Reducing FCPA Risks and Achieving Third-Party Compliance in the Pharmaceutical & Medical Devices Industries

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Pharmaceutical companies are in the cross-hairs when it comes to regulatory focus on ABAC compliance. In response to FCPA enforcement actions, the SEC has stated "*Bribery in connection with pharmaceutical sales remains as a significant problem despite numerous prior enforcement actions involving the industry and life sciences more generally. While bribery risk can impact any industry ... more work needs to be done to address the particular risks posed in the pharmaceutical industry*."

Beyond financial penalties and imprisonment, FCPA investigations can do lasting damage to a company's brand image and stock value. A study of 139 FCPA legal actions found that when a company is charged with both bribery and financial fraud violations, its market capitalization suffers an average cumulative drop of 54.9% [1]

It's clear that pharmaceutical and medical device companies, as well as their executives and directors, need to take compliance with the anti-bribery and anti-corruption regulations seriously.

And they need to be concerned about compliance with more than just the FCPA. Other nations and international organizations have passed laws and regulations similar to the FCPA. The Organisation for Economic Co-operation and Development (OECD) Anti-Bribery Convention, which has been signed by 36 OECD member states and 8 non-member states, establishes legally binding statutes for criminalizing bribery of foreign public officials in international business transactions.[2] Each signatory has established its own anti-corruption laws, many of which are modeled on the FCPA.

The UK is one of the OECD signatories. Like the FCPA, the UK Anti-Bribery Act is another extra-territorial anti-corruption law. In some aspects, it is even broader and more exacting than the FCPA.

For example, it makes no exceptions for facilitation payments and promotional expenses, and it sets no limits on fines imposed as penalties.

The FCPA, the UK Anti-Bribery Act, SAPIN II in France, and similar laws in other nations are all designed to discourage corruption, especially corruption in the form of bribing foreign officials to gain access to markets, resources, or other valuable assets. They are also designed to ensure that multi-national companies maintain financial accounts that are detailed and transparent enough to reveal corruption should it occur.

Failure to comply with these regulations can be costly. Pharmaceutical and life science companies felt the pain of over $456 million in US imposed sanctions for FCPA violations in 2020 alone. Most actions involved a third-party intermediary.

Penalties frequently reach tens to hundreds of millions of dollars—no trivial expense. Critically, companies can be penalized not just for their own actions, but also for those of the third parties they work with, including resellers, distributors, marketing agencies, manufacturers, business consultants, and other partners. The scope of these regulations is broad; the consequences for violations are onerous. Company leaders need comprehensive insight into the actions of their employees and third parties if they are to ensure that no one commits bribery or corruption infractions on their behalf.

1. http://www.masonlec.org/programs/foreign-corrupt-practices-act-enforcement
2. http://www.oecd.org/corruption/oecdantibriberyconvention.htm

Recent FCPA Penalties Against Pharmaceutical and Medical Device Companies

The largest FCPA enforcement action to date against a pharmaceutical company, was in 2018, when Teva Pharmaceutical Industries Ltd. agreed to pay $519 million to U.S. authorities after admitting to paying bribes in Russia, Ukraine, and Mexico to boost sales. More recent actions include:

$21 Million

Alexion Pharmaceuticals

Boston-based pharmaceutical company Alexion Pharmaceuticals Inc. agreed to pay more than $21 million to resolve charges that it violated the books and records and internal accounting controls provisions of the FCPA.

(7/2/20)

$340 Million

Novartis AG

Global pharmaceutical and healthcare company and its former Alcon subsidiary agreed to pay over $340 million to resolve SEC and DOJ charges arising out of conduct in multiple jurisdictions.

(6/25/20)

$8 Million

Cardinal Health, Inc

Cardinal Health agreed to pay more than $8 million to resolve charges that it violated the books & records & internal accounting controls provisions of the FCPA in connection with its operations in China.

(2/28/20)

$231 Million

Fresenius Medical Care AG & Co

The German based provider of products and services for individuals with chronic kidney failure agreed to pay $231 million to the SEC and Department of Justice in a global settlement to resolve violations of the FCPA in multiple countries over the course of nearly a decade.

(3/29/19)

$7.8 Million

Stryker Corp

The Michigan-based medical device company agreed to pay a $7.8 million penalty for insufficient internal accounting controls and inaccurate books and records.

(9/28/18)

$25 Million

Sanofi

The Paris-based pharmaceutical company Sanofi paid more than $25 million to resolve charges that its Kazakhstan and Middle East subsidiaries made corrupt payments to win business. The kickbacks were tracked in spreadsheets, where they were labeled as “marzipans.”

