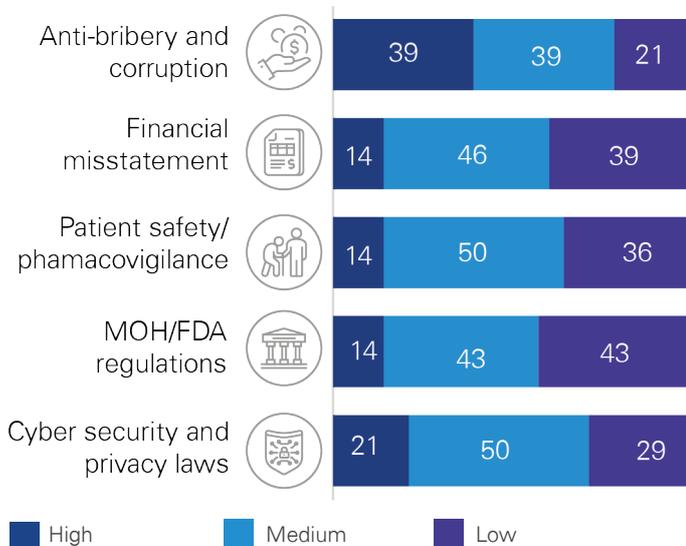


Bribery and corruption

Bribery and corruption was identified as the top compliance risk by Middle East Life Sciences professionals. In fact, 39% of those surveyed describe the risk of bribery and corruption for their businesses in the region as high.

In 2020, there were nine regulatory enforcements for FCPA violations around the globeⁱ—one-third occurred in the Life Sciences industry. Each of the three cases involved the passing of improper benefits to government officials, with the intention of influencing the purchase of products and/or to provide favorable regulatory treatment. In all cases, US regulators noted that the organizations lacked proper or complete books and records, as well as internal controls to detect inappropriate payments.

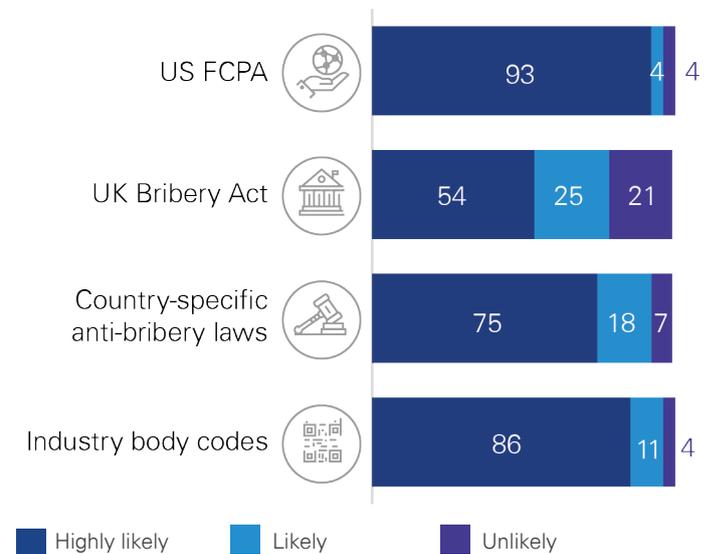
Please rate the below compliance risks for your company in the Middle East:



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

According to industry professionals, the US Foreign Corrupt Practices Act's (FCPA) was identified as the main ABC law driving compliance priorities for Life Sciences companies (93%), followed by industry compliance codes and regional ABC laws/health care practitioners' (HCPs) transparency reporting requirements.

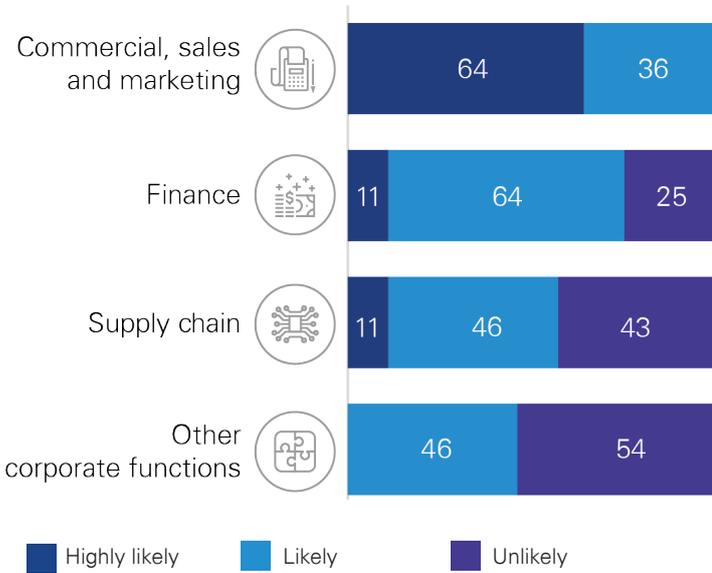
Likelihood of key regulatory laws driving compliance priorities in the Middle East:



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Sixty-four percent of respondents believed their commercial, sales and marketing departments are 'highly likely' to be exposed to bribery and corruption. In the Middle East, Life Sciences sales team and, at times, their distributors, have significant interactions with HCPs, who provide medical detailing of products and technical support for patient treatment. Whilst these engagements are necessary to ensure products are used safely and to drive sales, improper arrangements with HCPs may occur in order to retain sales.

How likely is each department within your company to be exposed to ABC risk?



