KPMG

Third-party risks in the pharmaceutical supply chain

Our point of view (PoV) on mitigating risks associated with third-parties in pharmaceutical supply chain

kpmg.com/in

KPMG. Make the Difference.

KPMG in India's expertise in delivering third-party risk mitigation services to clients

Over the years, KPMG in India has assisted numerous clients in undertaking detailed due diligences on their supply chains. We bring expertise across a range of countries, helping ensure extensive and tailored services for diverse needs.

For this case study, a sample population of 1,300+ third-parties - including manufacturers, distributors, retailers, raw material suppliers, and contractors - were included.

The geographical distribution of these third-parties is as follows

23 per cent
from the Asia-Pacific (APAC) region

61 per cent
from Europe, the Middle East, and Africa (EMEA)

14 per cent
from Latin America (LATAM)

2 per cent
from North America

Our APAC coverage includes countries such as India, China, Vietnam, South Korea, Philippines and New Zealand, among others

EMEA region comprises countries such as Italy, Czech Republic, Spain, Egypt, Sweden, Iceland, Greece and Poland, among others

LATAM includes countries such as Argentina, Guyana, Brazil, Mexico, Chile, Panama and Ecuador, among others.

Key findings from KPMG in India's analysis:

The pharmaceutical supply chain is confronted with various risks that can significantly affect both operational efficiency and public health outcomes. Issues such as bribery and corruption, emergence of counterfeit medications, environmental factors and damages, supply chain manipulation characterised by fraud or misrepresentation of products and theft, and diversion of pharmaceutical products, whether occurring during manufacturing, transit, or at distribution points, can result in shortages and illicit sales, further undermining the integrity of the supply chain.

Categories of risk

Social and governance issues, including health and safety concerns, child labour, regulatory non-compliances, make up about 27 per cent of the total risk in the pharmaceutical supply chain

27%

Bribery and corruption, accounts for 22 per cent of the risk, due to unethical practices and compliance breaches

22%

Financial losses, at 21 per cent, arise from tax disputes, and fraud, among other credit risk related issues

21%

Supply chain manipulation, making up 13 per cent, compromises the safe delivery of medications

13%

Counterfeit drugs, at 9 per cent, harm patient safety and erode trust in healthcare systems

9%

Theft and diversion, at 7 per cent, disrupt access to essential medicines and fuel illegal markets

7%

Environmental damage accounts for 1 per cent of the risk, primarily due to improper waste disposal practices in manufacturing and transportation processes.

1%

Types of third-parties exposed to risks

Distributors, representing 35 per cent, encounter risks associated with fraud and counterfeit medications

35%

Contractors, making up 47 per cent, presented risks associated with logistical failures, improper handling, and non-compliance with regulations

47%

Retailers contributing 7 per cent, introduce risks through the diversion of products and the sale of expired or counterfeit items

7%

Manufacturers account for 7 per cent, with common issues associated with them including production delays and regulatory non-compliances

7%

Vendor risks related to raw material suppliers, which constitute 4 per cent, primarily focus on fraud and quality concerns.

4%

How can pharmaceutical companies mitigate regulatory risks in their supply chain?

In order to manage the risks within supply chain, pharmaceutical companies must put appropriate measures in place to monitor and control the supply chain's operational activities. Due diligence plays a major role in mitigating these supply chain risks – be it due diligence prior to entering into the business with a supplier/third-party or ongoing monitoring on the existing suppliers, which includes ESG diligence and human rights due diligence.

01 Supplier/vendor due diligence

Benefits of supplier/vendor due diligence services:

- Increased transparency and visibility into potential vendors and partners
- Improved risk management and compliance
- Better decision-making and negotiation power
- Reduced financial and reputational risks.

02 ESG supply chain diligence

With an increased reliance on third and fourth parties in supply chains, ESG due diligence is gaining importance due to the following reasons:

- Regulatory and mandatory disclosures (in India and globally)
  - World Health Organization (WHO) Global Patient Safety Action Plan 2021-2030
  - U.S. SEC's mandatory climate disclosure proposal
  - General Pharmaceutical Council's Carbon Net Zero Sustainability Action Plan
  - The new German Supply Chain Due Diligence Act
- Profitable growth and financial impact along with risk and governance
- Fraud and reputational risks.

