

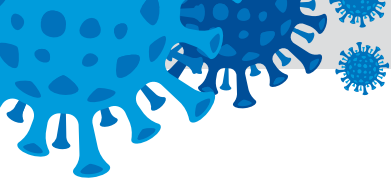


COVID-19: Fraud risks in the pharmaceutical and medical device sector



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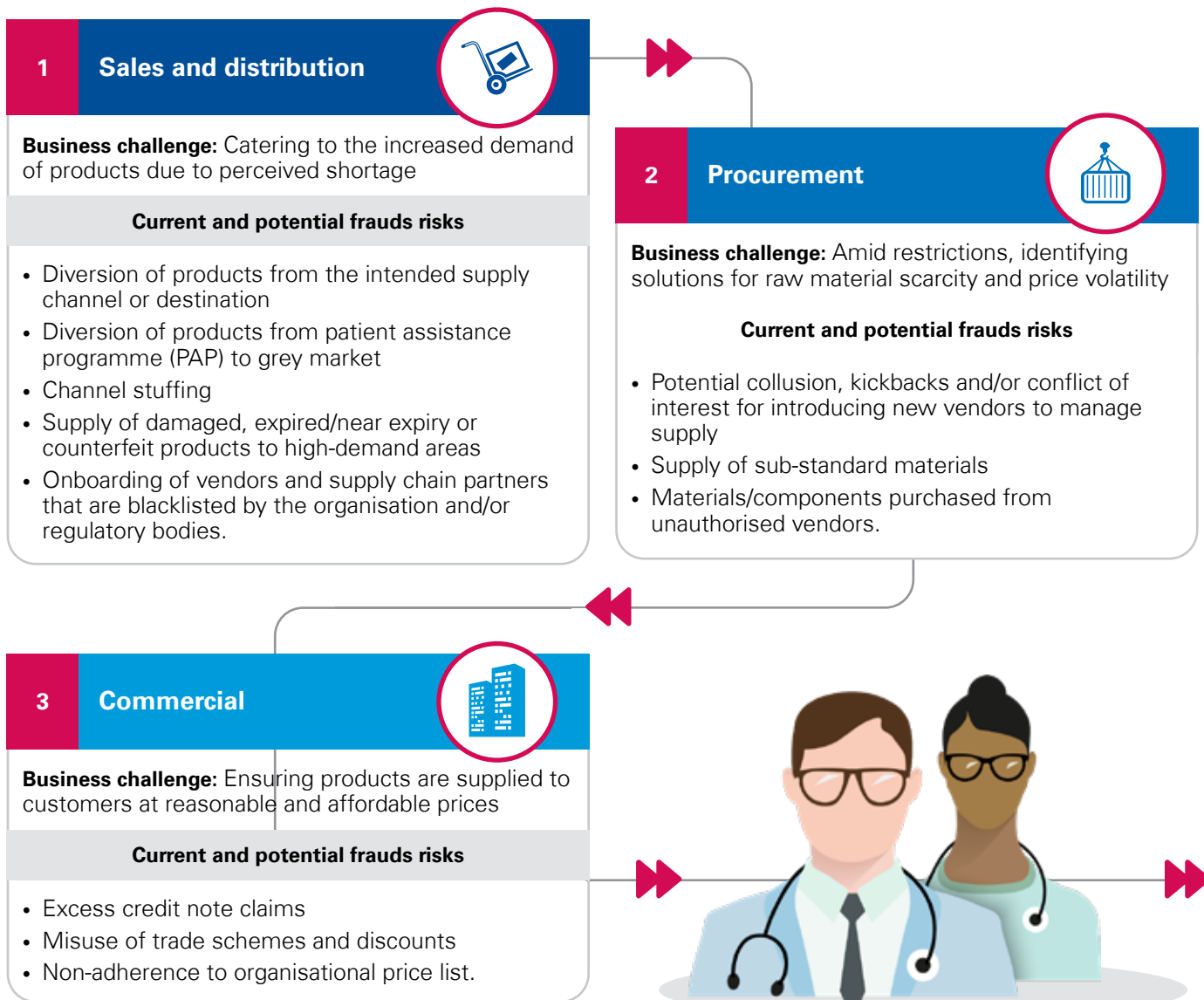
The COVID-19 pandemic has spread rapidly causing an unprecedented global health crisis while also posing challenges to the global economy. The Indian economy, which was already facing challenges, has been further stressed by the COVID-19 outbreak with almost every industry having to shut down or scale down its operations. With the nationwide lockdown that was implemented in the country, the economy has been impacted by demand and supply-side pressures, making economic recovery difficult at least over the short to medium term.

