



Building Trust in the Indian Pharmaceuticals and Life Sciences Industry

Private and confidential
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In FY23, the Indian pharma market saw a year-on-year growth of nearly 5 percent, reaching USD 49.78 billion. While exports grew a modest 3 percent, the domestic market increased 7 percent year-on-year¹.

This growth is partially a result of government initiatives and measures aimed at regulating industry practices, such as the Production Linked Incentive Scheme, Pharmaceutical Technology Upgradation Assistance Scheme, National Medical Devices Policy, Pradhan Mantri Bhartiya Janaushadhi Pariyojana, among others. With the right resources and impetus, the pharma market is poised to grow to USD 130 billion by 2030.

While the pharma industry has been gaining repute, several countries remain skeptical of increasing their dependency on Indian drugs. They are concerned about fraud and unethical behavior in the industry, as well as misconduct and non-compliance with prevailing standards for the production, testing and distribution of drugs.

¹ Source: <https://www.livemint.com/news/india/indian-pharmaceutical-industry-expected-to-reach-57-billion-by-fy25-with-improved-margins-report-11688979047839.html>



Common malpractices and non-compliance across the supply chain



While supply chains were traditionally linear, they are now transforming into dynamic, interconnected systems. These involve multiple tiers of procurement, manufacturing, and testing sites and extend to global, regional, and in-market storage, and distribution units. The supply chain is the golden thread that links discovery to delivery within the life sciences value chain.

Inadvertently, certain key risks and concerns may arise in the process of dealing with the myriad networks within the extensive pharma ecosystem.

Research and discovery

1

- Theft of intellectual property
- Misrepresentation of clinical trials to drug authorities

Manufacturing

2

- Manipulation of the vendor selection process
- Violation of trade sanctions
- Kickbacks from suppliers
- Conflict of interest
- Manufacturing violations and falsified reporting to drug authorities
- Misreporting of scrap generated and collusion with vendors for sale of such scrap
- Non-compliance of the suppliers with ESG norms and guidelines

Distribution

3

- Contamination of products
- Diversion of products to unauthorised markets
- Excessive payments to transporters
- Pilferage, theft of inventory, and unauthorised sale to end customers



4 Product launch and commercial operations

- Pilferage, theft of inventory, and unauthorised sale
- Inappropriate payments to customs agents
- Anti-competitive pricing strategies
- Bid-rigging for hospital or government tenders
- Channel stuffing
- Financial mismanagement
- Diversion of physician samples for commercial sales
- Diversion from institutional/government sales channel
- Misuse of sales and marketing schemes

5 Post-market surveillance and patient support

- Counterfeit products
- Inadequate disposal of expired products
- Incorrect sales reporting
- Malpractices associated with patient support programmes, such as product leakages and misuse of personally identifiable/ sensitive patient data

6 People, skills, and information systems

- Theft of confidential consumer data or product information
- Malicious acts by hackers to steal/ misuse data or other assets
- Data leakages

Addressing your issues across the value chain – How Deloitte can help fill the trust deficit?



We, at Deloitte, have been working with Indian and multinational life science companies to help build trust through the design of robust compliance programmes, assistance with identifying suspicious activities, and helping clients act proactively to reduce fraud and corruption risks.

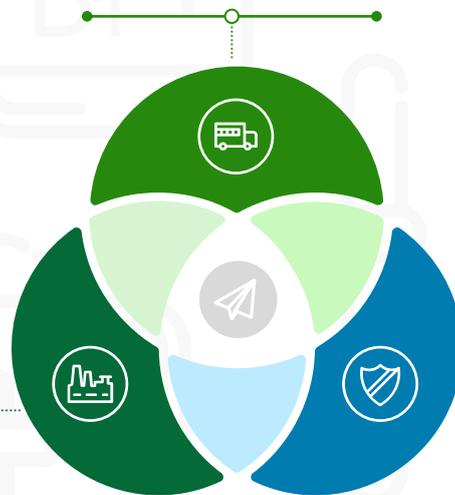
1 Help you deliver consistent quality of products



We help organisations evaluate relationships and quality standards with third parties that can reduce the occurrence of deviations from expected quality parameters.

Reviewing supply chain leakages

We can help prevent or reduce loss associated with quality and information leakages by conducting on-field mapping of the end-to-end supply chain and perform mystery shopping to identify gaps and leakages due to pilferage and breaches in the logistics chain allowing products to leak into the grey market.



Conduct integrity due diligence on contract manufacturers

We can conduct screening to identify red flags for high-risk contract manufacturers. This is done by gathering corporate intelligence to understand the background and reputation of the manufacturer and their employees..