03 Modern slavery and human rights due diligence

Modern slavery and human rights due diligence is gaining importance due to the following reasons:

- Regulatory and mandatory disclosures (in India and globally)
  - The UK Modern Slavery Act
  - EU Corporate Sustainability Reporting Directive (CSRD)
  - EU Corporate Sustainability Due Diligence Directive (CSDDD)
  - Singaporean Prevention of Human Trafficking Act
  - Australian Modern Slavery Act
  - Dutch Child Labour Due Diligence Law
  - UN Guiding Principles on Business and Human Rights (UNGPs)
- Identifying third-parties subject to issues such as discrimination, abuse and harassment, wages and working hours, forced labour and child labour, etc
- Prevention from reputational damage and potential penalties.

04 Conflict of interest /related party transactions

Conducting related party tracing to identify conflicts/collusion within the pharmaceutical supply chain is essential for:

- Preventing and managing potential conflicts that may undermine public health
- To maintain trust among the supply chain components such as suppliers, manufacturers, intermediaries, etc.

Conflict of interests can lead to potential compliance issues, enforcement actions, financial penalties.

Regulatory frameworks in the pharmaceutical supply chain

Regulatory compliance: a mandatory requirement to mitigate supply chain risks in pharmaceutical industry

In recent years, the healthcare and pharmaceutical industry has undergone significant changes driven by stringent regulatory requirements in disclosures, technological progress, the growth of remote care, shifting consumer habits towards innovative products, the effects of the COVID-19 pandemic, and the emergence of new competitors in the market.

The healthcare and pharmaceutical industries are witnessing worldwide expansion, fueled by progress in digital technologies. The market size valued at approximately USD1,559 billion in 2023, is projected to exceed USD2,832 billion by 2033, indicating a compound annual growth rate (CAGR) of 6.15 per cent from 2024 to 2033.

Regulatory compliance: a pillar of pharmaceutical supply chain integrity

Acknowledging the opportunity for expansion, governments across the world have initiated efforts to regulate the pharmaceutical industry. The pharmaceutical industry is heavily regulated by country-specific regulatory authorities. Considering the potential risks such as legal, financial, operational, and environmental risks, it is imperative for pharmaceutical manufacturers to have a thorough understanding of the regulatory authorities that oversee their operations in order to mitigate the risks associated with non-compliance.

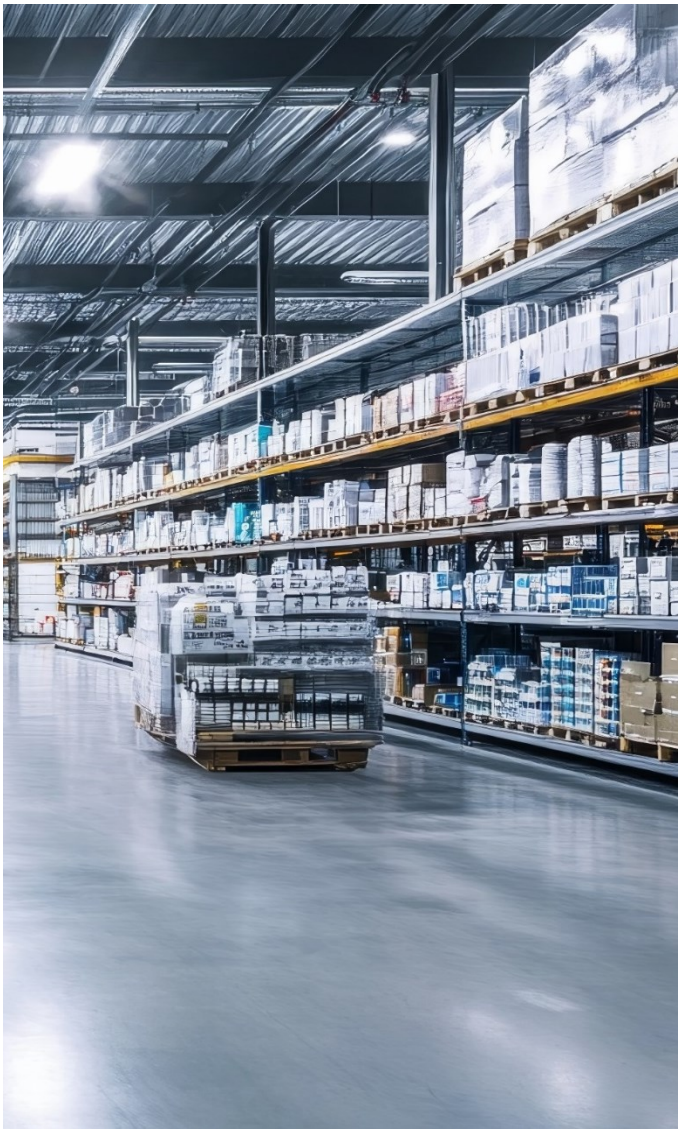
Regulatory approvals are mandatory in the U.S., Europe, and other regions across the globe for the introduction of new pharmaceuticals and medical devices into the market, as well as at each stage of the supply chain including raw material supply, manufacturing, distribution, and marketing, etc.

