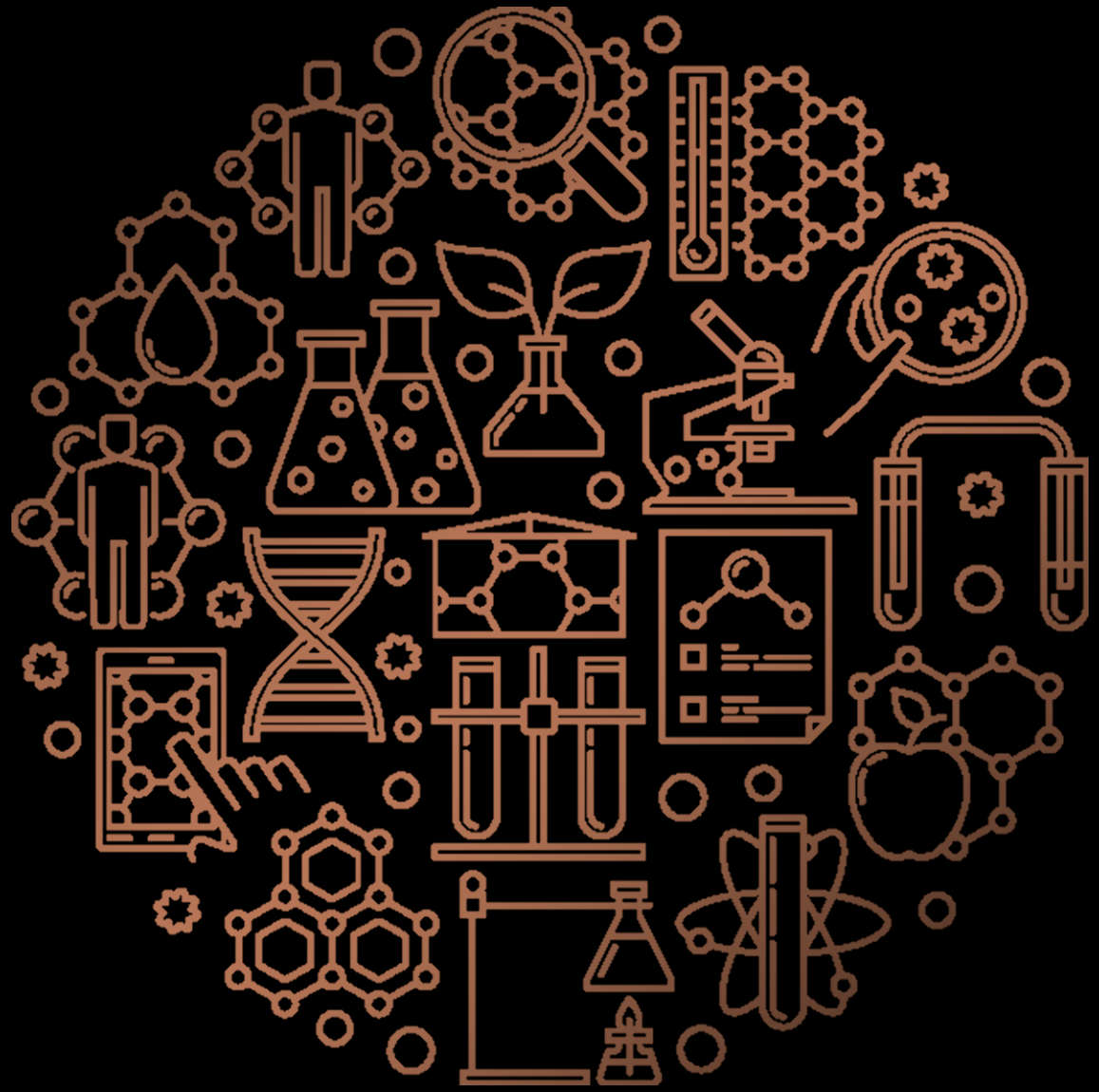
PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains



Managing Anti-Bribery and Corruption (ABC) Risks in the Pharmaceutical Industry

External Benchmarking on ABC Standards / Trends in Supply Chain

December 2020

Managing ABC Risks in Supply Chain – Benchmarking Report

Background

- The Pharmaceutical Supply Chain Initiative (PSCI) is a group of pharmaceutical and health care companies who share a vision of excellence in safety, environmental, and social outcomes across the whole of the global pharmaceutical and healthcare supply chain. The PSCI members work together to identify issues, develop common tools and approaches, build supplier capability, and partner with others to improve supplier practices.
- Currently, PSCI has 45 members worldwide, including 29 full-time members and 16 associate members.
- The PSCI Principles guide our work, and cover human rights, sustainability, and responsible business. As part of sustainability and responsibility business, in recent years, the organization has moved to address the issues around anti-corruption. During this time, regulations around anti-corruption have been tightened and stakeholder expectations have increased. PSCI wants to encourage and support members to continually enhance their anti-corruption program for compliance with the latest guidelines issued by different regulatory authorities around the globe. Organizations are expected to develop proactive, risk-based compliance programs that are tailored to the specific risk profile and are reasonably designed to prevent them and their employees/agents/suppliers from engaging in bribery or corrupt acts.
- This report has been created to help our member companies and suppliers strengthen the ABC risk management practice in their supply chain.

Contents

Disclaimer: Bribery and corruption has a very broad scope, with overlaps and implications arising from issues relating to human trafficking and human rights, environment, money laundering, etc. However, the primary focus of this report is on bribery and corruption risks, especially as they related to supply chain. This report is primarily based on information available on the public domain relating to industry / market trends, global regulations/legislations, enforcement actions, and leading industry practices. However, it also incorporates observations from our experience and interactions within the industry. There could be relevant events and circumstances occurring after the date of this report that could have an impact on the results contained in this report.

This report is intended strictly for internal reference and learning purposes. The inclusion of company names and / or examples does not constitute an endorsement of the individual companies by PSCI. The material in this report may be quoted and used, provided there is proper attribution.

Executive Summary

The PSCI Ethics subcommittee aims to develop a road map, through internal and external benchmarking, to help its member companies and suppliers strengthen the ABC risk management practice in their supply chain. This benchmarking report is broken into four segments:

Key industry trends and ABC risks in supply chain

Identifying emerging trends in the pharmaceutical industry

In recent years, there has been –

1. Increased demand and competition, leading to **increased willingness to participate in bribery schemes**
2. Increased dependence on third parties for **Patient Support Programs** leading to greater **ABC risk exposures**
3. Experimentation with **shared services (use of fourth-party logistic providers)** causing **increased scrutiny** for adherence to third / fourth party ABC considerations
4. Increased use of **vertical integration transactions** also increasing ABC risks

Additionally, **COVID-19 pandemic** caused major shifts in the global supply chains leading to –

- **Increased government interactions** leading to increased regulatory scrutiny
- **Increased competition for critical supplies,** leading to **bribery and illegal inducements**
- Increase in **unrealistic targets** leading to **increase in misconducts** and **whistleblower** activities
- Greater need for **compliance monitoring** and conducting internal investigations **through virtual platforms**

Global legislations and standards

Identifying the scope, actions required to be compliant with the requirements, and enforcements / sanctions applicable in case of noncompliance

Key global authoritative **minimum standards and key legislations** related to ABC risks, including elaboration of their **scope/applicability**, supply chain-specific guidance, and real-life **enforcement action scenarios**, are –

- U.S. FCPA
- UK Bribery Act
- Brazilian Clean Company Act
- The Prevention of Bribery Ordinance (Hong Kong)
- Prevention of Corruption Act (India)
- Russian Federation Federal Law On Corruption Counteraction
- Organization for Economic Co-operation and Development (OECD) Guidelines for Multinational Enterprises

Major trade and industry organizations that have issued supply chain guidance are

- AdvaMed
- International Pharmaceutical Federation (FIP)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Korea Pharmaceutical and Bio-Pharma Manufacturers Association

Major anti-corruption conventions are

- OECD - Convention on Combating Bribery of Foreign Officials in International Business Transactions
- United Nations Convention Against Corruption (UNCAC)
- European Criminal Law Convention on Corruption

Executive Summary (contd.)

Potential ABC risk scenarios in supply chain

Identifying scenarios of potential ABC risks, including the actions that companies can take to prevent these risks

Some of the key potential ABC risk considerations

Culture, governance, and internal controls – No reference to third-party fraud risk management programs, supply chain risk assessments not performed, kickbacks paid to procurement officer, and failure to respond to red flags.

Policies and procedures – Dated policies, improper payments, falsification of books, inadequate internal controls, creating fictitious invoices, absence of vendor contracts or invoices, and missing ABC clauses in contracts.

Third-party risk management – Due diligence conducted post execution of contract, not conducted on referrals, conducted as a one-time effort, inadequate documentation, lack of supplier selection process, potential conflict of interests with supplier, conducting business with sanctioned third parties.

Interactions with government officials and HCPs – Bribes paid to officials of government-owned entities, medical organizations/physicians, regulatory compliance officials, review committee members, enforcement and inspection officers.

Hiring and training – Lack of consistent / timely training, inadequate training in high-risk functions / regions, lack of ABC trainings to third parties, trainings not meeting regulatory guidelines, non-disclosure of potential conflicts of interest with the third parties.

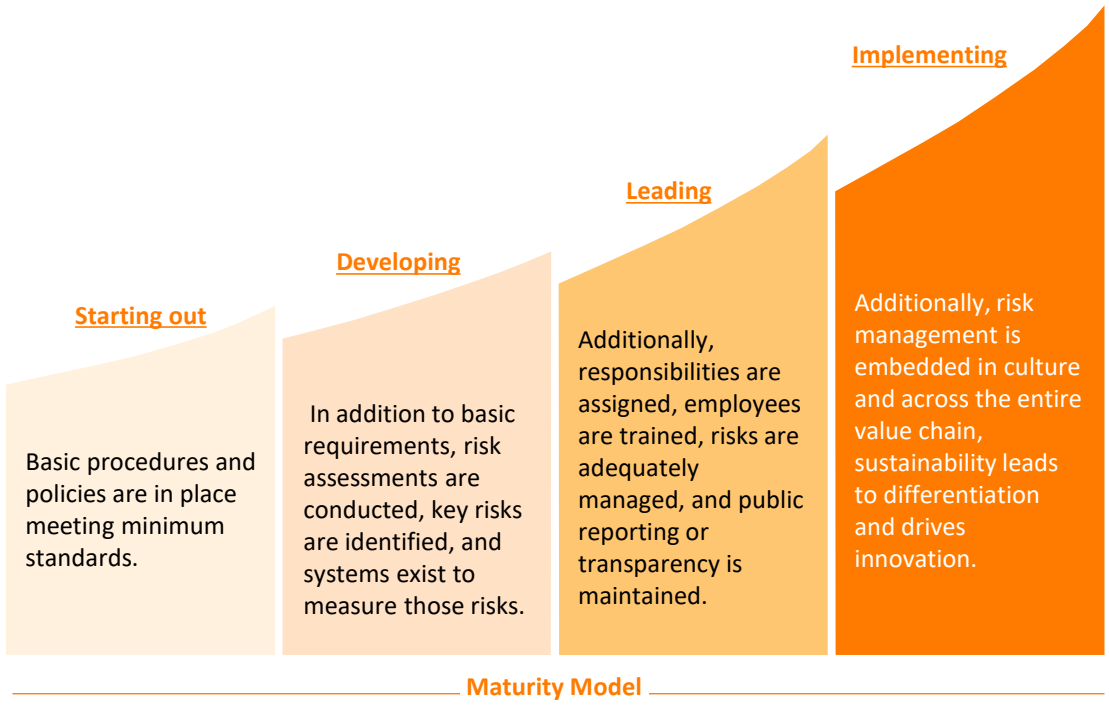
Confidential reporting and investigations – No whistleblower reporting channels, lack of awareness of such channels, channels unavailable to third parties and / or unavailable in local languages, inadequate incident resolution mechanism.

