Forensic Services

Helping to protect your business from fraud, misconduct and non-compliance
Introduction

The Indian Pharmaceutical Sector, currently valued at over USD 21 billion and growing at 13 percent CAGR, is the world’s third largest in terms of volume. This growing sector is poised to expand further as drugs across the world collectively worth USD116 billion go off patent in the next five years, opening up opportunities for Indian generic drug makers to compete in markets outside India.

While focusing on growth, companies may tend to give relatively less attention to internal controls and compliance requirements, thus exposing themselves to a wide range of risks including intellectual property theft, clinical trials frauds, revenue leakage and non-compliance with regulations such as the US FCPA.

However, like all business risks, fraud and non-compliance risks too can be effectively controlled by establishing an appropriate risk management strategy to protect brand integrity and reputation.

1 India Brand Equity Foundation, background on the Indian pharmaceuticals industry
2 The Asian Promise, report on the Asian pharmaceuticals industry, March 2011
Fraud and misconduct investigations

The pharmaceuticals industry is susceptible to significant levels of fraudulent activity with supply chain fraud dominating the list of key fraud risks. Additionally, the sector faces risks related to intellectual property (IP) theft, clinical trials frauds, misuse of sales promotion schemes by CFA agents and channel stuffing.

With increasing R&D costs and marketing expenses, most firms are entering into outsourcing relationships, thus exposing themselves to a variety of risks.

KPMG can help companies conduct regular monitoring on manufacturing and warehousing centers to ensure compliance with regulations and company code of ethics. We can conduct event-led investigations for clients by gathering and analysing data in cases of suspected fraud of any kind, helping them identify perpetrators and uncovering the modus operandi, collecting samples and independently testing the same. We also help gather evidence that can be presented in a court of law and assist the client in litigation.

KPMG’s Forensic team helps clients protect their business from fraud, misconduct and non-compliance, in turn helping organizations reduce reputation risk and commercial losses. We do this by providing independent proactive and responsive services through our investigative, accounting and technology capabilities. Our team has evolved over a period and comprises of more than 680 professionals, each one bringing a competitive and specific skill set.

Do you suspect that fraud or other financial losses have taken place in your business?

Common fraudulent practices in the pharmaceutical industry

- Misuse of expired/damaged goods
- Inadequate controls over disposal of expired/damaged drugs
- Clinical trials related frauds
- Misuse of sales promotion schemes by the CFA agents
- False claims by stockist/wholesellers for breakages?
- Discounted stock meant for institutions being sold to non-institutional customers
- Channel stuffing – sales staff and stockist/wholesellers/CFA colluding to push sales in order to meet targets.
- Lower quality material fraudulently procured and used in manufacturing.
Data-driven business intelligence solutions

The vast volumes of data residing within Pharmaceutical companies can be analysed to help them make decisions on various fronts and identify red flags. Our professionals use Forensic technology to analyse various data streams and generate meaningful insights. We can identify instances of channel stuffing and potential theft by analysing sales/vendor/employee related data. Our MIS dashboards also analyse consumption patterns and billings to identify potential red flags as well as provide insights into customer/ employee/ vendor behavior.

Fraud risk and loss management services

Pharmaceutical companies need a preventive-check mechanism for creating an anti-fraud environment and proactively addressing risks.

We can help clients assess their vulnerability to fraud and reduce fraud loss and revenue leakage by evaluating existing counter-measures, training staff by conducting fraud awareness workshops as well as ethics and compliance training programs, and developing effective anti-fraud policies, systems and controls. Our framework will help management to effectively implement both preventive as well as detective anti-fraud controls. We can also help clients in designing an effective Whistleblower mechanism supported by a Fraud Control Unit.

Key fraud risk management issues in the pharmaceutical industry

- Weak controls in vendor selection and vendor payment
- Weak controls over contract manufacturing
- Inadequate CFA/stockist/wholesaler management practices
- Weak controls over Field Force Expenses
- Lack of stringnt processes in vendor and debtor management

Are you concerned about regulatory or contractual non-compliance?

Regulatory compliance

With increasing international exposure, firms (and their vendors) must comply with the US Foreign Corrupt Practices Act (FCPA) as well as the UK Bribery Act. The US based Food & Drug Administration (FDA) has been critically viewing the activities of Pharmaceutical companies for potential enforcement actions. For Indian pharmaceutical firms, many of whom have significant relationships with firms in the US as well as the European Union, this calls for stringent compliance measures particularly in the area of bribery and corruption.

Based on our extensive and varied experience of regulated markets, in many jurisdictions, we can help clients in adhering to regulatory and compliance arrangements, including sector-specific compliance requirements, FCPA compliance, and compliance with social and environmental norms.

Contract compliance services

A significant portion of the Indian pharmaceutical industry comprises of contract manufacturing/ production where firms typically manage multiple contracts across the business operation at any point in time.

Misunderstanding over critical contractual issues such as yield, quality of raw materials procured and marketing and sale of the finished drugs, can affect project completion, impact revenue estimates, and dent the firm’s brand image. Therefore, it is imperative to ensure that vendors/ sub-contractors comply with their respective contracts to deliver an end product that is in line with desired standards and compliance needs.

We can help companies monitor compliance with respect to various contracts, including software end-user license agreements. We also help clients develop a framework to reduce non-compliance risks arising internally as well as from contractors.
Do you need support in effectively handling your disputes?