Pharmaceutical companies are increasingly depending on supply chains to tap into specialised expertise, cut costs, speed up product delivery, and manage logistics more effectively. However, throughout the supply chain stages, the third-parties have violated several regulations set by regulatory authorities. This reliance on supply chains exposes them to various risks, including regulatory, reputational, and operational risks.

Pharmaceutical companies depend on third-parties for various reasons, including gaining specialised knowledge and resources, reducing costs, and managing logistics.

Any company or third-party functioning in a heavily regulated industry such as pharmaceuticals must adhere to all rules and regulations set forth by the country-specific regulatory authorities. Regulatory frameworks are subject to frequent modifications, necessitating that organisations consistently revise their processes, documentation, and training initiatives.

Non-compliance with regulations may result in product recalls, financial penalties, and other significant repercussions. Hence, it becomes necessary for third-parties to adhere to the regulatory standards throughout the supply chain helping ensure the safety, efficacy, and quality of pharmaceutical products.



Source: BioSpace and Vision Report

Understanding regulatory compliance in pharmaceutical supply chain

Adhering to regulatory standards is essential and cannot be compromised in the pharmaceutical industry. Regulatory agencies formulate guidelines and regulations governing all aspects of the pharmaceutical process, including research and development, manufacturing, distribution, and marketing.

Regulatory risks within the pharmaceutical supply chain may encompass instances of non-compliance with established regulations, potentially resulting in delays in shipments or rejection by customs authorities.

Due diligence on their supply chains can help to identify and assess potential risks, which can assist pharmaceutical companies in effectively mitigating these risks.

An overview of the regulatory landscape within the pharmaceutical industry:

U.S. Food and Drug Administration (FDA) oversees food, drugs, medical devices, cosmetics, and tobacco products ensuring safety and compliance throughout the supply chain.

U.S. Foreign Corrupt Practices Act (FCPA) prohibits the provision of bribes to foreign officials for the purpose of obtaining business advantages. This legislation requires the implementation of thorough due diligence measures to ensure compliance.*

European Union (EU) Conflict Minerals Regulation establishes new due diligence and reporting obligations for EU importers, as well as for any company engaged in the trade of minerals sourced from high-risk regions.

European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU.

UK Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices, and blood components for transfusion.

India Central Drugs Standard Control Organization (CDSCO) regulates the approval of new drugs and clinical trials and ensures the quality of imported drugs.

Drug Controller General of India (DCGI) is responsible to perform licensing and controlling functions of CDSCO.

India National Pharmaceuticals Pricing Authority (NPPA) maintains the costs of drugs and their availability.

The German Supply Chain Due Diligence Act requires the implementation of a risk management system aimed at addressing human rights violations and environmental damage within supply chains. This legislation underscores the importance of due diligence in preventing corruption and promoting ethical practices.

The French National Agency for Medicines and Health Products Safety (ANSM) is responsible for safeguarding the safety of pharmaceuticals and health products available in the market.

* "On February 10, 2025, the U.S. President Donald Trump issued an executive order titled 'Pausing Foreign Corrupt Practice Act enforcement to further American Economic and National Security'. The order directs the U.S. Department of Justice (DOJ) to halt FCPA investigations and enforcement actions for 180 days. During this period, the DOJ will review its guidelines, abstain from initiating new investigations unless exceptions are granted, review existing cases, and issue updated policies to prioritise American interests and efficient use of resources. This is the first pause of FCPA enforcement since the statute was passed in 1977." Source: Harvard Law School Forum – FCRA

Typical 'risks' in a pharmaceutical supply chain

Due to complex supplier networks, the pharmaceutical industry is highly vulnerable to fraudulent activities, with supply chain fraud emerging as a predominant risk among various types of fraud.