Industry leading practices

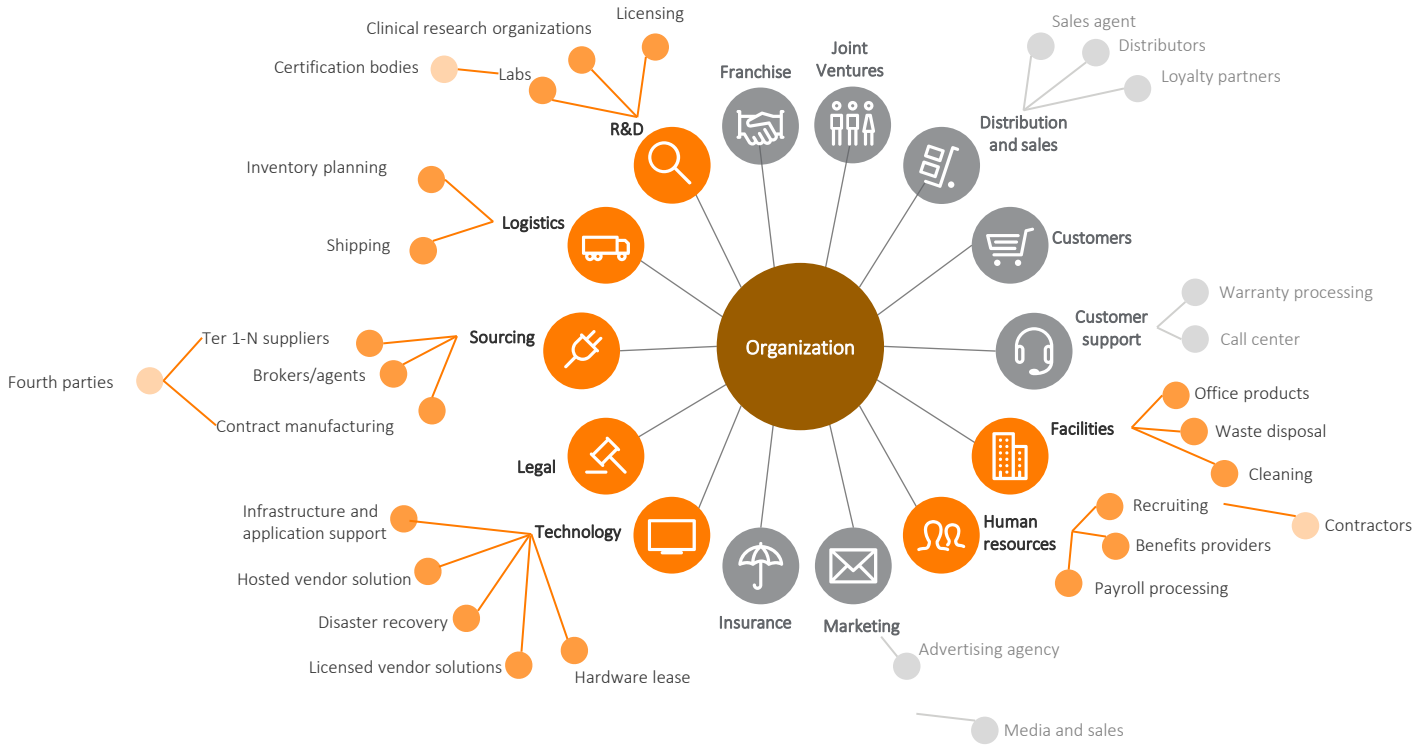
Identifying good practices adopted by companies across industries to manage the ABC risks in their supply chains

In each of the six risk categories, the good industry guiding principles and practices have been highlighted across the following stages of PSCI's maturity model.

This will allow companies to compare their current processes with the industry leading practices and evaluate their current level of maturity. It will also enable them to establish a future roadmap by and providing specific considerations that would be necessary to achieve the desired level of maturity.



Complexity of Third-Party Relationships in the Pharmaceutical Industry



The interactions with third parties typically go through a five-stage lifecycle, as described below. In this report, we have focused on highlighting the potential ABC risks and considerations that organizations could consider in each of these stages, specifically with respect to third parties with the organization's supply chain highlighted in the graphic.

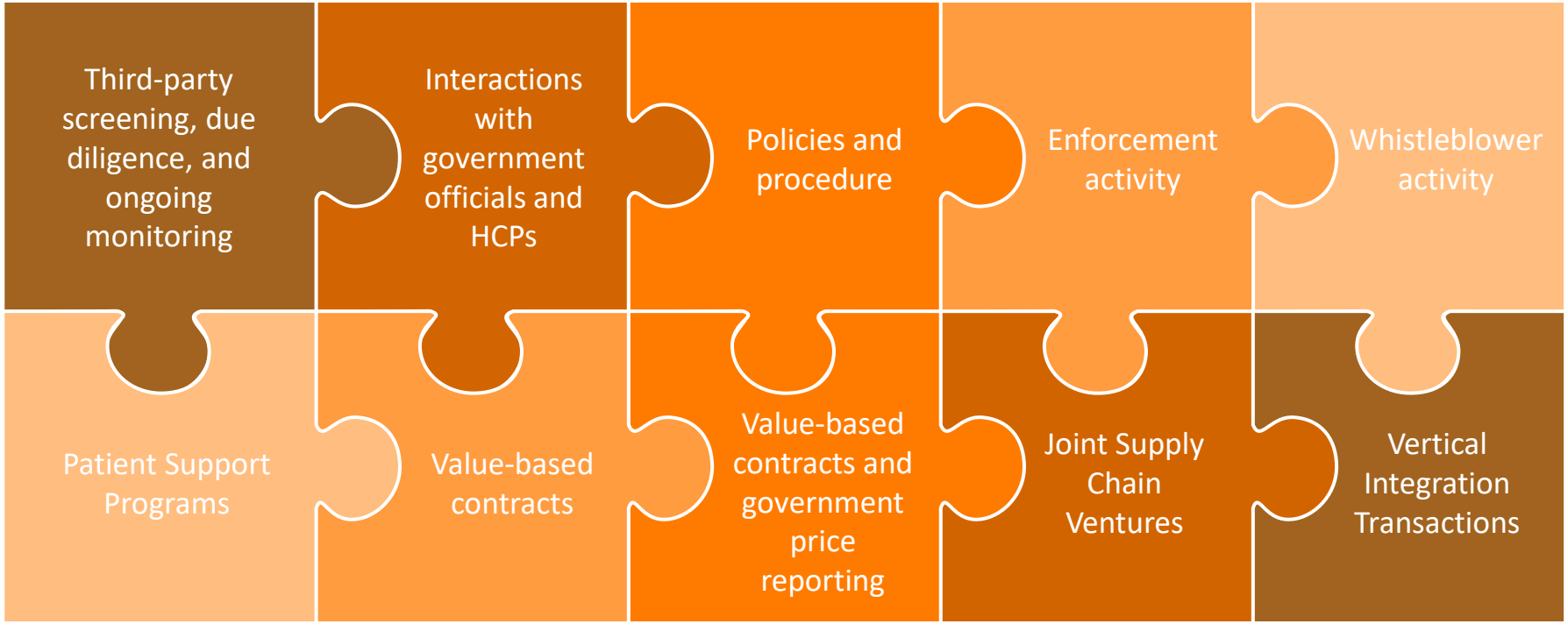
Third-party analysis pre-screening and selection	Onboarding	Contracting	Maintenance, governance, and monitoring	Offboarding/renegotiation
• Identify, profile third parties; develop selection criteria; and conduct due diligence/screening for compliance, performance history and financial fortitude	• Register new third parties into relevant systems • Set up third-party program, train third-parties on business processes, and define escalation points	• Initiate, negotiate, and draft contracts with new third parties • Manage contracts through their life cycle	• Monitor changes in regulatory compliance requirements • Monitor changes in third-party risk profile • Manage third-party risk and compliance • Conduct ongoing third-party assessments (and other remedial actions/investigations, where needed)	• Renegotiate contracts to more acceptable terms • Offboard third parties and revoke relevant access

Key industry trends and ABC risks in supply chain

Key Industry Trends and ABC Risks in Supply Chain – Overview

The ongoing pandemic has had an unprecedented effect on the pharmaceutical industry this year. While companies have been adapting to the new normal, there are heightened ABC risks, apart from the already existing risks in the industry, which might have significant future implications. It becomes pertinent for companies to continually review and understand the emerging risks and changes in the industry landscape, in order to be able to better forecast their future operating scenarios, identify and proactively address potential risks, and capture emerging opportunities.

This section elaborates on the key global market trends in 10 areas that have the potential to create ABC risks in the pharmaceutical industry, along with specific supply chain takeaways. These trends are derived from pharmaceutical industry publications, trends reported in the media, as well as those identified from industry experiences and could help companies identify emerging ABC risks relevant for the pharmaceutical industry, especially as they relate to supply chain.



Key Industry Trends and ABC Risks in Supply Chain (1/4)

Key supply chain takeaways

1 Third-party screening, due diligence, and ongoing monitoring

1. The **Covid-19** pandemic has caused major shifts in organizations' global supply chains. Pharmaceutical companies may have been forced to **cease and/or shift manufacturing** out of certain countries, **identify new vendors** to replace those that may have gone under, or quickly identify **new types of third parties** to adapt to a changing business model. It becomes critical to establish robust onboarding / due diligence processes to adequately mitigate the risks from these newer players.
2. Competition for critical supplies from small-specialized vendors may encourage the hiring of third parties who seek to obtain the materials through bribes or other illegal inducements. Companies responding to these developments will likely encounter material changes in the makeup of their third-party network, which further highlights the need for appropriate risk mitigation procedures (e.g., diligence, onboarding) to be in place, such as:
   - Set up a crisis management team/project management office, responsible for taking decisions during a pandemic.
   - Include key members from critical functions as a part of the crisis management team.
   - Schedule meetings or calls among members of the crisis management team on a periodic basis to evaluate the current situation.
   - Set up business continuity and recovery plans based on various scenarios.
3. Companies may manipulate clinical trial data and/or engage ghostwriters for clinical trial publications , to create a more favorable response to their drugs, as HCPs may rely on clinical trial data to make decisions on which medicines to use to treat patients.

- Because of the pandemic and the need for highly specific goods, supplies from a small number of vendors may encourage third parties through bribes or other illegal inducements.
- Entry of new third parties to address changes in the business model.

2 Interactions with government officials and HCPs

1. For many companies, the current crisis may lead to **additional interactions with government entities and officials**, particularly with the sharp increase in stimulus, increase in humanitarian aid and public healthcare programmes (such as vaccines, antibody research, procurement of PPTs, ventilators, vaccine cold chains, other Covid-aids, etc.), and other types of funding being poured into the global economy. Enforcement authorities will likely look to place heightened scrutiny on these interactions, which present opportunities to engage in corrupt and/or unethical behaviors to seek improper advantages.
2. Additionally, as the pandemic creates new opportunities to exploit weak oversight, inadequate transparency, or collude with those who control supply chains, authorities such as United Nations have placed greater weightage on accountability and transparency, terming corruption as "criminal, immoral, and the ultimate betrayal of public trust." This puts an additional onus on pharmaceutical companies as even the smallest bribery or corruption allegation could lead to outrage from public and from the authorities.

- Because of the current global crisis, and funding being poured into the global economy, there will be heightened scrutiny placed on interactions with government officials by corporate actors that engage in corrupt or unethical behavior to gain an improper advantage.

3 Policies and procedure

1. Many companies have found themselves subject to regulatory scrutiny when their compliance program (and related enhancements) lags behind changes in the company's risk profile. There are many ways in which the current pandemic has altered the state of the global economy and how pharmaceutical companies operate, which will inevitably cause a company's risk profile to change as well.
2. There may be new and/or emerging risks posed by shifts in operations, geographies, third-party interactions, and government touchpoints. Companies should **revisit their anti-corruption risk assessments** to ensure they are appropriately picking up on these new risk factors, and then tailor their compliance programs (e.g., policies, procedures, and controls) to appropriately respond to such risks.

- Additional and emerging risks from the pandemic may alter the way a company operates – specifically third-party interactions and government touchpoints.
- Companies should revisit their anti-corruption risk assessment and add any new risk factors.

Key Industry Trends and ABC Risks in Supply Chain (2/4)

Key supply chain takeaways

4 Enforcement activity

1. Covid-19 has increased the economic instability which in turn has **increased the risk of bribery and fraud** in the healthcare industry. The global enforcement agencies have indicated that while the enforcement activity has remained consistent, it is expected to increase in coming months.
2. As **Covid-19** has led to shortages in hospital beds, ventilators, and other hospital equipment, officials have warned of the increasing risk of bribery.
3. **Corruption and price gouging practices** may increase as governments spend more on treatment and vaccine research and providers seek to profit from limited supplies. These concerns point to a need for greater transparency on public and private spending, as well as procurement processes.
4. US and global regulators have declared that they will continue to monitor businesses' compliance with internal controls and disclosure obligations, and **expect internal investigations to continue, with the help of virtual platforms**. Agencies will take into consideration cooperating businesses' explanations as to why they are unable to satisfy a regulators' request or pay claims.

- Regulators believe that an increased demand on supplies from pharmaceutical and medical device companies may lead to a willingness to participate in bribery schemes.
- Globally, regulators have reaffirmed their commitment to enforcement activity, even in a global pandemic.

5 Whistleblower activity

1. It is likely that corporate whistleblower activity will increase in the near future. As employers take aggressive steps to respond to the crisis, employees may be pressured to meet unrealistic sales goals (or reduce costs) and other targets, potentially leading to increased wrongdoing as well as the discovery and reporting of such wrongdoing (either internally or externally).

- Need for robust whistleblower channels that also extend to third parties, to cater to the expected increase in whistleblower activity.

