Forensic Services
Pharmaceutical and Life Sciences

Pharmaceutical and life sciences companies are facing unprecedented compliance challenges. It is believed that the close regulatory scrutiny is unlikely to abate anytime soon. As the industry has expanded, the challenges have also multiplied along with the attendant risks.

Today, pharma companies cannot afford to ignore the corporate, reputational and personal risks associated to their business activities, no matter where they operate. Whether its sales and marketing practices or the transparency of a company’s spend on healthcare professionals and organisations, everything has come under the regulatory scanner.

**PwC India team expertise**

A global leader in serving the pharmaceuticals and life sciences industry, the PwC India team has extensive experience in working with pharmaceutical and medical devices companies on industry-specific strategic, operational, and financial issues. We work closely with proprietary and generic drug manufacturers, specialty drug makers, medical device and diagnostics suppliers, biotechnology companies, wholesalers and contract research organisations.

**Pharmaceutical and Life Sciences (P&LS) value chain**

<table>
<thead>
<tr>
<th>Research and Development</th>
<th>Manufacturing</th>
<th>Sales and Marketing</th>
<th>Distribution</th>
<th>Collaborations</th>
<th>Market Access</th>
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</thead>
<tbody>
<tr>
<td><strong>Research and Development</strong></td>
<td>• Intellectual Property theft</td>
<td>• Licensing and co-promotion issues</td>
<td>• Manipulation of clinical trial results</td>
<td>• Patenting and partnering disputes</td>
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<td><strong>Manufacturing</strong></td>
<td>• Issuance of warning letters by regulatory authorities</td>
<td>• Procurement fraud</td>
<td>• Contract manufacturing risks including royalty streams under contracting out or co-promotion agreements</td>
<td>• Fraud in toll manufacturing (yield percentage and conversion charges)</td>
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<td><strong>Sales and Marketing</strong></td>
<td>• Unethical HCP interactions</td>
<td>• Off Labelling</td>
<td>• Monitoring of marketing and promotional spend</td>
<td>• Parallel trades/Imports</td>
<td>• Non-Compliance with fall clause/NPPA</td>
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<td><strong>Distribution</strong></td>
<td>• Counterfeiting risk</td>
<td>• Misuse of promotional schemes by third parties</td>
<td>• Rising anti-bribery and corruption focus</td>
<td>• Lack of controls over near expiry products leading to potential grey market sales</td>
<td>• Channelling of institutional products to retail customers</td>
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<td><strong>Collaborations</strong></td>
<td>• Rising dependence on third party service providers</td>
<td>• Lack of visibility over third party operations including CFAs and distributors</td>
<td>• Concerns over integrity of business partners, third parties and intermediaries over suspicious dealings on behalf of the company</td>
<td>• Loss of royalties and revenue leakage</td>
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<td><strong>Market Access</strong></td>
<td>• Market access - expansion in new markets, emerging markets and semi/unregulated economies</td>
<td>• Misuse of free samples</td>
<td>• Misuse of patient access programs</td>
<td>• Misuse of special prices/schemes offered to distributors</td>
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</table>
With more avenues for innovation and profitability for the pharma and medical device industry, the future of the industry will be made or marred not only by the obvious success factors but also by a critical consideration of compliance and governance matters.

How we are best positioned to help you

Our team of experts help improve understanding of the risk and compliance framework of medical, clinical, sales and marketing staff, ethics boards and the changing landscape of payors in the pharmaceutical and life sciences sector. We help clients mitigate the integrity and compliance risks in working with: distributors, third parties engaging health care professionals (HCPs), contract sales organisations (CSOs), clinical research organisations (CROs), regulatory authority agents, sales agents and market research companies. We also help/support clients in assessing the integrity risks of entering or expanding in new markets.

Our service offerings

- Initial risk screening and design of third party due diligence process
- Integrity and reputational due diligence
- Establishing a compliance framework and testing effectiveness
- Conducting spend/expense reviews
- Anti-corruption and Anti-Bribery assessment
- Assessing the Patient support programs
- Investigating whistleblowing allegations
- Root cause analysis for brand protection and Intellectual property theft
- Counterfeiting and grey market sales investigations
- Electronic discovery and evidence
- Royalty audits

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