Identify theft of intellectual property through brand protection

This is a proactive exercise to identify counterfeit products by conducting market surveys and gathering intelligence to find the manufacturing source of the counterfeit product, and the role of any employees or distributors to facilitate its movement.



Addressing your issues across the value chain – How can Deloitte help?



2 Emphasise improved regulatory compliance



We can assist organisations by proactively identifying gaps and potential lapses in the compliance framework by conducting:



Review of ethics and compliance framework

We can help review an organisation's ethics and compliance framework by analysing relevant policies, assessing the compliance culture, reviewing the completeness and adequacy of the trainings, robustness of the contracts with third parties and evaluating effectiveness of the framework by reviewing sample transactions.



Forensic review of Patient Support Programme (PSP)

We can help identify and investigate malpractices and process deviations in enrolment of the patients in the PSP, gaps in processing, and storage of personally identifiable/ sensitive patient data, mismanagement by the secondary services provider, leakages in the delivery of products to patients, etc.



Due diligence of third-party intermediaries (TPIs)

We can help reduce the risks associated with high-risk TPIs by performing periodic risk assessments, including, due diligence of such TPIs and/or their key management personnel, to identify such parties and help design controls and checks to reduce/ remove the associated risks. Further, we can review the contracts with TPIs to validate the provision of right to audit, trainings of TPI's employees, adherence of the company's compliance programme, etc.



ESG assessments

We can help conduct a review of the vendor's policies, codes, and data management processes to assess its compliance with ESG regulatory norms and sustainability frameworks such as GRI Standard (Global Reporting Initiative), SASB Standard (Sustainability Accounting Standard Board) and BRSR (Business responsibility and Sustainability Reporting), including conducting peer reviews.



Competition assessments and economic analysis

We can help assist in litigation matters dealing with agreements (horizontal and/or vertical) between parties, unilateral business conduct that may fall foul of the Competition Act, 2002.



Regulatory compliance testing and review

We can help perform an independent compliance review, in line with the local and foreign anti-corruption legislative requirements. We can also help analyse the maturity of an organisation's compliance function, in line with industry best practices and regulatory obligations.



CSR Advisory and operational efficiency

We help provide a 360-degree view on CSR implementation from a programmatic, financial, operational and governance point of view. Our focused solutions look at building efficiencies across the entire project life cycle, including programme design and strategy, and our teams go the last mile during our end use monitoring visits. We also help carry out detailed and robust assessments to understand the impact created through CSR interventions.

Addressing your issues across the value chain - How can Deloitte help?



3 Re-affirm ethical business practices



There has been considerable emphasis on regulating benefits to health care professionals (HCPs)/ Key Opinion Leaders (KOLs) and managing the possible gaps in legal framework. To manage this risk, we can assist by conducting:

This can include assistance in analysis of sales data to identify trends and patterns such as excessive discounts, unusual sales returns, unusual spikes in sales indicative of channel stuffing.

This can also include analysis of incentive schemes for sales teams at specific periods and for certain product lines at the ebb of sales cycles.

Conducting review of marketing spends with focus on benefits extended to HCPs to identify trends/ patterns of excessive honorarium payments, repetitive sponsorships, and lavish travel and entertainment for sponsored HCPs/ KOLs.

This also includes a proactive review of benefits extended to HCPs including review and suggestions on honorarium benchmarking.

Reviewing the distribution of physician samples to HCPs to identify trends/ patterns of excessive disbursement to select/ preferred HCPs and undertaking market studies to identify the source of physician samples infiltrating the commercial market.

Proactive forensic analysis of sales data and validation of incentive pay schemes

Review of benefits extended to HCPs

Review of disbursement of physician samples

Benchmarking of honorarium and distributor margins

Analysis and testing of tendering process

Conducting review of the marketing practices of the company alongside a benchmarking study to understand criteria, purpose, frequency, and range of honorarium payments to HCPs.

Examining the tendering process and testing compliance with the company's policies as well as the avenues for corruption, including bid rigging and manipulation of tender specifications to restrict competition.

Addressing your issues across the value chain - How can Deloitte help?