6 Patient Support Programs (PSPs)

1. PSPs have received significant attention from regulators in 2019. While risk management has not been a traditional priority in patient services, the dependence on third parties (such as hubs and distributors) to operate high touch, high cost, specialized programs brings a host of compliance considerations, ranging from Anti-Bribery and Anti-Kickback exposures to drug safety and pharmacovigilance. PSPs for products that cross multiple therapeutic categories add yet another layer of complexity for compliance professionals.
2. Additionally, pharmaceutical and medical product manufacturers might get tempted to leverage PSPs to gain preferential treatment for their products, which could lead potential violations of the Anti-Kickback Statute and False Claims Act.
3. In recent years, pharmaceutical companies have moved toward creating a global PSP framework, which has opened them to various legal, regulatory, and industry standards and the threat of multiregulated anti-corruption, local law and industry code violations, and other exposures. Hence, among other logistical factors, companies would need to account for different legal regimes and industry codes applicable to its PSP.
4. Covid-19 has also impacted the design of patient support programs over the long term, such as increasing the need for multichannel engagement solutions, focusing on intelligent design of patient-centric, risk-informed support programs.

- The dependency on third parties (such as hubs and supply chain distributors) to operate specialized PSPs bring increased compliance considerations around Anti-Bribery and Anti-Kickback exposures to drug safety and pharmacovigilance.

Key Industry Trends and ABC Risks in Supply Chain (3/4)

Key supply chain takeaways

7 Value-based contracts (VBCs)

1. As the cost pressures on healthcare systems continue to increase globally, increasing number of pharmaceutical companies are evaluating the need for value-based pricing, contracting, and reimbursements.
2. While there is a burgeoning interest in accelerating the execution of VBCs, many organizations do not have the **infrastructure needed to support VBCs** across their market offerings. Infrastructure challenges include having the systems to collect, aggregate, and store reporting data, as well as contract administration that can effectively oversee complex relationships with payers. Furthermore, once a VBC is in place, advanced analytics are needed to ensure that the value proposition is realized in practice. While value-based payment arrangements are themselves complex, they also expose life sciences companies to **patient privacy and anti-kickback issues,** as well as other government price reporting compliance considerations.
3. Existing laws around fraud and abuse, such as the Anti-Kickback Statute, do not address VBC arrangements.
4. To achieve compliance in a complex and ambiguous regulatory environment, life sciences companies will need to have a deep understanding of the VBC landscape, as well as benchmark arrangements other drug companies have entered into, and work closely with their counsel.

- There is a broader shift from volume to value-based contracts, which many companies do not have the infrastructure needed to support across their market offerings.
- Current fraud and abuse laws do not directly address value-based contracts; however, pharmaceutical value-based arrangements are under consideration.
- Value-based contract terms must protect against the perception that clinical decisions are influenced by value-based contracting.

8 VBCs and government price reporting

1. Current government price reporting requirements do not address VBC arrangements and make certain VBC arrangements challenging for manufacturers to enter into. Further, there have been challenges with certain payment over time VBC arrangements due to the impact on average manufacturer price and associated inflation penalty as part of the MDRP. Finally, VBC arrangements may be structured as bundles, creating operational challenges for drug companies—any type of bundling will need to be unbundled for statutory price calculations— and the more complex the bundling (temporal, products, entities, etc.) the greater the potential impact on overall operations.
2. Pharmaceutical companies should consider adopting a concerted approach for meeting the challenges and opportunities of VBC arrangements. Considerations include:
   - Scenario analysis. A company should develop a forecasting and scenario analysis framework for potential VBCs that include the products in its portfolios.
   - Prepare for rapid implementation. Given the complex relationship between public and private drug pricing, controls should be in place to assess whether commercial decisions might have secondary effects on government programs. In all, it is advisable to develop an operational roadmap and process flows that outline operational changes whenever a new contracting approach is implemented.
   - Have the players in place. Companies will need to assign responsibilities and develop processes to support the **ongoing monitoring of novel contracting strategies**.

- Current government price reporting requirements do not address VBC arrangements, thus making them challenging for manufacturers to enter into.

Key Industry Trends and ABC Risks in Supply Chain (4/4)

Key supply chain takeaways

9 Joint Supply Chain Ventures

1. A few pharmaceutical companies have started experimenting with 'shared services', primarily to support joint product development initiatives. However, the vast majority of companies still build, own, and operate their own supply chain infrastructure.
2. Experience in other industries has also demonstrated the benefits of managing distribution collectively and increasing demand for biologics has stimulated the development of specialist logistics providers capable of handling very sensitive pharmaceutical freight. This is an area that requires heightened attention in the current pandemic, as the global issues relating to trafficking in persons and other **human rights violations is expected to increase through corrupt practices** related to procuring biological specimens, especially with the use of multiple global intermediaries / facilitators.
3. Moreover, some of the most sophisticated third-party logistics (3PL) providers – i.e., companies that offer freight management and warehousing – are expanding into supply chain management and coordination services. And it is arguably these fourth-party logistics (4PL) providers that can deliver the greatest improvements.
4. It will still be the **responsibility of each individual pharmaceutical company to adhere to all third-party anti-bribery, anti-kickback considerations**, no matter if there are shared supply chain resources between companies.

- Pharmaceutical companies have started experimenting with 'shared services' to support joint product development and supply chain initiatives.
- The potential use of 4PL providers to reduce supply chain costs in these types of joint 'shared services' arrangement places increased scrutiny on each pharmaceutical company to adhere to all third-party (here fourth-party) anti-bribery consideration.

10 Vertical Integration Transactions

1. Driven by a desire to reduce cost, improve care, keep up with competitors, and participate in evolving reimbursement programs, healthcare providers are increasingly undertaking vertical integration transactions.
2. Vertical integration is an expansion up or down the service or supply chain beyond a company's current line of business. In the health care industry, vertical integration translates to organizations offering, directly or indirectly, a broader range of services on the continuum of the delivery of health-care services.
3. Vertical integration may **increase anti-kickback risk** if different service lines run by the same company are in a position to influence referrals or induce the purchase of products from other parts of the company.
4. Vertical integration may increase risk under the Stark Law if compensation paid to physicians is based on the volume or value of referrals made by the physician to the company.

- Vertical integration may increase anti-kickback risk if different service lines run by the same company are in a position to influence referrals or induce the purchase of products from other parts of the company.
- Companies must ensure that physician compensation generally is not based on any profits related to referrals for designated health services and is based on the fair market value of the services.

Global legislations and standards

Global Legislations and Standards – Overview

As evidenced by the recent trends, ABC compliance and the mitigation of ABC risks continue to be a major challenge for the pharmaceutical companies to address, in both domestic and international markets.

While there are global legislations around ABC risk mitigations, many countries have adopted their own specific and more sophisticated rules and legislations for companies to adhere to. The companies need to ensure that they are up to date with the regulations applicable in the markets they operate in and stay compliant with the laws.

This section elaborates on the major global standards and legislations related to ABC risks. It provides companies with a comparative view of seven major global legislations and standards (and guidelines issued by the OECD) across parameters such as scope, nature of advantage, provisions, and exemptions under facilitation payments, among others. The comparative analysis also highlights the significance and applicability of these regulations with respect to the pharmaceutical supply chain ABC risks, and provides guidance on the behaviors which are prohibited, or which companies need to adhere to avoid these risks.

This section also provides additional guidelines issued by major trade and industry organizations and major anti-corruption conventions.

Comparison of Major Global Legislations and Standards (1/3)

	FCPA (US)	Bribery Act, 2010 (UK)	Brazilian Clean Company Act (Brazil)	The Prevention of Bribery Ordinance (Hong Kong)	Prevention of Corruption Act (India)	Russian Federation Federal Law On Corruption Counteraction (Russia)	Organization for Economic Co-operation and Development (OECD) Guidelines for Multinational Enterprises
Scope/Applicability	Applicable to the U.S. companies, their employees, officers, directors, and agents, in both the US and abroad.	Applicable to companies incorporated in the United Kingdom as well as individuals who are British citizens or ordinarily resident in the UK.	Applicable to business companies and sole proprietorships, foundations, associations of entities or persons, and foreign companies with registered offices, branches, or representation in Brazil, legally or de facto organized.	Applicable to both public and private sector; public sector bribery involving public servants includes only Hong Kong public servants; private sector bribery is not extraterritorial in and of itself but can cover bribery of foreign officials.	Applicable to the whole of India (other than the state of Jammu and Kashmir) and to all Indian citizens, irrespective of their geographical location; it may also apply to foreign companies doing business in the Indian territory.	Foreign citizens, stateless persons, non-residents of the Russian Federation, foreign legal entities with civil legal capacity, established in accordance with the legislation of foreign states, international organizations as well as their branches and representative offices (foreign organizations), accused (suspected) of corruption offences outside the Russian Federation, are legally liable under the legislation of the Russian Federation in cases and in the manner provided for by international treaties of the Russian Federation and federal laws.	Applicable to multinational enterprises (all entities within the multinational enterprise- parent companies and/or local entities) operating in or from adhering countries (which could be OECD and Non-OECD countries).
Who is being bribed	Foreign public officials	Any person (not limited to foreign public officials)	Domestic public officials as well as foreign public officials	Public, private, and foreign officials	Public servants	Any person	Domestic public officials, foreign public officials and employees of business partners
Nature of advantage obtained	Money or anything of value.	Financial or other advantage.	Finance, pay, or subsidize the performance of a prohibited act; bid rigging and fraud in public procurement.	Money, property, and any other valuable substance.	Financial or anything of value.	Money, valuables, other property or services of material nature, other rights of property for oneself, or for third parties.	Pecuniary advantage or other/improper advantage.
"Active offence" vs. "passive offence"	Active offence	Both active and passive offences	Active offences	Both active and passive offences	Not defined	Not defined	Not defined
Facilitating payments	Exception for payment to a foreign official to expedite or secure the performance of a routine (non-discretionary) government action.	As per Serious Fraud Office, guidance facilitation payments were illegal before the Bribery Act came into force and they are illegal under the Bribery Act, regardless of their size or frequency.	Brazilian law does not make any exception for facilitation payments, which are prohibited and considered to be bribes.	There is no exception in Hong Kong Prevention of Bribery Ordinance for exchange of facilitation payments. Unlike FCPA, there is no defence for such payments in the ordinance. It also extends to private officials in the country.	Prevention of corruption act does not provide any exception for facilitation payments made to the public servants.	There are no specific rules regulating facilitation payments. Therefore, such payments are subject to the prohibition of bribery under the Administrative Offences Code and Criminal Code.	The use of small facilitation payments is prohibited or discouraged in internal company controls, ethics and compliance programs or measures, and, when such payments are made, they are to be accurately recorded in the books and financial records.

Comparison of Major Global Legislations and Standards (2/3)

