement for sameness of labeling for a biosimilar and its branded counterpart, which means that biosimilar manufacturers may not be able to rely on preemption to shield against product liability claims and may face liability for failing to provide adequate information in its labeling. Companies should therefore assess the need for product-specific information in biosimilar labeling even when the U.S. Food and Drug Administration does not deem it necessary.

8. Avoid Getting Bound by Transactional Documents Intended to be Nonbinding

Recent cases highlight the risk that terms in letters of intent or heads of terms may be deemed legally binding unless the parties state otherwise in clear invalidating provisions. Because companies typically want most terms in these documents to be nonbinding, they should include invalidating language where appropriate. Similarly, it is important to avoid agreements to agree and agreements to negotiate in good faith unless additional provisions clarify the parties' intent regarding such clauses.

9. Update Anti-Corruption Policies and Controls

Anti-corruption enforcement is changing across the globe. Many countries with a traditionally lax enforcement record, including Brazil, China and Japan, are now playing an active role, and the first Deferred Prosecution Agreement was recently approved under U.K. law, which will likely serve as a template for future enforcement. These developments highlight the need for companies to identify country-specific enforcement risks in each region where they are doing business and assure that their policies sufficiently address those risks.

10. Lock Down GMP Compliance of Contract Manufacturers and Suppliers

Regulators are closely scrutinizing contract manufacturing organizations and active pharmaceutical ingredient suppliers, particularly in China and India. Enforcement against one of these partners can have disastrous consequences, including agency refusal to approve marketing applications for affected products. Assuring their compliance is therefore critical for protecting your product pipeline.

—By Torrey Cope, Maurits J.F. Lugard and Chen Yang, [Sidley Austin LLP](#)

[Torrey Cope](#) is a partner in Sidley's Washington, D.C, office.

[Maurits J.F. Lugard](#) leads Sidley's EU life sciences regulatory team and has nine years of regulatory and legal experience at the [European Commission](#), advising on health and safety related trade barriers. He is based in Sidley's Brussels Office.

[Chen Yang](#) is a partner in Sidley's Beijing office and leads Sidley's China life sciences practice.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.