

KING & SPALDING

COVID-19 Vaccine Rollout

The COVID-19 Vaccine Global Rollout and Associated Corruption Risks

Frequently Asked Questions

Which anti-corruption laws affect the COVID-19 global vaccine distribution effort?

The **U.S. Foreign Corrupt Practices Act** (“FCPA”) will affect the global dealings of companies with ties to the United States, as well as any companies that commit an act that is part of an FCPA violation in the United States. The FCPA is two-pronged: (1) its accounting provision requires “issuers” (companies with registered securities in U.S. markets, and companies required to file reports with the Securities and Exchange Commission (“SEC”)) to comply with certain books and records and internal controls requirements; and (2) its anti-bribery provision prohibits paying, authorizing, or promising “anything of value” to a foreign government official to gain or maintain business or a business advantage. “Anything of value” is broad. It includes gifts, entertainment, preferential treatment, loans, travel expenses, and other types of benefits. Businesses involved in vaccine and treatment distribution are most immediately at risk of violating the anti-bribery provision. Businesses that promise to give foreign officials priority access to vaccines or treatments, give vaccine samples for any advantageous purpose, provide value in exchange for regulatory approval of a vaccine or treatment, or other similar activities risk running afoul of the FCPA. This is particularly true in countries with government-run healthcare systems, in which healthcare professionals will be considered foreign officials under the FCPA. *For more general information on the FCPA, please see King & Spalding’s Foreign Corrupt Practices Act FAQ [here](#).*

The **UK Bribery Act 2010** (“UKBA”) prohibits the giving and receiving of bribes, includes a strict liability corporate offense and has aggressive extraterritorial effect. For any individual or corporate person with a “close connection” to the UK (e.g. British citizen or UK-incorporated or established company), the UKBA will extend to cover their dealings and activities globally. Moreover, even non-UK companies that are “carrying on business, or part of a business” in the UK are exposed to potential strict corporate liability under Section 7 of the UKBA, and this liability can be triggered by an “associated person” located anywhere in the world engaging in bribery in relation to the company’s products or services. The four general offenses under the UKBA are (1) bribing another person; (2) being bribed; (3) bribing a foreign public official (the “Section 6 Offense”); and (4) a commercial organisation failing to prevent bribery by associated persons (the “Section 7 Offense”). The global rollout of COVID-19 vaccines and treatments invites risks of violating all four offenses; however, businesses should make an extra effort to avoid committing a Section 6 Offense, particularly where medical care providers or other counterparties are government owned and/or operated. Businesses should also satisfy themselves that they will not run afoul of a Section 7 Offense, particularly in their use of third-party service providers in high risk jurisdictions. A robust and meaningful anti-bribery compliance program can give a business a complete defense to any Section 7 liability. *For more general information on the UKBA, please see King & Spalding’s UK Bribery Act FAQ [here](#).*

In addition to the FCPA and UKBA, an increasing number of countries have anti-corruption laws that prohibit conduct similar to that covered by the FCPA and UKBA. Multinational companies operating in multiple jurisdictions should familiarize themselves with the local anti-corruption laws to ensure that they comply with various local laws.

How may bribery and corruption investigations emerge in relation to the global rollout of the Covid-19 vaccine?

Bribery and corruption investigations will emerge in various different ways. We think that businesses need to be vigilant in three key areas:

- **Acquiring government approvals/permits to conduct business in country:** Scrutiny of companies that need to receive various approvals from government agencies at a variety of levels is likely to increase. For example, businesses operating in Europe will need to seek approvals from the European Commission and a Joint Negotiation Team representing seven-member states, as well as the members states themselves. There may be risks whereby government officials involved in the approval process at a variety of levels may seek improper payments or incentives to provide or accelerate approvals. Moreover, businesses should also be aware of the bribery risk associated with asking foreign officials to increase use of a specific vaccine or treatment once it is approved.
- **Winning government contracts:** Entering into contracts, either directly or indirectly, with governmental bodies to provide products or services may also be subject to additional scrutiny. It is important to remember that health care providers are government officials in many countries. Government officials involved in the process of procuring supplies, negotiating contracts, or identifying companies may seek improper payments or incentives in order to select a company for a contract or increase the value of the contract. There may also be similar scrutiny based on allegations that government officials steered lucrative contracts to companies in which they have a direct or indirect interest or that are owned/controlled by political allies.
- **Commercial corruption and kickbacks in the supply/distribution chain:** A number of global anti-corruption laws (notably the UKBA) prohibit commercial bribery, in addition to bribery of government officials. For companies entering into contracts with private health care providers or hospitals, individuals from those entities may seek improper payments or incentives that would be prohibited by these laws.

What is already happening in this arena?