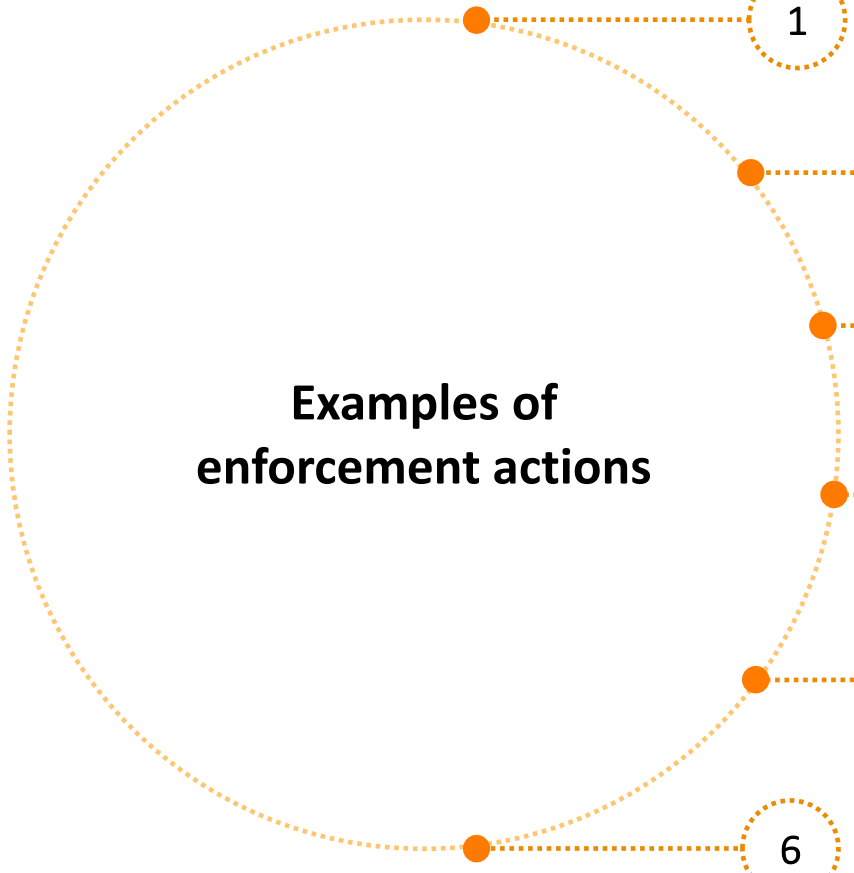
	FCPA (US)	Bribery Act, 2010 (UK)	Brazilian Clean Company Act (Brazil)	The Prevention of Bribery Ordinance (Hong Kong)	Prevention of Corruption Act (India)	Russian Federation Federal Law On Corruption Counteraction (Russia)	OECD Guidelines for Multinational Enterprises
Corporate Criminal Liability	• Yes, criminal liability can be imposed on companies and individuals for knowingly failing to comply with the FCPA's books and records or internal controls provisions. As with the FCPA's anti-bribery provisions, individuals are only subject to the FCPA's criminal penalties for violations of the accounting provisions if they acted "willfully." • A false certification may give rise to criminal liability for false statements.	• Yes, liability imposed for failure to prevent an act of bribery unless the corporate entity can demonstrate that it had adequate procedures to prevent such an act occurring, is a considerable change in the approach towards corporate criminal liability. An important feature of the new Bribery Act is its extraterritorial reach and its application to non-UK companies. A foreign company which carries on any "part of a business" in the UK could be prosecuted under the Bribery Act for failing to prevent bribery committed by any of its employees, agents, or other representatives, even if the bribery takes place outside the UK and involves non-UK persons.	• No (Civil and Administrative liability only). Brazilian law provides for criminal liability of legal persons only in exceptional cases, such as those of environmental crimes. In all other cases, criminal liability only applies to individuals, not to companies. • The Brazilian Supreme Court has decided that corporate criminal liability is independent of the criminal liability of the individual who committed, or somehow assisted, in the offense. This means that even if the authorities do not pursue the individuals involved in an environmental crime, the authorities can start criminal proceedings against the company if they consider that the legal requirements of Section 3 of Federal Act 9,605/1998 are fulfilled. • However, Law nº. 12,846/2013 ("Anti-Corruption Law"), Law No. 12,529/2011 ("Antitrust Law"), and Law 8666/93 ("Public Procurement Law") are strict liability statutes.	• Yes, due to the individualistic nature of some offenses, such as fraud, bribery, and money laundering, the Commercial Crime Bureau and the Independent Commission Against Corruption focus on the prosecution of individuals instead of companies because the individuals are the actual parties at fault and are readily identifiable. That said, companies can still potentially be held criminally liable but are usually subject only to enforcement actions such as search and seizure of documents from the company's premises for the purpose of the investigations.	• Yes, bribe giving is a specific offence and the concept of corporate criminal liability applies for acts of bribery. • Where an offence under this Act has been committed by a commercial organization, such organization shall be punishable with fine, if any person associated with such commercial organizations gives or promises to give any undue advantage to a public servant intending – a) to obtain or retain business for such commercial organization; or b) to obtain or retain an advantage in the conduct of business for such commercial organization	• Yes, criminal liability for violations of anti-corruption laws, antitrust, and public procurement regulation. • There is criminal and administrative enforcement of Russia's anti-bribery laws. The concept of civil enforcement of bribery laws is foreign to the Russian legal system. • Article 19.28 of the Administrative Offences Code (unlawful remuneration on behalf of a legal entity) prohibits the bribery of foreign public officials by legal entities. This offence punishes the illegal transfer, offering, or promise of money, securities, or other property, valuable services, or other property rights to a foreign public official on behalf, or in the interest of a legal entity, in return for the foreign public official using his or her authority to act in favor of the legal entity.	• The OECD Guidelines provide non-binding, voluntary principles and standards for responsible business conduct in a global context consistent with applicable laws and internationally recognized standards. • Companies that have allegedly failed to adhere to the Guidelines' standards may risk having a formal complaint to an established National Contact Point (NCP). NCP 'statements' are taken seriously and can lead to adverse consequences, including debarment, divestment, and other reputational consequences.

Comparison of Major Global Legislations and Standards (3/3)

	FCPA (US)	Bribery Act, 2010 (UK)	Brazilian Clean Company Act (Brazil)	The Prevention of Bribery Ordinance (Hong Kong)	Prevention of Corruption Act (India)	Russian Federation Federal Law On Corruption Counteraction (Russia)	OECD Guidelines for Multinational Enterprises
Exemption for Facilitation Payments	• Yes, there is an exception for bribery provisions under FCPA. Specifically, there is an FCPA facilitation payment exception which companies may be able to claim if the payments made are for a good reason. • Facilitation payments are different from bribes because they are not a payment to gain a contract. A facilitation payment is usually a payment made to cover licensing or fees related to the project. This can get tricky though, as bribes can be labeled as facilitation payments to cover up the violation. As such, someone making a facilitation payment needs to follow some strict procedures to ensure that it will not be mistaken for a bribe.	• No, all facilitation payments are considered bribes, regardless of size or frequency. However, the revisions point out that such payments will not necessarily be prosecuted if they do not rise to a certain level.	• No, the Brazilian anticorruption legal framework does not allow facilitation payments. Provided they meet the criteria, therefore, facilitation payments can be considered bribery, no matter how small the amount.	• No, the Prevention of Bribery Ordinance does not permit facilitation payments and does not provide a statutory defense on a de minimis basis. The ordinance prohibits advantage to 'expedite' the performance of a public function.	• No, there is no exception that allows making facilitation payments to public servants in India.	• There are no specific rules regulating facilitation payments.	• The Guidelines recommend that, in general, enterprises should avoid making efforts to seek exemptions not contemplated in the statutory or regulatory framework related to financial incentives.
Supply Chain-Specific Guidance	It is unlawful to directly or indirectly bribe any foreign official to influencing any act or decision of such foreign official in his official capacity for the benefit of the supply chain of business.	It is unlawful to directly or indirectly bribe any foreign official to influencing any act or decision of such foreign official in his official capacity for the benefit of the supply chain of business.	It is unlawful to promise, offer, or give, directly or indirectly, an undue advantage to a public agent or a related third person in an attempt to prevent, disturb, or defraud the performance of any act of a public official with respect to supply chain.	It is unlawful to procure any contract with a public body related to providing service and supplying of any article, material, or substance (as categorized under supply chain) in exchange of the payment of the price.	It is unlawful to bribe public servant by a commercial organization to obtain or retain business or retain an advantage in the conduct of supply chain of business.	It is unlawful to giving bribe, acceptance of bribe, or other illegal use by a physical person of his/her official position for the purpose of profiting in the form of money, valuables, other property, or services of material nature under supply chain.	It is unlawful to directly or indirectly offer, promise, give, or demand a bribe or other undue pecuniary advantage to public officials or employees of business partners, to obtain or retain business or other improper advantage with respect to supply chain.

In addition to the major global legislations and statutes outlined above, there are additional existing and upcoming legislations, which increase legal certainty about the standards expected from companies with respect to interactions with their supply chain partners. For example, the upcoming legislation - EU mandatory due diligence – which is expected to be presented in 2021, would require businesses to carry out due diligence in relation to the potential human rights and environmental impacts of their operations and supply chains.

Enforcement actions examples across major global legislations and standards



1

FCPA (US)

A generic drug maker paid millions of dollars in bribes to overseas officials to promote its products, to win contracts/business and to gain approval for the sale of its drugs.

2

Bribery Act, 2010 (UK)

The Serious Fraud Office is investigating a case of fraud against a major pharmaceutical manufacturer for bribing doctors to promote and prescribe the company's drugs in a foreign market.

3

Brazilian Clean Company Act (Brazil)

A medical device company schemed to use high discounts, fake invoices, and made improper payments through third-party commercial representatives and distributors to induce doctors to use its products and increase sales.

4

The Prevention of Bribery Ordinance (Hong Kong)

A former chief financial analyst of a financial intermediary was found conspiring with the sales representative of the bank to deceive the bank in granting a loan referred by the financial intermediary. The loan applicants were coached not to disclose that they were referred by the financial intermediary.

5

Prevention of Corruption Act (India)

A major generic drug maker paid damages to the tune of $500 million to settle on corporate fraud related to unethical production of medicines that compromised on quality. The company had deceived regulators around the world by submitting fraudulent data that made its drugs appear bioequivalent to brand-name drugs.

6

Russian Federation Federal Law On Corruption Counteraction (Russia)

A pharmaceutical company admitted to systemic corruption over more than a decade and its transgressions included the bribing of top health officials, payments to offshore accounts, and the handing over of cash-filled envelopes to doctors.

Major Trade and Industry Organizations

Apart from the global standards and regulations, few major pharmaceutical trade and industry organizations also focus on providing guidelines for their members to address the ABC risks. Some of these organizations and their guidance are detailed below.

AdvaMed

1. Foreign Corrupt Practices Act: Facilitate ethical interactions between the parties involved globally.
2. Physician Payment Sunshine Law: Provide patients with enhanced transparency into the relationships their health care providers have with life science manufacturers, including medical technology companies.
3. Distributor Guidance: recommends elements of a successful (“Third-Party Sales and Marketing Intermediaries" or "Third-Party SMIs”) compliance program and serves as an important resource for any medical technology company engaging in Third-Party SMIs interactions overseas.

International Pharmaceutical Federation (FIP)

FIP specifically recommends that:

1. All supply chain stakeholders work together to develop and improve medicines shortages reporting systems in order to share, in a timely manner, information that provides transparent insights on potential unavailability problems.
2. Pharmaceutical manufacturers ensure continued supply of medicines considering a balance between the ethical duty of meeting patients’ needs and the economic and financial decisions.

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

1. IFPMA is specifically targeting customs that are common business practices in certain parts of the world, but that may create the appearance of a bribe, conflict of interest, or improper influence when viewed outside of their cultural context (regardless of the intent behind the gift). This is in line with the IFPMA Ethos, also new to the 2019 Code, which “aims to shift from a rules-based to a values-based code.”
2. Anti-bribery legislation has potential application to the giving of gifts to HCPs; these acts criminalize (among other behavior) the giving of cash or gifts to foreign government officials intended to influence them or improperly secure business.

European Federation of Pharmaceutical Industries and Associations (EFPIA)

EFPIA’s commitment to the following ethical principles:

1. “Patients are at the heart of what we do.. ESPIA aspires to ensure that everything they do will ultimately benefit patients.
2. EFPIA acts with integrity, interacts in a responsible manner, and aims to ensure that their communications with stakeholders are accurate, legitimate, and balanced.
3. EFPIA is committed to ensure that transparency is respected.

Korea Pharmaceutical and Bio-Pharma Manufacturers Association

1. Recognizes the mission of pharmaceutical companies and shall exert their best efforts to develop pharmaceuticals that are superior in efficacy and highly safe through active investment in research and development.
2. Eliminate all unlawful and improper transactions from the distribution of pharmaceuticals in order to establish fair competition and transparent distribution order demanded by society, and also, with regard to collaborative relationships with healthcare professionals, the Korea Pharmaceutical Manufacturers Association (KPMA) shall maintain and develop such relationships based on a high sense of ethics and transparency.

Major Anti-Corruption Conventions

Below are the key principals and actions, defined by some of the major global conventions, that firms can adopt to address their ABC risks.

OECD - Convention on Combating Bribery of Foreign Officials in International Business Transactions

Countries Ratified: 44 countries

The OECD Convention obligates its signatories to criminalize the bribery of foreign public officials. Targeting the offering side of bribery transactions, it requires parties to the Convention to make it a crime, under their national legal systems, for individuals or corporations to promise, offer, or give a bribe to a foreign public official in order to obtain or retain business or some other improper advantage in the conduct of international business.

Under the Convention, Parties also agree to:

- criminalize the bribery of officials of international organizations;
- criminalize business-related bribes to foreign public officials made through intermediaries;
- impose criminal or comparable civil penalties on those who bribe foreign public officials;
- provide for the confiscation of bribes and bribe proceeds where such a penalty exists under national laws;
- make bribery an extraditable offense; and
- prohibit off-the-books accounts and similar practices typically used to hide such bribery.

The Convention encourages all Parties to work together to prevent and deter the bribery of foreign public officials in international commerce and to provide mutual legal assistance in combating bribery. **Parties to the Convention have also agreed to eliminate the tax deductibility of such bribes under domestic law**.

European Criminal Law Convention on Corruption

Countries Ratified: 14 countries

1. The Criminal Law Convention on Corruption is an ambitious instrument aiming at the coordinated criminalization of a large number of corrupt practices. It also provides for complementary criminal law measures and for improved international co-operation in the prosecution of corruption offences.
2. The Convention is wide ranging in scope and complements existing legal instruments. It covers the following forms of corrupt behavior normally considered as specific types of corruption:
   a) active and passive bribery of domestic and foreign public officials;
   b) active and passive bribery of national and foreign parliamentarians and of members of international parliamentary assemblies; and
   c) active and passive bribery in the private sector.
3. The briber can be anyone, whatever his capacity (businessman, public official, private individual, etc.). If, however, the briber acts for the account or on behalf of a company, corporate liability may also apply in respect of the company in question (Article 18). Nevertheless, the liability of the company does not exclude in any manner criminal proceedings against the natural person (paragraph 3 of Article 18). The bribed person must be a public official, as defined under Article 1, irrespective of whether the undue advantage is actually for himself or for someone else.