Risk category	Key vulnerabilities	Illustrative examples
Financial risk	• Liquidity issues • Credit risk/Poor ratings by credit agencies • Working capital issues • Outstanding tax disputes	• A pharmaceutical raw material supplier was accused of importing goods using an incorrect customs code. • The supplier failed to pay value added tax and customs duties on imported goods • The supplier was penalised by the local regulator with a fine exceeding USD5 million along with additional back tax penalties, with a potential impact on its financial stability and long-term profitability.
Operational risk	• Regulatory adherence to local compliance • Risks related to quality • Instability in the supply chain.	• A program associated with a pharmaceutical manufacturer, aimed at managing diabetes, had faced operational risks due to third-party's involvement in conducting research and causing supply chain challenges • The program was criticised for its unreliable research methodology • A contractor withheld an assessment report, heightening concerns about the program's efficacy leading to risks such as reputational harm, regulatory scrutiny, and potential legal liabilities.
Environmental (E) risk	• Waste disposal policies • Unsustainable practices • Climate change impact • Pollution control breaches • Circular economy challenges. • Greenwashing • Bluewashing	• A third-party contractor faced scrutiny for violating hazardous waste regulations and the global waste management accord by exporting waste improperly • Investigations revealed that the contractor had shipped 60 tons of medical waste without required approvals • The contractor faced fines of more than USD2.5 million for improper waste management and disposal.
Social (S) and Governance (G) risk	• Regulatory non-compliances • Data breach risks of patient information • Health and safety concerns • Child labour • Conflict of Interest between supply chain partners and employees of pharma companies	• A pharmaceutical manufacturer faced the Foreign Corrupt Practices Act (FCPA) violations due to bribing the officials of its distributors at state-owned hospitals • The unlawful payments were falsely recorded as legitimate business expenses in financial statements • The manufacturer agreed to pay a fine of more than USD200 million.
Reputational risk	• Reputational risk arising from 'risk of the unknown' such as beneficial owners, key management personnel • Negative media coverage • Public exposure of compliance failures	• An investigation revealed that a network of healthcare professionals and pharmaceutical distributors were engaged in unethical practices to promote specific medications • This network caused significant reputational harm to associated distributors • The distributors faced a fine of over USD40 million for inadequate oversight of third-party relationships, further damaging their reputation and shareholder confidence.

Typical 'risks' in a pharmaceutical supply chain

Risk category	Key vulnerabilities	Illustrative examples
Quality control risk	• Rapid technological changes • Supply chain complexity • Cross-jurisdiction quality challenges • Affected manufacturing practices.	• A pharmaceutical manufacturer faced allegations of adding unapproved substances to products and concealing changes by omitting critical manufacturing documentation • Regulatory authorities banned the sale and manufacture of the affected drugs, advising healthcare professionals not to prescribe them • The manufacturer faced reputational damage and more than USD65 million in penalties for inadequate oversight of third-party manufacturing.
Regulatory risk	• Rising regulatory scrutiny • Cross-border legal challenges • Industry standards shift quickly • Compliance tech adaptation lags.	• A pharmaceutical raw material supplier faced a patent infringement lawsuit from a competitor over an immune-suppressant drug • The competitor countered with a lawsuit asserting its own patent rights, which was upheld by the court, dismissing the supplier's claims • The situation resulted in approximately USD50 million in penalties on the supplier for regulatory non-compliance across various jurisdictions.
Legal, and compliance risk	• Non-compliance leading to fines • Contractual obligations • Potential product recalls • Exposure to legal actions.	• A pharmaceutical manufacturer, faced allegations of forming a cartel to maximise profits, leading to higher drug prices and restricted supply • The manufacturer faced legal risks and a penalty of 10 per cent of its annual global revenue, alongside reputational damage.
Concentration risk	• Reliance on key suppliers • Limited resource diversification • Vulnerability to supplier issues.	• A pharmaceutical manufacturer discovered heavy reliance on a single supplier for active pharmaceutical ingredients (APIs), which had engaged in fraudulent activities, producing substandard APIs • Regulatory authorities issued a recall of affected drug batches, leading to severe production delays and supply chain disruptions • The manufacturer faced reputational damage, regulatory scrutiny, and financial losses of more than USD25 million.

KPMG in India contacts:

Akhilesh Tuteja
Head
Clients & Markets
E: atuteja@kpmg.com

Vijay S Chawla
Partner and Lead
Life Sciences sector
E: vschawla@kpmg.com

Maneesha Garg
Partner & Head – Managed Services
Head – Forensic (Managed) Services
E: maneesha@kpmg.com

Vipul Jain
Partner – Managed Services
Forensic
E: vipuljain@kpmg.com

Ummehaani
Partner – Managed Services
Forensic
E: ummehaani@kpmg.com

kpmg.com/in

Access our latest insights
on KPMG Insights Edge

Follow us on:

kpmg.com/in/socialmedia

KPMG Assurance and Consulting Services LLP, Lodha Excelus, Apollo Mills Compound, NM Joshi Marg, Mahalaxmi, Mumbai - 400 011 Phone: +91 22 3989 6000, Fax: +91 22 3983 6000.