4

Help you extract greater value from data



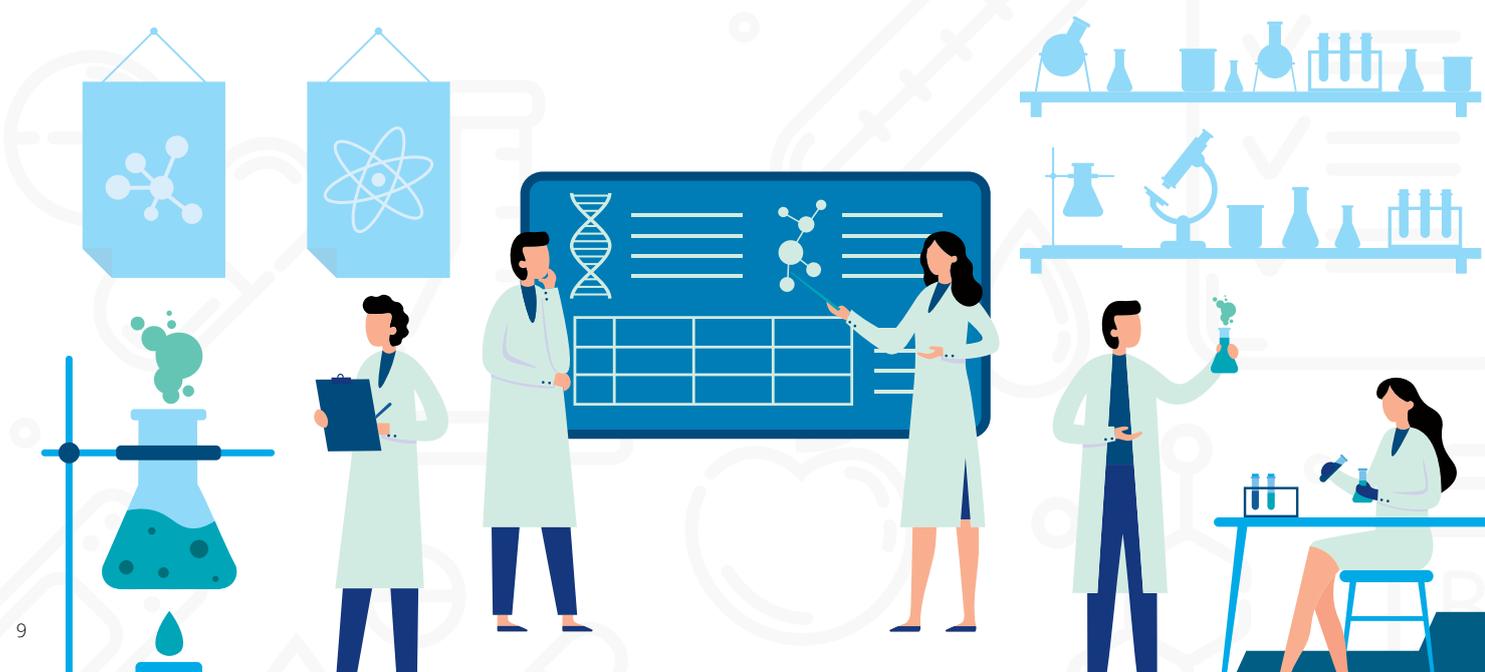
Process mining and data analytics

We can help organisations detect control weaknesses, improve compliance, enhance fraud detection, and drive continuous improvement. By leveraging the insights provided by process mining, organisations can optimise their controls and mitigate risks more effectively.



Socio-economic impact assessment

A socio-economic assessment of business operations can strengthen pharmaceutical companies' image by harnessing the multifaceted impact they create for various stakeholders, either directly or indirectly. Applying economic modelling techniques/tools on company specific data for metrics such as revenue, investment in R&D, employment, tax contributions, & community initiatives, can be used to quantify this impact.



Addressing your issues across the value chain – How can Deloitte help?



5

Manage risk and exposure



Fraud investigation

We support our clients by independently conducting event-led investigations to help identify the source, modus operandi, involvement of individuals, quantum, and mitigation measures for unforeseen incidents. Our investigative procedures include review of books, e-Discovery and document review, and public domain research coupled with field intelligence.



Litigation and dispute advisory

Drawing on our deep expert witness, financial analysis, damage quantification, and discovery capabilities, we give our clients the insight and understanding they need to strengthen their case, at all stages of a business dispute or complex litigation.



Cyber incident response

We can help conduct investigations related to forms of cyber-crime and data breach such as business email compromise, ransomware, malware attacks, network intrusion, incident response etc.



Fraud risk management

We can assist with the development of anti-fraud policies, procedures, and controls, as well as design, and deliver customised trainings to management and staff.





Despite being dubbed the “pharmacy of the world”, the Indian life sciences industry has a long journey ahead to build trust and credibility as the go-to country for all things pharma. While fraud and malpractice are pervasive in most industries, the impact of such malpractices in this sector can be detrimental. Companies operating in the pharma and life sciences industry are slowly realising that an investment in compliance is key to build trust with its stakeholders and improve business prospects.

Connect with us

To discuss your business challenges and understand industry best practices, please contact:

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