United Nations Convention Against Corruption (UNCAC)

Countries Ratified: 186 countries

The UNCAC Convention addresses six principal topics that:

1. Mandatory and permissive preventative measures **applicable to both the public and private sectors, including accounting standards for private companies**
2. Mandatory and permissive criminalization obligations, including obligations with respect to public and private sector bribery, and trading in influence and illicit enrichment
3. Private rights of action for victims of corrupt practices
4. Anti-money laundering measures
5. Cooperation in the investigation and prosecution of cases, including collection actions, through mutual legal assistance and extradition
6. Asset recovery

Each state party is required to take necessary steps to establish appropriate systems of procurement, based on transparency, competition, and decision making that are effective in preventing corruption, and such systems shall address:

a. The public distribution of information relating to procurement procedure and contracts
b. The establishment of conditions for participation, selection, award criteria, and tendering rules, in advance
c. The use of objective and predetermined criteria for public procurement decisions
d. An effective system of domestic review, including an effective system of appeal
e. Where appropriate, measures to regulate matters regarding personnel responsible for procurement

In addition to these conventions, the **World Economic Forum Partnering Against Corruption Initiative (PACI),** which has 90 ratified countries, has also laid out principals relating to–

- Corporate leadership and responsibilities
- Risk assessment and continuous improvement
- Policies, procedures, and internal controls
- Training and communication
- Reporting of complaints

Potential ABC risk scenarios in supply chain

Note:

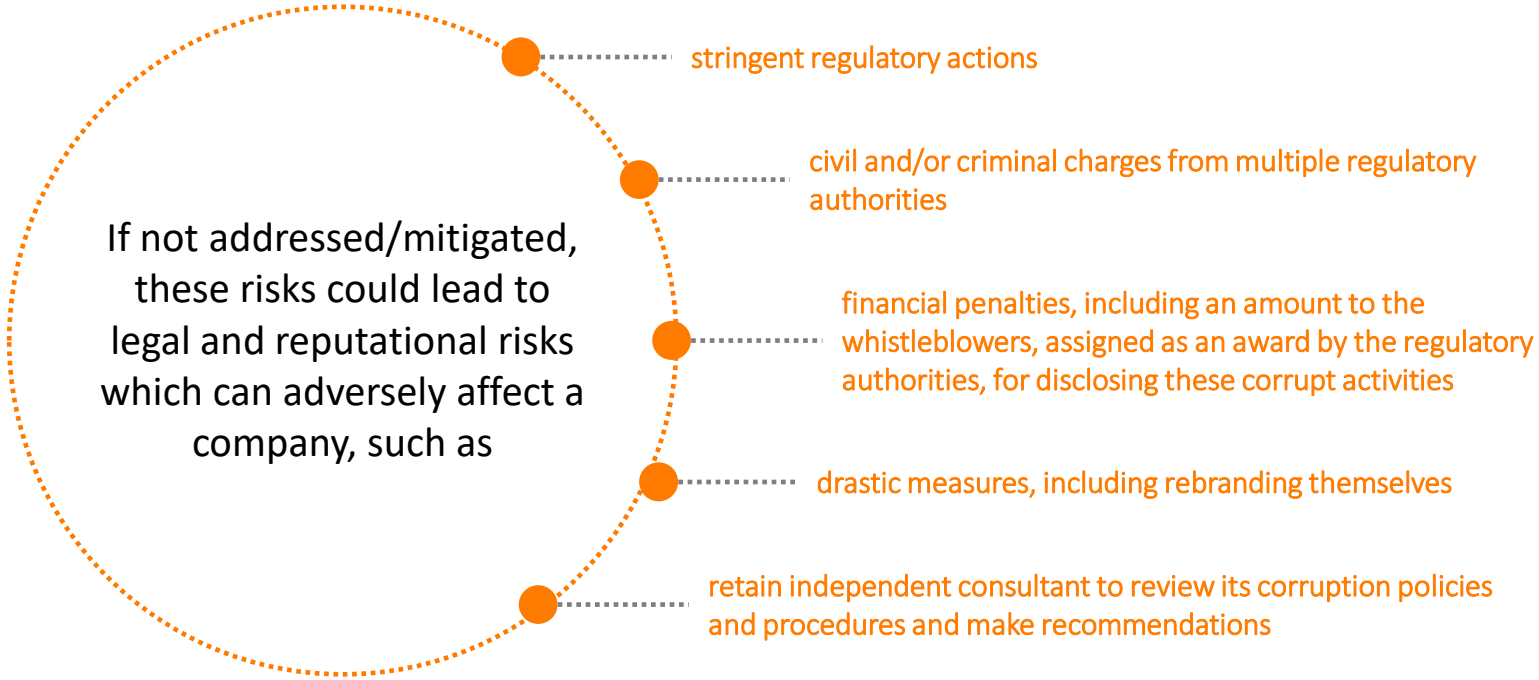
1. The bulk of the potential risks and red flags are identified from real-life scenarios derived from enforcement actions, and industry reports. This has been supplemented with additional scenarios identified from our experience/interactions within the industry, which may not be available on the public domain.
2. While most of these potential risk areas are identified in pharmaceutical and life sciences industry, some of them relate to companies from other industries, but is equally relevant / applicable to the pharmaceutical and life sciences industry.

Potential ABC Risk Scenarios in Supply Chain – Overview

Supply chains are one of the key sources that can cause bribery and corruption risks in the pharmaceutical industry. There are a number of core ABC risks that supply chains can present, including but not limited to:

- third-party may pay a bribe to another business or government official to win a mandate, obtain a license or approval, or a government bid,
- third-party may pay or accept a bribe in connection with their role in the supply chain,
- in some markets, third-party service provider, such as an intermediary, could themselves be a foreign official creating a high ABC risk,
- employees may use third parties to create a 'slush fund' that can be used for bribes, or
- third-party may be under regulatory scrutiny or investigation relating to their pay bribes on behalf of another client and be investigated by the regulators, which might result in investigation of company's business interactions with the third-party.

Potential consequences

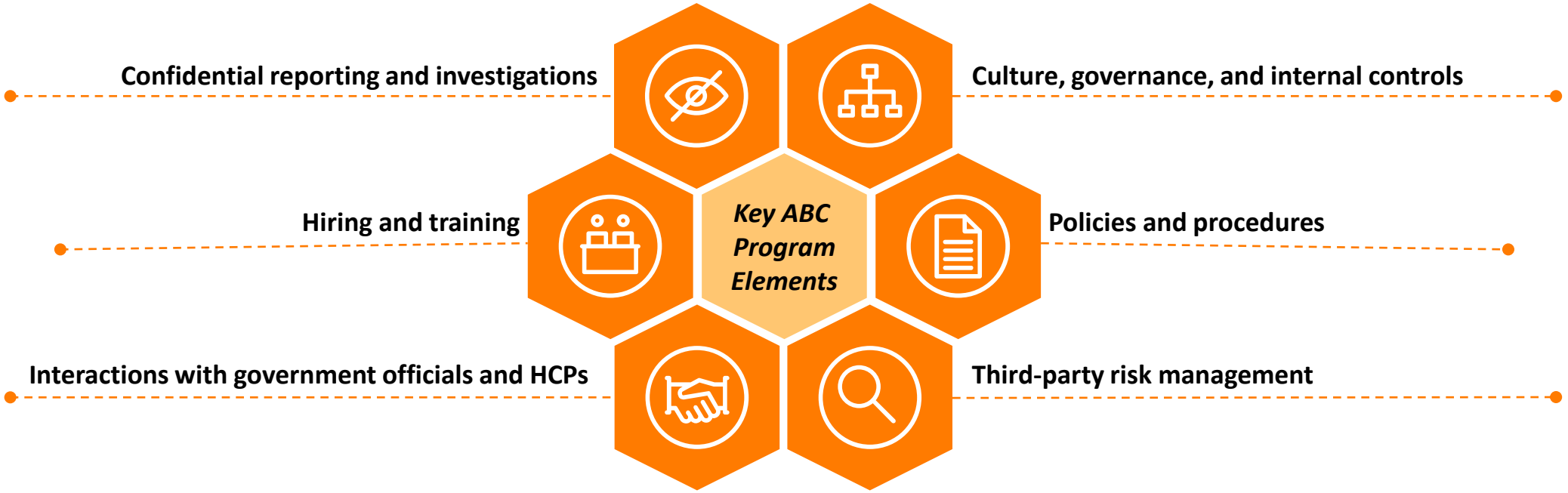


In certain scenarios, it is possible for the consequences to extend to the individuals.

There have been several real-life scenarios where the regulatory action included the arrest, indictment, or conviction of the companies' executives, with outcomes ranging from of criminal charges to jail sentences and deportation of international employees.

Potential ABC Risk Scenarios in Supply Chain – Overview (contd.)

The following slides cover the potential unmanaged supply chain risk considerations within **six key elements of an ABC-focused risk management and compliance program,** as indicated below. Companies can compare their own practices with those outlined here, to evaluate their exposure to the potential ABC risk scenarios.



In addition to the potential risk scenarios, this section also outlines some of the **remediation actions** that companies have taken or can undertake to prevent the occurrence or recurrence of such risks.

Furthermore, this section provides **real-life scenarios of enforcement actions** and other consequences for companies that engaged in the risky behaviors and actions, as they can serve as a reference. Not all examples are from within the pharmaceutical industry; however, they have been selected, based on their applicability and relevance across industries.

Potential ABC Risk Scenarios (1/6)

Culture, governance, and internal controls

Risk scenarios

1. Company's Code of Conduct has no/minimal reference to third-party fraud risk management initiatives/programs.
2. Company does not perform any risk assessments around their supply chain/procurement function.
3. Company regularly receives bids for raw materials from multiple overseas suppliers. Prior to submitting its bid, one of the suppliers offers a kickback to the Company's procurement officer, asking for information on bids already submitted by other suppliers.
4. Company fails to respond effectively to the red flags that indicated bribes being given to expedite a drug or medical device approval.
5. The procurement officers give precedence to certain suppliers to their own advantage.

Remediation actions companies can take to avoid the risk exposure

- Set a strong tone at the top to ensure that the employees of the company act ethically, support compliance investigations, and periodically review the ethics code and ABC laws with their employees.
- Simplify the risk management framework into lines of defense, including line management, compliance functions, and internal audit services.
- Create or highlight the role of ethics, compliance, and/or risk executives and divisions, who were tasked with the oversight of all risk management functions and compliance investigations.
- Encourage third parties to enable their employees to report concerns or illegal activities in the workplace through formal reporting structures.
- Take action against third parties who threaten or engage in retaliation or harassment of any person who has reported, or is considering reporting, a concern in good faith.
- Modify remuneration and the performance target systems for employees to reduce incentives triggering corrupt behavior.
- Incorporate regular rotation of employees in key positions in the procurement process and encourage them to take some minimum time off.
- Ensure that the management communicates the anti-corruption message throughout the company and repeatedly stresses on it in the staff training sessions.

Potential ABC Risk Scenarios (2/6)

Policies and procedures

Risk scenarios

1. Some of the company's global and local policies and procedures are dated, some as long as five years.
2. Improper payments to third parties, falsification of books, failure to devise, and maintain an adequate system of internal controls.
3. Creation and maintenance of fictitious invoices from third parties by subsidiaries, while showcasing the parent company that it was in compliance with the required accounting policies, causing the parent company to report incorrect financial statements.
4. Discrepancy between vendor invoices and contractual agreement.
5. Absence of contracts or absence of relevant ABC clauses in the contracts with third parties.
6. Missing formal vendor invoices and/or business rationale for third-party payments.
7. Third-party payment processing is not in line with policy and is incorrectly classified in the general ledger.
8. Bypassing of procurement policies/procedures and ordering products directly from the supplier without requesting and comparing different offers.

Remediation actions companies can take to avoid the risk exposure

- Revise ABC policies to introduce third-party risk management process, including forbidding the offer, payment, or acceptance of bribes by third-parties acting on behalf of the companies.
- Implement additional controls and adopt principles-based compliance policies to maintain high standards of ethical business conduct.
- Appoint an independent compliance consultant to conduct review of its internal controls and compliance, including the policies aimed at third-party risk management.
- Establish a dedicated team to ensure that the third parties are assessed against the company's policies/principles and appropriate remediation steps have been taken, including amending contracts.
- Build supplier obligations relating to adherence to the company's principles/code of conduct, into contractual terms.

Potential ABC Risk Scenarios (3/6)

Third-party risk management

Risk scenarios

1. Procurement/legal team conducting the due diligence on third parties, post execution of contract.
2. Due diligence on third parties is performed only in select regions and/or conducting them inconsistently in different regions.
3. Due diligence is not performed on third parties that are referred by company employees and/or existing third parties.
4. Due diligence is optional for one-time vendors for cost-efficiency purposes.
5. Absence of guidance on declaration to Confidentiality Clause and non-adherence to Company's Code of Conduct.
6. Inconsistent or inadequate documentation around the resolution of due diligence risk indicators.
7. Lack of a comprehensive supplier selection process.
8. Failure to confirm suppliers' compliance to legal regulatory requirements.
9. Conflict of interest between the procurement executive and the supplier, such as personal relationships, leading to artificial bidding and biasness while awarding a contract.
10. Knowingly continuing to conduct business with third parties,, which have questionable integrity, are prohibited, or are sanctioned/blacklisted (i.e., named in official sanctions lists, NGO reports, etc.).
11. Conducting business with vendors or suppliers that are state owned entities, especially in countries known for corruption (e.g., low in Transparency International Corruption Perception Index).
12. Conducting business with corrupt third parties, who siphon off funds for illegal purposes and are fictitious suppliers, who issue fabricated invoices without providing any goods or services.
13. Inadequate due diligence on suppliers and vendors involved in the clinical trial processes, such as those assisting in obtaining regulatory approvals, site selection and contract negotiation, biospecimen transport and storage, data analysis, and other services.