9/4/18

“Bribery in connection with pharmaceutical sales remains as a significant problem despite numerous prior enforcement actions involving the industry and life sciences more generally,” said Charles Cain, FCPA Unit Chief, SEC Enforcement Division. “While bribery risk can impact any industry, this matter illustrates that more work needs to be done to address the particular risks posed in the pharmaceutical industry.”

Aggressive Investigations and Larger Penalties

Compliance teams should take note that the DOJ continues to prosecute pharmaceutical companies and medical device manufacturers for violations. Prosecutions against individuals, in general, are also on the rise, and so corporate executives should be aware of this trend towards individual responsibility as well.

"We should focus on the people who play significant roles in setting a company on a course of criminal conduct. We want to know who devised and authorized criminal schemes and hold them accountable.

Our individual accountability policy is designed to drive change and lead more companies to implement meaningful proactive compliance programs. Change can be difficult in large organizations. But the ability to adapt to change is an essential survival skill."

Deputy Attorney General Rod J. Rosenstein, March 2019.

With the significant focus on the industry, together with the high costs associated with ABAC violations, companies should be focused on areas in which they can improve compliance, including the way in which they manage their third parties.

Ensuring Compliance

What do companies need to do in order to demonstrate due diligence and compliance with FCPA and other anti-bribery and corruption regulations?

Companies need to:

- Document and distribute code of conduct guidelines for employees and third parties.
- Implement clear accounting and financial control processes so that income and expenses can be monitored and tracked in sufficient detail for uncovering unlawful actions such as bribes.
- Establish clear criteria for vetting and onboarding third parties.
- Centralize information about third parties so monitoring can be comprehensive and timely.
- Apply a risk-based approach to due-diligence.
- Ensure third parties are monitored on an on-going basis.
- Implement processes for re-assessing third parties when regulations change and when news of third-party infractions appears.

Key trends in ABAC enforcement globally

The following five key trends should be kept in mind by pharmaceutical and medical device companies as they review their anti-bribery and corruption (ABAC) compliance programs.

1. **Using deferred prosecution agreements.** Deferred prosecution agreements (DPAs) are becoming an increasing feature of ABAC cases.

2. **Evolving environment around prosecution of individuals.** Governments around the globe are ramping up their rhetoric when it comes to the prosecution of individuals for bribery and corruption crimes.

3. **Increasing World Bank and multilateral development bank (MDB) influence and enforcement.** Since 2010, the World Bank has entered into more than 50 cooperation agreements with regulatory agencies, governmentd epartments, and other bodies to promote ABAC initiatives. Companies can expect the World Bank to exert more influence going forward.

4. **Growing coordination among governments and regulatory authorities.** This has both a challenging and a beneficial side. Governments are coordinating more around prosecutions, but they are also beginning to coordinate penalties more too, so that there isn't a "piling on" effect.

5. **Developing use of social media and investigative journalism.** Prosecution for criminal behaviour is no longer restricted to the courts. Companies that behave badly are increasingly finding themselves the focus of journalists or social media outlets.

Many companies attempt to implement anti-bribery and corruption controls, but end up falling short in one or more of the following areas:

Lack of focus on third parties.
Companies might establish a code of conduct for employees but neglect to share that code of conduct with third parties. Without clear direction from the company itself, some third parties might decide that they have unspoken permission to bend rules and engage in risky behavior

Static criteria for third parties.
Companies might document a set of criteria for third parties, but fail to update criteria when laws, market requirements, or other conditions change.

Lack of periodic reviews/ongoing monitoring
Companies might vet third parties once, but fail to implement a system for ongoing monitoring and attestations.

Data silos.
Data on third parties might be distributed across different geographic regions and corporate divisions and stored in disparate data repositories, preventing executives and the compliance team from achieving a comprehensive, centralized view of third party compliance.

A large pharmaceutical or medical device company may work with tens of thousands of third parties, all of which need to be assessed routinely for compliance with regulations, which themselves may change every few years.

Managing this analysis requires an automated solution that makes it easy for third parties and company managers to collect, manage, and analyze data needed for third-party risk and compliance.

Relying on ad hoc data collection—such as paper forms or Excel spreadsheets and FTP servers—is far too risky. Companies need a comprehensive solution that gives them the far-reaching and timely visibility they have been missing in third-party risk and compliance.

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5 Best Practices For Managing ABAC Risk

Best practices that organizations around the globe are implementing within their third-party risk management programs for ABAC compliance, include:

1. **Aligning policies and processes to recognized standards and guidance**

   Organizations usually have ABAC regulations that they must adhere to when structuring their ABAC programs. However, organizations should also seek to align their ABAC programs to at least one of the standards that exist today.