The life sciences sector is at the centre of the COVID-19 crisis, be it with providing timely medical supplies, including personal protective equipment (PPE) or helping in the recovery of COVID-19 patients. Indian life science organisations have had to rapidly adapt to the crisis while facing financial, technological and operational challenges.

For the pharmaceutical sector, reliance on China for active pharmaceutical ingredient (API) has exposed India to potential supply disruptions and price volatility. India's position as a producer and supplier of drugs and vaccines for possible treatment of COVID-19 has, however, opened up new opportunities for businesses and medical diplomacy.

For the medical device sector, India has been reliant on the import of critical medical devices, depending on the product category, as the domestic manufacturing has remained low, confined to low-value products. The outbreak, however, has opened up opportunities for import substitution and for organisations to focus on manufacturing the devices in India.

Currently, while the pharmaceutical and medical device organisations are striving to resolve their business continuity issues amidst social-distancing norms, there is a threat of business processes being exposed to fraud risks as noted below.






4 Marketing 

Business challenge: Capitalise the opportunity of increased demand through marketing and promotions

Current and potential frauds risks

- Excessive/improper payments to healthcare professionals
- Gifts and entertainment provided to healthcare professionals to influence procurement of essentials at hospitals
- Funds siphoned off through fictitious health camps/ medical education events
- Ghost patients in PAP
- Off-label marketing.

5 Compliance 

Business challenge: Government mandated COVID-19 restriction poses a bribery and corruption threat

Current and potential frauds risks

- Improper payments to third parties, such as distributors and agents, assisting with clearances and supply of products during lockdown
- Excessive payments to state-owned healthcare facilities.

6 Production and quality assurance 

Business challenge: Safeguarding product quality while there is a push to supply products

Current and potential frauds risks


- Data integrity issues at manufacturing plants (owned/contract manufacturers)
- Potentially bypassing regulatory norms to increase production.

7 Technology 

Business challenge: Push for technology solutions to ensure business continuity

Current and potential frauds risks

- Phishing scams to access sensitive organisation information
- Cyber frauds and data breaches in organisational devices that are being operated on unsecured networks
- Fake e-pharmacies taking payments and not supplying products
- Charity scams by using non-existent charities to invite donations from individuals and organisations.

8 Human resources 

Business challenge: Employees working remotely

Current and potential frauds risks

- Unauthorised transactions/alterations in the accounting system
- Creating and making payments to dummy vendors and ghost employees
- Insider trading
- Theft of organisations' data.



How can KPMG in India help?



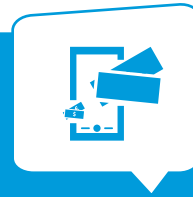
Fraud risk management

Developing a framework for anti-fraud policies, systems and controls



Fraud and misconduct investigations

Develop a case-specific rapid action plan that emphasises confidentiality above all and helps clients find and assess the relevant facts concerning alleged or suspected fraud, misconduct or other improprieties.



Anti-bribery and corruption compliance framework

Due diligence for compliance with related laws and training/awareness programmes for employees and third parties and controls



Pro active data analytics

Data analytics enables 'extending the reach' instead of sampling random transactions and can spot potential red flags. For example, identify patterns/instances indicative of channel stuffing, potential bribery and corruption risk, fraud and misconduct incidents and violations of policies



Data integrity compliance

Technology driven and algorithmic-based electronic good manufacturing practices (eGMP) solution to conduct a proactive assessment, training and reactive investigation related to potential data integrity issues across different functions



Third party reviews and investigations

Reviews/investigations on contract manufacturing units (CMUs), vendors/supplier/distributor to identify breach of compliance, if any and a serious deterrent to fraud



Brand protection investigations

Investigation on counterfeit and grey market products



Fair market value investigations

Investigations related to regulations that demand that the payment made for goods and services is reasonable and represents a fair market value for that product or service



Cyber fraud investigations

To assess the cybersecurity readiness and maturity, rapid cyber incident response, containment of threats, monitor cyber threats and test cyber controls

Forensic in life sciences



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