Remediation actions companies can take to avoid the risk exposure

- Introduce processes to determine the risk profiles (tiering) of third-parties / suppliers.
- Introduce robust audit rights and termination clauses in the third-party contracts, to assess and address compliance with the ABC requirements.
- Expand the third-party due diligence process beyond a "check the box" activity that accepts the third-party documentation at face value.
- Conduct periodic supply chain risk assessment via workshops with key stakeholders and transactional testing of potentially high-risk transactions (for e.g., transactions in countries with a poor Transparency International Corruption Perception Index score, transactions with government officials, PEP, state-owned entities, high value cross border transactions, etc.)
- Employ both internal consequences management, such as legal advice and informative communication actions, and external consequences management, such as supplier contractual remediation actions.
- Ensure that the third party's payment processes require proof of services rendered, before any payments are made to third parties.
- Introduce an enterprise-wide system for ongoing third-party compliance and monitoring.
- Clinical trial sponsors to conduct appropriate vendor selection and due diligence while selecting providers for clinical trial and related services.
- Leverage technology and automation in due diligence processes, including. screening, monitoring, etc.

Potential ABC Risk Scenarios (4/6)

Interactions with government officials and HCPs

Risk scenarios

1. Bribes to procurement officials of a government-owned entity to secure preferential bid assessment, to release confidential information on bids, to skew procurement requirements, or to lax enforcement of the supplier's contractual obligations.
2. Manipulation of clinical research data by bribing the medical organizations and physicians supporting clinical trials.
3. Bribes or kickbacks to regulatory compliance officials, data review analysts, and review committee members for clinical trials processes.
4. Establishing manufacturing processes in countries with poor compliance and enforcement environments, thus reducing the company's focus on establishing strong compliance processes around manufacturing, procurement, etc.
5. Establishing manufacturing processes in partnership with state-owned entities in countries prevalent with corruption.
6. Conducting business with vendors or suppliers that are state-owned entities, especially in countries known for corruption (e.g., low in TI CPI index).
7. Bribes and/or collusion with the enforcement and inspection officers, who ensure quality and safety control in the manufacture and marketing of registered and licensed pharmaceutical products, in order to hide the deficiencies and non-compliance in manufacturing process.

Remediation actions companies can take to avoid the risk exposure

- Perform robust third-party due diligence and conduct assessment of circumstances of payments made to the third parties.
- Establish a process where payments to third parties are not approved, unless there is a clearly documented justification that it is a necessary part of doing business.
- Incorporate organizational checks and balances into the procurement process such as double-checking before authorizing payments above a certain value and assigning specialists to the procurement department to check the legitimacy and rationale of payments.

Potential ABC Risk Scenarios (5/6)

Hiring and Training

Risk scenarios

1. Lack of consistent and timely training provided to employees and third parties, especially those interacting with government entities.
2. Dedicated and tailored anti-bribery training is not delivered to those in high-risk functions or regions.
3. Non-availability of training certificates or delays in completion of trainings.
4. Gaps in the third parties' understanding of policy and compliance clauses guidelines, books and records keeping, and internal controls expectations.
5. Lack of consistency in providing ABC trainings to the third parties.
6. The training content is not robust or in line with latest regulatory guidelines. It does not include practical examples/real-life scenarios to help facilitate better understanding of ABC procedures.
7. Employees do not disclose potential conflicts of interest with the third parties, if any, in a timely and ongoing manner.
8. The trainings related to ABC and third-party interactions are not taken seriously by the key stakeholders of the procurement department.

Remediation actions companies can take to avoid the risk exposure

- Ensure all third parties complete Code of Ethics training and other mandatory compliance trainings, that cover company's expectations, zero tolerance policy, channels for reporting, etc.
- Mandate that all third parties complete the compliance trainings.
- Active leadership support for the introduction of training measures (e.g., by attending the pilot trainings, introducing company-wide voluntary commitments, and a code of conduct).
- Ensure that trainees are actively involved in training sessions through role-playing, open dialogues, or other interactive training methods.

Potential ABC Risk Scenarios (6/6)

Confidential reporting and investigations

Risk scenarios

1. No/low awareness about hotline and the proper channels for reporting a potential violation.
2. Unavailability of whistleblowing channels and/or non-dissemination of this information to third parties.
3. Third parties are not aware of who in the company is responsible for compliance monitoring and/or investigations.
4. Hotline channels are not available in local languages in non-English-speaking regions.
5. The incident resolution mechanism is inadequate and issues are not solved within a reasonable time frame.

Remediation actions companies can take to avoid the risk exposure

- Strengthen employees' understanding of their Codes of Conduct and encourage employees to report violations in good faith without fear of retaliation.
- Establish well-documented investigation protocols and remediation action steps and maintain consistent disciplinary procedures.
- Encourage employees of third parties to report suspected violations of law, rules, and regulations related to their work with the company, including fraud, either through their own internal reporting channels or through the company's reporting channels.
- Establish a whistleblower system that can be accessed by suppliers and is actively communicated to them in relevant local languages.

A provider of medical equipments employed third-party and an agent in foreign country, who in turn bribed government officials to obtain approvals and procure supply contracts.

- *Without having any experience in using third-party agents in another country, the company employed a third-party and an agent in a high-risk country, who met with government officials, on behalf of the company, to procure supply contracts.*
- *The third-party and agent conspired to use the payments from the company to bribe the officials in order to obtain approvals and hid the scheme from the company, by communicating in local language and misrepresenting the usage of funds.*
- *The company failed to conduct adequate due diligence on the third parties and to follow internal controls procedures. Its internal controls failed to detect/prevent third-party expenses delineated as both official and unofficial fees; failed to ensure that payments were made to entities with contractual arrangements; and did not have adequate anti-corruption policies in place.*
- *It also failed to provide ABC training to its employees on how to conduct business in countries with high corruption risk.*
- *The company was penalized for violating Canadian Corruption of Foreign Public Officials Act and the FCPA.*

A medical products and services provider made improper payments to government officials in several countries to procure business and failed to conduct due diligence on its third parties.

- *The company made improper payments through a variety of schemes, including sham consulting contracts, falsifying documents, and funneling bribes through a system of third-party intermediaries.*
- *It failed to have sufficient internal accounting controls, provide anti-corruption training, or perform due diligence on its third parties.*
- *In many instances, the company's senior management actively engaged in corruption schemes and directed employees to destroy records of the misconduct.*
- *The company agreed to pay more than $250 million to resolve the Securities Exchange Commission and U.S. Department of Justice investigations related to its violations of FCPA across multiple countries for nearly a decade*

Within the pharmaceutical industry

Key global enforcement actions faced by companies

Supply chain specific, outside pharmaceutical industry

The agents and employees of a drug manufacturing company bribed foreign officials to obtain regulatory approvals.

- *The employees and agent of the company made improper payments to foreign officials in various countries to obtain regulatory and formulary approvals, sales, and increased prescriptions for its products.*
- *These bribes were concealed by improperly recording the transactions in accounting records as legitimate expenses for clinical trials, freight, promotional activities, marketing, training, travel, and entertainment.*
- *The company agreed to pay more than $15 million penalty for violating the FCPA by bribing healthcare professionals employed by foreign governments.*

An oilfield services company failed to conduct proper bidding process and selected a supplier posing high FCPA risk.

- *The company failed to conduct competitive bidding or substantiate the need for a single source of supply. It violated the internal controls by first selecting the supplier and then deciding the services to be contracted, rather than first deciding the services and then selecting the appropriate supplier.*
- *The company executives avoided internal accounting controls, which required review and approval of contracts above a threshold value in high corruption risks countries.*
- *The company agreed to pay more than $30 million to resolve charges that it contracted a supplier that posed significant FCPA risks and violated the internal accounting controls provisions. Its executive also paid a $75,000 penalty for causing the violations, circumventing internal accounting controls, and falsifying books and records.*

A confectionary company made payments to a consultant to obtain government licenses and approvals in developing country.

- *The subsidiary failed to conduct due diligence on and monitor activities of the consultant, who submitted invoices and was paid for the work supposed to be done by the company employees themselves.*
- *The subsidiary did not accurately and fairly reflect the nature of the services performed by the consultant, in its parent entity's books and records. The parent entity, in turn, did not implement adequate compliance controls at subsidiary level to identify improper or unauthorized payments.*
- *The company agreed to pay more than $13 million to settle charges of violating the internal controls and books-and-records provisions of FCPA.*

Industry Leading Practices

Industry Leading Practices – Overview

In order to address the risks within supply chain, it is imperative that companies proactively assess their existing risk management programs and policies and take relevant steps to improve their supply chain risk management. While most of the companies face bribery and corruption risks, their risk mitigation approaches, and risk controls should be designed to achieve a level of maturity that matches the scale of their complexity and risk profiles.

The maturity model below has been developed by PSCI, based on an understanding of industry practices. It highlights the guiding principles and practices commonly observed at each stage of maturity, from 'starting out' to 'leading.' The industry leading practices that have been identified in this section have been segregated into the stages of this maturity model, as each organization is at a different maturity stage and a 'one size fits all' approach cannot work.

Starting Out	Developing	Implementing	Leading
• Compliance with law • Necessary policies in place • Minimum standards are being met	**PLUS** • Audits/baselines/risk assessments complete • Key risks and highest impacts identified • Measurement and recording systems in place • Management responsibility has been allocated • Targets and objectives set	**PLUS** • Processes in place with clear responsibilities for key staff • Employees are aware and trained as appropriate • Targets generally being achieved • Improvement projects • External verification • External partnerships being developed • Public reporting or other transparency • Risks are adequately managed	**PLUS** • Embedded in culture • External recognition/awards • Taking an advocacy stance • Approach includes whole value chain • External partnerships across industry • Supporting partners/customers to improve • Sustainability drives innovation • Sustainability leads to differentiation and commercial advantage

In addition to identifying industry leading practices to help companies and their supply chain improve and progress across the maturity model, this section further provides real-life scenarios where companies have adopted some of these leading practices to proactively address their supply chain ABC risks. These examples are not all from within the pharmaceutical industry, but they have been selected, based on their applicability and relevance across industries.

Industry Leading Practices (1/7)

Culture, governance, and internal controls

Starting Out

Process:

1. A Code of Conduct exists that references topics such as bribery, interactions with government officials, gifts, etc.
2. A Code of Conduct or Ethics Policy is made available to all employees but there may not be a process for monitoring receipt/acknowledgement.
3. Leadership expectations are not always explicitly communicated and there may not be a designated leader that is responsible for managing third-party and/or ABC risks.

Developing

Process:

1. Process is in place for monitoring the hotline and investigating any issues and is included as part of company's annual training. The process includes mention of hotline, the importance of reporting, speaking up, and remediation actions. There is no separate training on the hotline.

People:

2. All employees and third parties read and sign the Code of Business Ethics and acknowledge their right and responsibility to report possible ethical or policy violations.
3. There is a formal structure around periodic reporting to leadership (e.g., updates to the audit committee/board, reports to the chief risk officer/chief ethics and compliance officer).
4. The top leadership makes it clear to its employees that the appointment of third parties are subject to risk-based due diligence to mitigate potential corruption risks.

Implementing

Process:

1. Clear, documented responsibility for anti-bribery and corruption apportioned to a single senior manager or a committee with appropriate terms of reference.

People:

2. Management demonstrates visible and active commitment to implementation of ABC program and communicates a strong "tone at the top," including policy reminders.
3. Management communicates that disciplinary sanctions, including termination, will be enforced in case of abuse or disregard of the third-party due diligence process.
4. Employees and third parties confirm that they read and understood the company's Code of Conduct.
5. Third parties are required to acknowledge the Code of Conduct and significant policies at the time of onboarding and on an ongoing basis (typically, annually).
6. Employees disclose their financial and other interests, including any relationships with third parties (personally or through family members).

Leading

Process:

1. Adherence to policies is a metric for employee evaluation and continuation of third-party relationships.
2. Upon discovery of wrongdoing, guidelines are in place for prompt remediation, timely and voluntary disclosure to regulators, and cooperation with regulatory authorities.
3. Disciplinary measures for any wrongdoings are clear, applied reliably and promptly, and are commensurate with the nature of the violation of Code of Conduct.
4. Possible consequences of noncompliance is specified, including various stages of escalation culminating in cancelling the suppliers' contract in severe cases.

People:

5. Employees are required to disclose/acknowledge periodically their financial and other interests, including any relationships with third parties (personally or through family members).
6. Senior management monitors the third-party due diligence process; periodically reviews its suitability, adequacy, and effectiveness; and implements improvements where needed.
7. Company reassesses its due diligence measures to ensure that they are adapted to the organization's evolution.

Industry Leading Practices (2/7)

Policies and procedures

Starting Out

Process:

1. Policies and procedures are fragments and/or not clearly documented.
2. There is an overarching Ethics Policy or Code of Conduct, but it is not broken into separate topical policies around gifts, entertainment, interactions with government officials, charitable contributions, etc.
3. Approval matrix and limits/thresholds may be verbally agreed but not defined in the policy/Standard Operating Procedure documents.