   These standards provide important guidance and best practices for ABAC programs, including how assessments and due diligence should be structured. Some firms adopt several standards to be sure they are implementing a truly best practice approach to ABAC, particularly around third-party ABAC risks. Key standards include ISO 37001, Transparency International's Business Principles for Countering Bribery, the Wolfsberg Anti-Bribery and Corruption Compliance Program Guidance, and the World Economic Forum's PACI Principles for Countering Bribery.

2. **Integrating with third-party intelligence content.**

   Connecting directly with data and information feeds – which provide intelligence on third-party corporate structure, financial crime, and fourth parties – is essential today for an ABAC program. It is almost impossible for an ABAC team to source and input this information manually. There is simply too much information being produced too quickly for ABAC teams to be able to keep up with manual research and inputting data.

   Failing to have access to this data in a timely way could result in the organization being exposed to risk unnecessarily. Having a manual process can also slow down the third-party approval process, hampering the business. Good third party data feeds with ABAC components include Refinitiv, Arachnys, Dow Jones, and LexisNexis.

3 **Performing assessments on all third parties, segmented by risk exposure**.

It's important for organizations to screen all of their third parties and to understand their inherent risk associated with bribery and corruption exposure.

First, without inherent risk assessment information, it's impossible for a company to truly understand its overall inherent ABAC risk position from a portfolio perspective.

Second, third parties also have third parties – often referred to as fourth parties.It's important for organizations to know if any of these fourth parties are a bribery or corruption risk, especially if they undertake work associated with an organization's contract.

Third, it is important that the entire assessment program is risk-based – that is, the level of detail required by the assessment is in line with the level of risk the third party presents. Organizations should segment their third parties by risk profile and criticality to ensure that higher risk relationships receive a more in-depth review, while those that don't meet risk thresholds aren't required to go through unnecessary processes.

4 **Scoping the level of due diligence by risk.**

ABAC checks can be a particularly challenging aspect of third-party onboarding because of the complexity of ownership structures, various regulatory requirements, and the volume of data that often has to be collected. Different third parties will require varying levels of due diligence. Some will require enhanced due diligence, while others will require less intense vetting.

Organizations should be able to determine the level of due diligence required for a new third party relationship, based on set criteria such as a risk score or criticality. Being able to adjust third-party due diligence levels by risk will help make the overall onboarding process more efficient and a better experience. As a result, it should reduce overall cycle times, helping the business to better meet its goals.

5 **Maintaining automated continuous monitoring**

A third party's risk profile can change overnight, exposing the organization to unanticipated risk. For example, a change in ownership, the exposure of a bribery scandal, or a corruption event at a fourth party could have an enormous impact on the third party's ABAC risk score. Organizations need to be immediately aware of significant changes in the ABAC posture of their third parties, including non-compliance and negative headlines. Attempting to undertake ongoing monitoring manually is extremely difficult. This approach is time and resource consuming and prone to error. Automating monitoring through the use of information feeds and third-party risk management software makes notification immediate and actionable. Automated, continuous monitoring for changes in risk profile can then be used to trigger incident reports as well as remediation or termination plans as required.

Finally, ensuring all of this action is auditable is also extremely important, as it will help you report and demonstrate compliance to auditors and examiners.

Taking a proactive approach to third-party ABAC compliance that follows best-practice helps ensure that your business and its reputation are protected and that you are operating with the level of ethical integrity your stakeholders and the wider community expect. And if that's not enough, it also helps keep your name off the ever-growing list of enforcement actions.

Conclusion

The U.S. DOJ, other government agencies, and industry regulators are committed to increasing the breadth of anti-bribery and corruption investigations and the severity of penalties for non-compliance.

Pharmaceutical and medical device companies need to be prepared with a comprehensive and flexible solution for third-party risk management that can also manage to the business scale, business complexity, and business change dynamics of their enterprise.

Aravo for

Anti-Bribery and Corruption Compliance

Aravo for Anti-Bribery And Corruption Compliance (ABAC) is a pre-built SaaS application that accelerates your ability to implement an extensible, best practice ABAC program to reduce third-party risk.

The only specialized solution built from the ground up to incorporate guidance from the OECD, US Foreign Corrupt Practices Act (FCPA), UK Bribery Act and ISO 37001, Aravo for ABAC Compliance manages, tracks, and analyzes bribery and corruption risks in your third-party relationships.

The multi-faceted compliance challenge of anti-bribery and corruption is coming at organizations from all angles: US FCPA, UK Bribery Act, Sapin II, and more. To be compliant today requires a defensible record of due diligence and monitoring of third-party relationships. To do this in manual processes encumbered by documents, spreadsheets, and emails is ineffective, inefficient, and certainly not agile. It also lacks a robust audit trail and system of record to defend the organization. Organizations today need a strong system of record of ongoing/continuous anti-bribery and corruption activities that can be found in a third-party management platform.