In the United States, the Department of Justice (“DOJ”) and SEC have scrutinized businesses’ global dealings related to vaccine distribution. Pharmaceutical companies developing and distributing vaccines in the past few decades have been drawn into FCPA investigations, and the U.S. government is likely to scrutinize global dealings surrounding COVID-19 vaccine and treatments. In the past five years alone, DOJ and SEC have investigated 13 companies in the healthcare industry for FCPA violations. Some of the largest FCPA settlements in the U.S. have been in the healthcare / life sciences industry, demonstrating that the authorities are familiar with the types of misconduct that occur in the industry and they have a playbook for investigating it.

The UK Government is equally alive to the risks of increased corruption in the wake of COVID-19 and the urgent vaccine and treatment rollout. The Government’s “World Anti-Corruption Day” newsletter in December 2020 stated that the UK has been positively reviewed for its compliance with the UN Convention against Corruption and Ministers reiterated the UK’s commitment to this agenda at a recent G20 meeting of Anti-Corruption Ministers.

It was also noted that the Government is working with countries in Latin America, Africa and Southeast Asia under its Prosperity Fund Anti-Corruption Programme and Eastern Europe under its FCDO-funded Partnerships for Development Programme, to build crucial digital capability with a focus on responding to the urgent digital demands of COVID-19. Lisa Osofsky, the Director of the Serious Fraud Office (“SFO”), has also signaled that the SFO is actively looking into pandemic-related or enabled fraud and criminality.

The European Anti-Fraud Office also warned governments to be on their guard against offers to provide them with COVID-19 vaccines, in a press release dated February 15, 2021.

What are the biggest risk areas?

- **Health Care Professionals (“HCPs”) are “government officials” in many countries:** HCPs in a substantial number of non-U.S. countries (where nationalized health systems are more common) are considered “government officials” under many anti-corruption laws. This significantly expands the potential for violations of law since anything of value provided to HCPs in many countries could expose the company to corruption risks. Companies need to understand clearly whether parties they are dealing with may be considered government officials pursuant to anti-corruption laws so they can take appropriate precautions to mitigate such risk.
- **Prioritized access to products may be a “thing of value” under anti-corruption laws:** Given the high demand for COVID-19 vaccines/treatments, companies may be asked to provide their products on a priority basis to government officials or key stakeholders, their colleagues, or even family members. Companies should consider carefully what local protocols have been put in place for distribution. Offering or providing priority access to vaccines/treatments may be considered a “thing of value” and may amount to a *quid pro quo* if given in exchange for a benefit to the company, such as accelerated approvals or larger contracts with the government, hospitals, or clinics to distribute / administer the company’s product.
- **Use of third parties to facilitate the distribution of vaccines / treatment / supplies:** Particularly for companies that do not have well-established business or government contacts in new markets, it may be necessary to engage the help of a third party (e.g., distributors, marketers, other business partners) to support efforts to win business. If third parties are needed, careful attention must be paid to vetting and monitoring them to ensure they do not introduce corruption risks to the company. Global anti-corruption laws generally prohibit even the indirect payment of bribes, so companies may be found to have violated those laws if third parties acting on their behalf engage in misconduct. Indeed, certain non-U.S. anti-corruption laws (including the UKBA) contain strict liability provisions that can result in a company incurring criminal liability for bribes offered or paid by third parties, even where there is no evidence that the company itself intended (or instructed) the third party to engage in any bribery on its behalf. Criminal liability of this type has significant knock on consequences for companies that rely on government contracts, including mandatory debarment (which in the EU can be indefinite in duration).

How can I manage these risks?

Be proactive.

- Do not shy away from due diligence or de-prioritize it due to time constraints. Consider tailoring third party due diligence to the current climate which may help flag risks before any violations occur, particularly if there are government touchpoints.

- Monitor third parties continuously after due diligence is complete. Ongoing monitoring can prevent compliance failures and allow businesses to rectify them before the commencement of an enforcement action.
- Conduct risk assessments and review current procedures. This is critical if you are navigating new relationships, geographies or sectors.
- Remain mindful of the risks associated with government contracting, particularly where interacting with the government is new, or is happening in new areas. Consider reviewing government touchpoints and ensuring there is adequate internal oversight.
- Ensure your business leaders remain visible, act with integrity and send a clear message to employees and third-party service providers about their expectations. Take steps to evaluate and confirm that the compliance team has adequate support and resources to successfully operate without cutting corners.
- Ensure there is adequate training provided to employees dealing with third parties or governments, particularly if this is something new to them. It is important that employees know exactly how to report compliance vulnerabilities or failures they identify.
- Ask questions. King & Spalding is happy to answer any queries you may have to help navigate the fast-paced and ever-changing environment in which we are currently operating.