Developing

Process:

1. An effective ABC control framework is in place to identify and assess bribery and corruption risks.
2. Anti-corruption program includes directions, process definitions, training, and communication measures. It clearly lays out what is expected, what assistance is available, and who the contact person is if employees have any questions.
3. For companies having varying risk-based methodologies, there is a clear justification for the differing approaches and processes to ensure that the results of each methodology are aligned at the enterprise level.

People:

4. The policies and procedures are clear and concise and are reviewed at least annually by the management, unless a business event/action or a report from internal audit, legal, or compliance warrants an interim update.

Implementing

Process:

1. Periodic gap analysis of existing ABC procedures is conducted against applicable legislation, regulations, and guidance and procedures are updated to reflect changes in these laws and regulations.
2. Process for continuous identification of emerging risks based on local laws, market changes, and other regulatory conditions is in place.
3. Global policies and procedures are centrally maintained (such as on the company Intranet) to provide relevant departments access to the most-current versions.
4. Bribery and corruption risk assessments are used to inform the development of monitoring programs; policies and procedures, and training; and are embedded into operational processes.
5. The Supplier Code of Conduct is established and includes anti-corruption policy.
6. Review relevant anti-corruption legislation in the countries of operation, at domestic and international level – and support and develop local policies and procedures with specific language in contracts and codes of conducts.

Leading

Process:

1. Policies and procedures cover expected behavior, escalation processes, conflicts of interest, expenses, gifts and hospitality, whistleblowing, monitoring and review mechanisms, and disciplinary sanctions for breaches.
2. The Supplier Code of Conduct is aligned with the industry/international standards.
3. ABC programs are aligned with at least one standard, which provides guidance and best practices, including the structure of assessments and due diligence.
4. Policies and procedures are reviewed by a rating organization and are benchmarked against peers. They are supplemented with guidelines, hypothetical examples, FAQs, and additional resources to help answer employees' questions.
5. Contractual negotiations/supplier contracts should clarify either no subcontracting or sub-contracting to be authorized by the company.
6. The Code of Conduct requires the sub suppliers to adhere to the same principles as laid out in the Code.
7. Company examines whether measures, including monitoring, training, communication, and whistleblower systems, should be extended to the sub-suppliers.

Industry Leading Practices (3/7)

Third-party risk management

Starting Out

Process:

1. Monitoring and compliance programs are applied across business lines and regions in a “one size fits all” approach.
2. Third parties may be onboarded based on verbal agreements.
3. Background screening is not mandated prior to onboarding a new third-party.

Developing

Process:

1. Written contracts are in place with third parties, including all the clinical trial service providers, and include specific ABC compliance clauses and conflict-of-interest provisions.
2. Business justification, third-party screening, and risk assessments are conducted prior to accepting a third-party.
3. Annual compliance questionnaires and risk assessments are performed on each business unit and/or region; corruption perceptions index and other risk indicators (sanctions, legal framework) are considered for each region.
4. The legitimacy of suppliers is established by checking sanctions lists, press databases and professional social networks, or a service provider specialized in risk assessment.
5. Suppliers are asked to provide regular and proactive self-assessments and/or reports.

Implementing

Process:

1. Contracts include robust clauses covering audit/termination rights for anti-corruption violations. Right to audit clauses are exercised through periodic audit programs.
2. Questions on anti-corruption are integrated into existing supplier questionnaires and are sent at regular intervals.
3. Risk assessments identify the nature and extent of interactions and the policies and procedures applicable to those interactions.
4. Advanced third-party due diligence processes, including criminal background checks, government connections, and other red flags.
5. Company identifies and categorizes third parties on a continuous basis. Heightened due diligence is performed on third parties judged as higher risk based on the due diligence plan and protocols.
6. Compliance questionnaire responses (e.g., value of donations, number of third-party intermediaries) are verified on a periodic basis, and any discrepancies are promptly investigated. For each business line/country, compliance program assesses if the program is being implemented in good faith.
7. Third parties submit an annual certification of compliance with applicable ABC laws.

Leading

Process:

1. Advanced due diligence considerations include reputational and corruption risk in addition to financial/credit risk. In-country experts or resources are engaged in more opaque jurisdictions to gather information on third parties.
2. Bribery or corruption risks identified in one business line/country are examined for applicability across other business lines/countries.
3. Enterprise-wide system in place for ongoing third-party compliance and monitoring. Enhanced due diligence procedures include a review of the third-party’s own ABC controls.
4. Risk assessment is performed on the supply chain of the suppliers and remediation efforts are prioritized according to corruption risk.

Technology:

5. Automated continuous monitoring is done through the use of information feeds and third-party risk management software; highlighting significant changes in third parties’ ABC position, including risk, noncompliance, and red flags.

Industry Leading Practices (4/7)

Third-party risk management (contd.)

Starting Out	Developing	Implementing	Leading
			Technology: 6. Continuous auditing processes leveraging data analytics, allowing consistent sharing/comparison of results across businesses and geographies. 7. Use of anti-corruption analytics, such as data mining, visual analytics tools, statistical analysis, and external data, sources to identify anomalies and unusual patterns and heighten the focus on high-risk third parties or employees. 8. Company conducts faster and cost-effective selection of suppliers using procurement platforms and e-auctions, along with improved due diligence audits, facilitated by optimized data storage and analysis of response to risk assessments. 9. Company leverages compliance software programs which provide, direct data input, work-flow management and red-flag alerts for third-party monitoring.

Industry Leading Practices (5/7)

Interactions with government officials and HCPs

Starting Out

Process:

1. An expense reporting system exists but does not have the capability to drill down to the underlying data, making review and monitoring cumbersome.
2. Third-party payments require appropriate supporting documentation, including details of beneficiaries and a valid business purpose before reimbursement.
3. Basic protocols and dollar threshold in place for third-party payments.

Developing

Process:

1. Clear policies are in place for payment or courtesies related to government officials.
2. Political and charitable donations are approved at an appropriate level, with compliance input, and subject to appropriate due diligence.
3. Local management cannot approve their own expenses above a certain threshold.
4. Compliance or internal audit reviews expense reports periodically, and any anomalies or discrepancies are promptly investigated.
5. Cash advances or usage of petty cash is limited to de minimus amounts and is infrequently used.
6. Bank accounts are reconciled on a monthly basis to reduce the potential risk of misappropriation and/or off-book payments.

Implementing

Process:

1. The expense reporting system is customized for monitoring and identification of potential improper payments.
2. Processes for filtering gifts and hospitality payments by employee, and type of hospitality, for analysis and identifying unusual or unauthorized payments and deviations from approval limits.
3. Well-defined protocols and dollar thresholds are established for different categories of third-party payments.
4. Established process is in place for monitoring and tracking of spend to third parties.

Leading

Process:

1. Policies mandate the use of preapproved vendors for major purchases of products and/or services.
2. Policies mandate approval of expenses involving government officials.
3. Expense reporting system is structured for anti-corruption (identification by employee of third parties who may be government officials).
4. Expense reporting system is integrated with time/billing system to allow a correlation between expenses and billings/reimbursements, where possible.
5. The expense reporting system is customized for real-time monitoring and follow-up/escalations.
6. Regular and thorough monitoring of third-party payments to check, for example, whether a payment is unusual in the context of previous similar payments.

Industry Leading Practices (6/7)

Hiring and Training

Starting Out

Process:

1. ABC training is delivered only virtually or not at all.
2. Training is only provided for new hires, with no refresher trainings.
3. Attendance is not mandatory/tracked.
4. Training is generic and not tailored to business risks or function/role.
5. Limited due diligence performed on applicants during onboarding and limited screening or inquiry into government connections of applicant.

Developing

Process:

1. Periodic refresher training is required, and attendance is tracked.
2. Training includes definitions of what constitutes a government official and state-owned enterprise ("SOE").
3. Trainings are industry/business function focused and reflect business risks.
4. Pre-hiring due diligence performed on applicants, including inquiry into government connections.

Implementing

Process:

1. ABC topics are embedded into broader policies and procedures and trainings.
2. Trainings are interactive and include case studies, scenarios, or examples that will enhance the learning experience of the participants.
3. Combination of live and virtually delivered trainings, which includes periodic refresher trainings.
4. Training is tailored based on role and responsibility levels.
5. Compliance with ABC training is made mandatory for employees and third parties.
6. Training sessions are devised and modified on the basis of feedback. They cover practical examples rather than quoting only legislations.
7. Companies implement communication and education methods to build awareness among supplier personnel on the negative impacts of corruption and ways to prevent it and/or respond. These methods can include in-person training/supplier conferences, web-based training, interactive web experiences (webinars and blogs) and one-way communication (e.g., flyers, emails,)

Leading

Process:

1. Frequent campaigns and events are organized to support ABC trainings.
2. Vendor certifications are established, and ABC trainings are extended to suppliers, vendors, and other third parties, especially those considered higher risk. The third parties are trained what to do if they encounter problems or have any concerns.
3. Gauge effectiveness of third-party training by scenario-based quizzes and comparing the number of third-party-related compliance inquiries received before and after training.
4. Notifications are sent to employee, supervisor, and Compliance and Human Resources for any noncompliance and remediation.
5. Heightened due diligence on targeted positions with higher risk (e.g., procurement executives) crosschecked against politically exposed persons lists.

Technology:

6. Trainings are focused with respect to risk and requirements profiles and are integrated into everyday work with virtual/mobile trainings, different languages, interpersonal interaction, space to share experience, and rapid feedback.

Industry Leading Practices (7/7)

Confidential reporting and investigations

Starting Out

Process:

1. A basic internal audit process exists.
2. A confidential reporting mechanism, such as whistleblower hotline, is available to employees but it may be managed internally by HR or Legal.
3. Details about whistleblowing hotlines are visible and accessible to employees.

Developing

Process:

1. An internal audit process is established, sufficiently funded, and is monitored by an independent committee, such as Audit Committee.
2. Existing reporting channels provide adequate levels of protection and communication to employees.
3. Periodic awareness about the confidential reporting mechanism is made among the employees and employees confirm their knowledge on the existence of the confidential reporting mechanism.

Implementing

Process:

1. Well-documented confidential reporting process is in place for monitoring the hotline and the steps taken for investigating issues (whom to escalate to, when to involve specialists, data privacy and confidentiality, etc.).
2. Well-defined process for undertaking the internal investigations is in place. The investigation scope, workplan, approach, findings, etc., is documented and communicated.
3. Effective whistle-blower hotline that accommodates multiple languages and time zones is in place.

People:

4. Employees are encouraged to report and seek guidance on any potential risks or violations, by regularly providing real-life examples of “red flags.”
5. Employees use the confidential reporting process without fear of retaliation.

Leading

Process:

1. An efficient, reliable, and properly funded process for investigating allegations and documenting the company’s response, including any disciplinary or remediation measures taken, is in place.
2. A mechanism for employees and others to report suspected or actual misconduct or violations of policies on a confidential basis and without fear of retaliation.
3. Companies take “lessons learned” from reported violations and the outcome of any resulting investigation to update their internal controls and compliance program and focus future trainings on such issues, as appropriate.
4. The hotline is extended to customers, vendors, and other third parties the company does business with.

Technology:

5. Technologies such as artificial intelligence and machine learning can make screening and investigations more efficient, effective, responsive, economical, and thorough.