Dispute advisory services

Businesses may encounter disputes due to performance of parties under a contract, default on payments (at vendor level), deviation from the proposal results or violation of compliance requirement. Litigation can delay project completion, resulting in losses. It is therefore important to present evidence in a manner that will help resolve the case fast and favorably.

We can provide accounting advice to assist in the resolution of disputes and in the processes of arbitration, litigation, mediation, transaction disputes and insurance claims. Our e-discovery capabilities can help ensure immediate and convenient access to evidence for review by legal teams and clients, irrespective of the format and volume. We collect, manage and process paper and electronic records.

We work closely with clients and legal teams to provide realistic and authoritative assessment on key accounting issues and/or quantum in dispute. This can help clients negotiate from a position of strength. We can also independently quantify claims for our clients and testify as an expert witness. KPMG’s international forensic network can provide assistance in resolving multi-jurisdictional disputes from the point of view of the claimant or the respondent.
Our value proposition

Extensive experience

We have investigated in over 400 cases of economic crime of various kinds including some of the most high profile cases featured in leading financial dailies. Our services are proactive and reactive, addressing a wide range of issues including kickbacks and bribes, financial misrepresentations, accounting frauds, fraud in loan portfolios, malicious emails, data theft, internet fraud, credit card fraud and funds siphoning.

Dedicated and trained resources

Our team comprises of management professionals with in depth industry experience, certified fraud examiners, former police officers, chartered accountants, certified public accountants, business ethics professionals, environment specialists, social workers, technology professionals and analysts. They are supported by our on-site investigation team that verifies facts in person, thereby increasing the credibility of our services.

Technology-backed solutions

We produce accurate and objective reports with fast turnaround time, by using proprietary technology tools. Our dedicated forensic technology laboratory can mine and analyse large volumes of data in paper and electronic formats in minutes and effectively support on-site investigations.
Select credentials

Brand protection
Our client wanted to identify individuals/entities indulging in the supply and manufacturing of counterfeits to its eye care products. KPMG Forensic assisted the client in identifying key individuals, distribution networks, and supply chain involved in the trade of counterfeits of the client’s product. We ascertained the upstream and downstream supply chain of identified players and gathered intelligence on other players involved in similar activities in the market, and the modus operandi adopted by the counterfeiters. We also ascertained the scope and extent of the client’s counterfeit product market in India, including the product intended for both the Indian domestic market and the export market.

Intellectual property theft
Our client, a large manufacturer of APIs and solid oral dosage forms, suspected certain employees of divulging sensitive information to outsiders. KPMG Forensic was hired to review the major business areas of one of the divisions within the company. A review of sales and marketing, supply chain, compliance framework, CAPEX, F&A, HR and other functions of the company was carried out. We used data analytics for identifying the email exchanges to outsiders by accessing the personal email accounts of suspected employees. It was revealed that the employees of the company passed on sensitive and confidential information to an ex-employee and other outsiders using their personal email accounts.

We also helped determine the confidential information that was being passed on to persons outside the company and the modus operandi. We assisted in litigating criminal civil charges on the accused.

US FCPA compliance review and training
Our client, a leading global specialty chemicals producer, wanted us to conduct training on FCPA compliance procedures for key employees of its Indian subsidiaries and joint venture partners. Our training helped the company address specific queries / situations faced by its Indian employees.

For another client, an international pharmaceuticals firm, we conducted a limited review of FCPA related controls and documentations of two key employees in India. We helped the company assess the extent of risks and how best to comply with regulation.

Procurement fraud
Our client, a large Pharmaceuticals company, suspected kickbacks in all their major contracts for civil/construction and other procurements made. KPMG Forensic assisted the client by independently investigating into the affairs of the company, and helped identify instances of purchases where certain suppliers were favoured during the procurement. We also helped identify the modus operandi for diversion of the finished goods.

Fraud risk and regulatory compliance assessment
KPMG Forensic assisted our client, a large listed pharmaceuticals company, in evaluating the extent of existing management oversight; role of audit committee and board; and internal audit and fraud control unit in the periodic prevention and detection of fraud in the organisation. We also conducted gap analysis on the fraud risks and scenarios identified by the management.

KPMG also evaluated the adequacy of the design and operating effectiveness of anti fraud controls to mitigate the risk of fraud. Additional statutory requirements from the perspective of SOX 404 compliance like the FCPA Act were identified and a remediation plan was developed.

Accounting irregularities and financial mis-reporting
Our client, a large multinational diagnostic company in the UK, had concerns about its Indian operations and reporting. KPMG Forensic carried out a review of the operational areas viz., sales, cash and bank transactions, payroll and employee reimbursements, financial reporting, purchases and HQ reconciliation. Our report indicated the lack of accuracy and genuineness of sales (including cut offs), lack of authenticity of payroll and employee reimbursements. We also identified several regulatory non compliances.
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Contact us

Sandeep Dhupia
Partner and Head
Forensic services
M: +91 124 3345 008
E: sdhupia@kpmg.com

Jagvinder Singh Brar
Partner
Forensic services
M: +91 124 3074 000
E: jsbrar@kpmg.com

Mohit Bahl
Partner
Forensic services
M: +91 124 3074 703
E: mbahl@kpmg.com

Shobhit Agarwal
Partner
Forensic services
M: +91 124 3345 011
E: shobhita@kpmg.com

www.kpmg.com/in