Michael Rasmussen, GRC 20/20

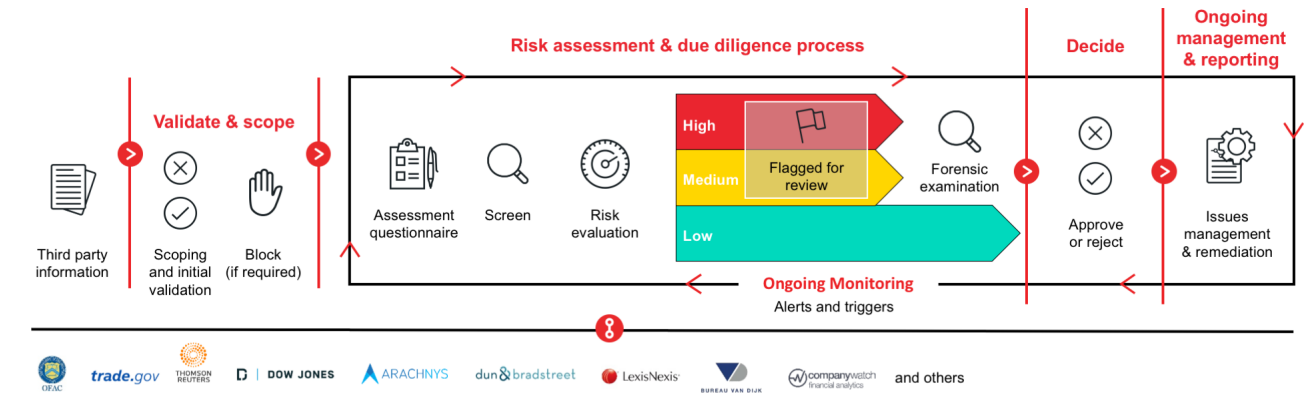
Key Benefits

- **Face audits with confidence.** Incorporating international standards and guidance for combating corruption, Aravo for ABAC Compliance provides enhanced due diligence, continuously monitors risk, and creates an easily accessible audit trail.
- **Make risk visible to all of your stakeholders.** With role-based ABAC dashboards and reports, you always know the inherent and residual risks, can segment and manage third parties according to their risk profiles, and can trigger appropriate remediation or termination.
- **Enforce internal controls across the enterprise.** Create a single source of truth for third and fourth party data using automated workflows to balance centralized control.

End-to-end ABAC third-party risk management capabilities

Engineered to accelerate your best practice third-party risk management program, Aravo for ABAC Compliance includes:

- Proactive initial assessments that prevent any consideration of sanctioned or embargoed entities or individuals.
- A comprehensive, proprietary ABAC questionnaire that maps directly to industry guidance and standards set by the OECD, FCPA, UK Bribery Act, and ISO 37001. Assessments are scoped according to risk profile to ensure both rigor and efficiency.
- Enhanced due diligence to ensure that entities and individuals are thoroughly vetted according to the amount of risk they pose. Optionally, you can integrate third party data sources you use now or in the future (such as Refinitiv, Dow Jones, Arachnys, or LexisNexis) to incorporate those investments into your enterprise third-party risk mitigation strategy.
- Automated ABAC workflows to enforce policies and procedures for ABAC compliance and collect supporting documentation. All activities and actions are logged in a secure audit trail that can be readily accessed for auditing and other oversight activities.
- Continuous monitoring to alert you to any changes that could impact a third party risk profile. When appropriate, these alerts will trigger a remediation workflow or termination.
- Out-of-the box role-based ABAC dashboards and reports that provide all stakeholders the visibility they need.



Why choose Aravo for ABAC Compliance?

Our proven track record. Aravo has an unparalleled history of successfully implementing ABAC solutions for global brands with some of the most complex third party ecosystems in the world.

Our third-party risk expertise. Legacy enterprise systems like ERP or GRC can't analyze third party ABAC-specific risk at the enterprise, entity, and engagement levels. Point solutions lack the ability to view ABAC risk in the context of overall third party risk. As the market's leading specialist provider in third party risk management solutions, Aravo gives you both ABAC specific functionality and the ability. to view, analyze, and mitigate enterprise risk from multiple perspectives.

Our extensible platform. Get the immediate benefits of accelerated deployment of your ABAC compliance program with the flexibility to adapt to future needs. Aravo gives you the option of merging your own customer content and scoring with pre-built, best practice capabilities. You can also extend your solution to address other risk domains because Aravo for ABAC Compliance is seamlessly integrated into Aravo's common third party risk management platform.

ARAVO

The Definition of Better Business

Better business is built on acting with integrity. It commands better performance, delivering better efficiency, collaboration, and financial outcomes. It inspires trust. But better business is more than that – it's about lifting the ethical standard of an entire business ecosystem to build a better world.

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