Industry Leading Practices – Case Studies

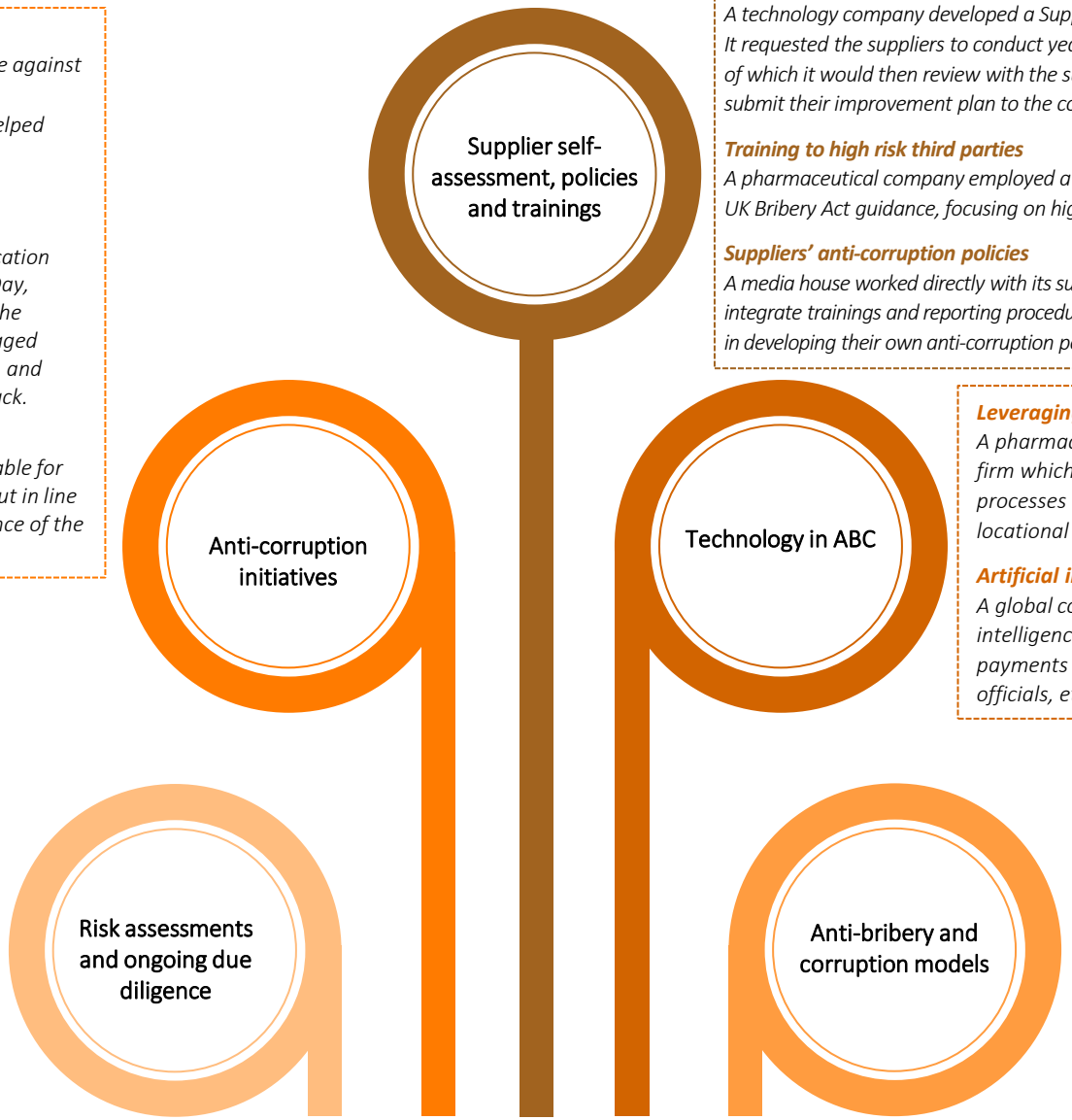
Global initiative against corruption
An engineering company became a member of a global initiative against corruption, which provides a framework for the design and implementation of corporate anti-corruption policies and this helped enhance practices globally through peer exchanges and the determination of best practices.

Campaigns on International Anti-Corruption Day
A technology manufacturer arranged anti-corruption communication campaigns around a designated International Anti-Corruption Day, designed to empower its employees to take leadership roles in the conversation about bribery and compliance. The program leveraged journalism, social media, employee-generated content, gaming, and peer-group participation to socialize learning and gather feedback.

Accountability to senior executives
A pharmaceutical company supply chain management accountable for ensuring that procurement activity within their area is carried out in line with the company strategy, and for the governance and assurance of the third-party risk management and reporting.

Ongoing supplier engagement program
A pharmaceutical company implemented an ongoing supplier engagement program, which reflects the specific geographical and/or supply sector risk areas, focusing on the gaps in third-party understanding. It also provided support around subject matter expertise, coaching and documentation, to help suppliers understand the expectations, identify gaps, and raise awareness in its own organization for responsible business practices.

Precontract risk assessment
A telecommunications company conducted pre-contract corruption risk assessments and inspection of the supplier's anti-corruption program and sustainability issues.



Self-assessment by suppliers
A technology company developed a Supplier Code of Conduct, which it communicated to all its suppliers. It requested the suppliers to conduct yearly self-assessments to verify compliance with the Code, the results of which it would then review with the suppliers. Occasionally, the company would also request suppliers to submit their improvement plan to the company.

Training to high risk third parties
A pharmaceutical company employed a risk-based approach to training, consistent with the US FCPA and UK Bribery Act guidance, focusing on higher-risk geographies and higher-risk third parties and activities.

Suppliers' anti-corruption policies
A media house worked directly with its suppliers when anti-corruption issues came to light and helped them integrate trainings and reporting procedures to enhance their anti-corruption policy. They also assisted suppliers in developing their own anti-corruption policy, where they did not have one.

Leveraging research firm and risk analytics
A pharmaceutical company became a member of an analytics research firm which helps it optimize and strengthen the risk management processes and supply chain, with global risk analytics and real-time locational monitoring.

Artificial intelligence in compliance
A global conglomerate, in its policy, outlined implementing artificial intelligence-based software to help compliance with ABC policies, track payments to third parties, and track expenses related to government officials, etc.

Scenario-based ABC model
A financial institution employed scenario-based models to imagine a set of ABC risks that may have an increased frequency or impact. It used these models and ABC subject matter experts to identify scenarios of interest that enable the company to picture the real and most relevant ABC risks based on its geographic footprint, clients, products, and services.

Appendix

Glossary

Terms	Definition
Bribery	• The offering, promising, giving, accepting, or soliciting of an advantage as an inducement for an action which is illegal, unethical, or a breach of trust. Inducements can take the form of money, gifts, loans, fees, rewards, or other advantages (taxes, services, donations, favors, etc.).
Corruption	• The abuse of entrusted power for private gain. Examples are 1) abuse of the power given to an individual by another person or organization, 2) activity that is beyond the position or remit of a person, or 3) benefits obtained for an employee's personal gain, rather than for their organization.
Conflict of Interest	• A situation where an individual or the entity for which they work, whether a government, business, media outlet, or civil society organization, is confronted with choosing between the duties and demands of their position and their own private interests.
Employees	• Employees include a company's directors, officers, employees, and advisors, whether they work for the company on a full-time, part-time, consultative, or temporary basis.
Facilitation payments	• A form of bribery coined in 1988 when the United States Congress amended the Foreign Corrupt Practices Act in 1988 and created an exception for 'facilitating or expediting payment[s]' made to foreign officials to expedite or secure the performance of 'routine governmental actions.' 15 U.S.C. §§78dd-1(b), 78dd-2(b), 78dd-3(b). See the portal guidance on small bribes.
Health Care Organizations (HCOs)	• Any legal person (i) that is a health care, medical, or scientific association or organization such as a hospital, clinic, foundation, university, or other teaching institution or learned society whose business address, place of incorporation, or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.
Health Care Professionals (HCPs)	• Any natural person that is a doctor; a member of medical, dental, pharmacy, or nursing professions; or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend, or administer a medicinal product and whose primary practice, principal professional address, or place of incorporation is in Lithuania. For the avoidance of doubt, the definition of HCP includes (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply, or administer medicinal products and (ii) any employee of a member company whose primary occupation is that of a practicing HCP but excludes all other employees of a member company and a wholesaler or distributor of medicinal products.
Kickback	• A payment or in-kind bribe given in return for facilitating a commercial transaction such as a contract or a loan. The term kickback describes its most common form where a portion of a contract fee from an awarded contract is returned to the person approving the contract.
Medicaid Drug Rebate Program (MDRP)	• A program that includes Centers for Medicare and Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Approximately 600 drug manufacturers currently participate in this program.
Patient Support Programs (PSPs)	• An organized system where a marketing authorization holder receives and collects information relating to the use of its medicinal products. Examples are post-authorization patient support and disease management program, surveys of patients and healthcare professionals, information gathering on patient compliance, or compensation/reimbursement schemes.
Stark Law	• The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements.
Third-party*	• For anti-corruption purposes, a third-party is a prospective or contracted business associate including agents, distributors, lobbyists, brokers, consultants and other intermediaries, joint venture and consortia partners, contractors, vendors, and suppliers.
Value-based contracts (VBCs)	• A written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures.

*For the purpose of this presentation, we have focused on supply side third parties, such as supplier, vendors, intermediaries, contractors, etc.

Key Sources (1/2)

Key markets and industry trends

Internal projects and interviews, experience, and industry knowledge

Research Publications:

- Deloitte Center for Health Solutions: Healthcare and Life Sciences Predictions 2020, Supply Chain Supplemental
- Supply Chain Quarterly: The Top 10 Supply Chain Risks of 2019
- Lexology: Carpe Diem: A Holistic Strategy for Assessing supply Chain Compliance Risk in a Covid-19 World
- Gartner for Supply Chain: Weathering the Storm: Supply Chain Resilience in an Age of Disruption
- Ernst & Young: Managing bribery and corruption risk in the life science industry
- Pricewaterhouse Coopers: Pharma 2020: Supplying the future – which path will you take?
- Hogan Lovells: Supply Chain: Issues & Analysis on Bribery and Corruption in 2020
- Ropes & Gray: Global Healthcare Compliance News & Analysis 2016-2019
- LGM Pharma: Top 2020 Pharma Supply Chain Logistics Trends
- AmerisourceBergen: Five Trends on the Horizon in the Pharmaceutical Supply Chain
- Transparency International Pharmaceutical & Healthcare Programme
- Statement on Corruption in the Context of Covid-19 by UN
- RSM: Understanding kickback threats within patient support programs
- Lexology: Four Key Considerations When Building the Compliance Framework to Go Global with Patient Support
- IQVIA: Design and Refine Patient Support Programs for a COVID-19 World
- Tribeca Knowledge: 6 pharma trends for 2018 that will shape the industry
- OECD publications on Human trafficking and corruption

Minimum standards and key business requirements

Regulatory and International / Multi-lateral Organizations:

- Department of Justice (DOJ) Office of Public Affairs
- Serious Fraud Office
- Controladoria Geral da Uniao – CGU (Brazilian Federal Comptroller General)
- Independent Commission Against Corruption (ICAC)
- Central Vigilance Commission (CVC)
- Federal Assembly of the Russian Federation
- The U.S. Securities and Exchange Commission
- Business & Human Rights Center – Proposal for an EU wide mandatory human rights due diligence law
- World Economic Forum – Communities – PACI
- Council of Europe
- United Nations (Office on Drugs and Crime)
- OECD Guidelines for Multinational Enterprises (2011)

Trade and Industry Organizations:

- AdvaMed
- International Pharmaceutical Federation (FIP)
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Korea Pharmaceutical and Bio-Pharma Manufacturers Association

Legislations / Research Publications:

- Anti-Bribery and Books & Records Provisions of the Foreign Corrupt Practices Act
- Bribery Act 2010, UK
- Clean Company Act (Lei da Empresa Limpa) – LAW N. 12.846, of August 1, 2013
- Prevention of Bribery Ordinance (Chapter 201, Laws of Hong Kong)
- The Prevention of Corruption Act, 1988
- The Russian Federation Federal Law On Corruption Counteraction
- OECD - Convention on Combating Bribery of Foreign Public Officials in International Business Transactions
- Partnering Against Corruption Initiative
- Explanatory Report to the Criminal Law Convention on Corruption, Strasburg, 27.I. 1999
- United Nations Convention against Corruption

Media References:

- Enforcement and Compliance
- American Society of International Law
- Export.gov
- The Guardian
- Industry Week
- Wall Street Journal
- Reuters
- The Moscow Times

Key Sources (2/2)

Potential Risks and Red Flags

Internal projects and interviews, experience, and industry knowledge

Regulatory bodies:

- Department of Justice (DOJ) Office of Public Affairs
- The U.S. Securities and Exchange Commission (SEC)

Research Publications:

- United Nations Global Compact: Fighting Corruption in Supply Chain : A Guide for Customers and Suppliers
- United Nations Global Compact: Stand Together Against Corruption A practical guide to help prevent corruption in the supply chain
- Preventing Corruption in Supply Chain: How Companies Can Address Challenges
- World Economic Forum: Good Practice Guidelines on Conducting Third-Party Due Diligence
- Savannah Wisdom: Corruption within the pharmaceutical supply chain to the developing world
- Corporate Research and Investigations (CRI) Group - How Can Life Sciences Companies Prevent Bribery And Corruption
- Transparency International – Global Anti-bribery Guidance Best Practice For Companies In The UK And Overseas
- Volkovlaw Blog – Clinical Trials and Corruption Risks
- Transparency International – Corruption in the Pharma Sector
- The Bureau of National Affairs, Inc.: Medical Research Law & Policy Report

Media References:

- The FCPA Blog
- FCPA Professor
- Foreign Corrupt Practices Act Clearing House – Stanford Law School
- Annual reports of global pharmaceutical companies

Good Practices

Internal projects and interviews, experience and industry knowledge

Research Publications:

- BSIGroup.com
- Arctic Intelligence
- Kroll - Anti-Bribery & Corruption Benchmarking Report
- Transparency International UK – Global Anti-bribery Guidance Best Practice For Companies In The UK And Overseas
- Transparency International – Business Principals for Countering Bribery
- Financial Services Authority (FSA) -Anti-bribery and corruption systems and controls in investment banks
- Standard Chartered - The ABC of Anti Bribery and Corruption: Assessing the Risks
- World Economic Forum: Good Practice Guidelines on Conducting Third-Party Due Diligence
- Preventing Corruption in Supply Chain: How Companies Can Address Challenges
- United Nations Global Compact: Stand Together Against Corruption A practical guide to help prevent corruption in the supply chain

Forum:

- Human Rights and Business Dilemma Forum

Media References:

- Aravo
- Pharmaceutical Commerce
- Sustainability report of global pharmaceutical company

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

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