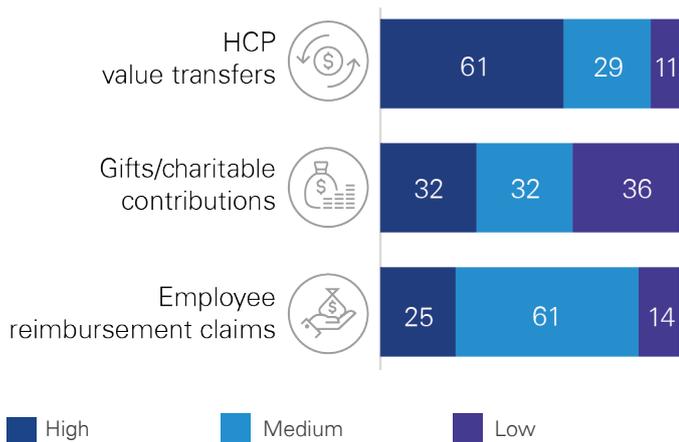
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey



With respect to other activities, 'Value transfers to HCP' was rated as high risk for bribery and corruption by 61%. Life Sciences companies have inhouse systems for workflow approval of HCP spending and subsequent monitoring. However, risk stems from compliance officers' reliance on the accuracy of information provided by the sales team, as well as distributors or other third parties, who deal directly with HCPs.

Charitable donations were identified as another area of concern, with nearly one-third of industry leaders (32%) indicating a high potential for misconduct. The existence of public-private partnerships or semi-government companies in the region may, at times, makes it difficult to identify a government official. Some respondents also highlighted concerns with their patient support/assistance programs. Although these are carried out independently by third parties, there is potential for abuse. This stems in part from the fact that Life Sciences companies are only able to conduct limited audits, due to data privacy restrictions around handling patient records.

Please rate the level of risk associated with each of the following:



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey





Anti-bribery awareness

The majority (86%) of respondents stated that while they are aware of and trained for ABC requirements, the third parties they work with are unlikely to have a similar level of training. Forty-three percent of industry leaders reported that in general, their third parties are aware of ABC laws but are not trained regularly.

Are your employees and third parties aware of the ABC laws and related compliance requirements?

Employees:



86%

Well aware and trained regularly



14%

Aware but not often trained

Third parties:



54%

Well aware and trained regularly



43%

Aware but not often trained



4%

Not quite aware and never trained

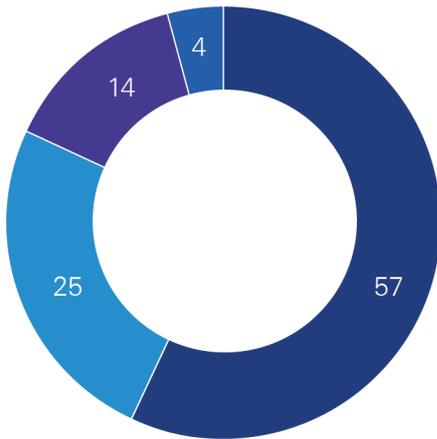
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

ABC compliance program

For the past three years (2018 through 2020), four FCPA enforcements occurred that included Middle East Life Sciences business operations.ⁱⁱ Interestingly, 36% of respondents expect their company to handle more than 10 internal bribery and corruption investigations in a year across the region. However, an equal number of respondents (36%), believed their company would handle less than five.ⁱⁱⁱ

All Life Sciences professionals who participated in the survey have a global ABC compliance program which has been rolled out for their Middle East operations. Regional standard operating procedures (SOPs) are aligned with global programs, while taking into account Middle East regulatory requirements and industry compliance codes (i.e. the Gulf Code on Pharmaceutical Promotional Practices, MEA code and MECOMED). In fact, more than half (57%) described their existing Middle East ABC compliance programs as ‘advanced.’

Please rate the maturity of your organization’s current ABC compliance programs in the Middle East:



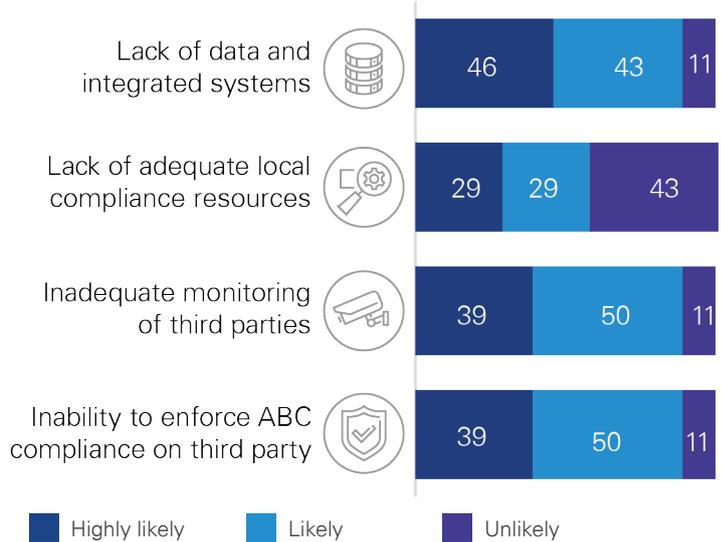
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Key challenges when identifying bribery and corruption risks

The majority of Life Sciences companies do not have permanent establishments in the Middle East. Companies operate through regional technical and scientific offices (TSO). Sales and distribution activities, as well as some marketing and promotional activities, are directly carried out by distributors—with limited or no oversight by the TSO. According to industry

professionals, a lack of data and integrated reporting systems are the most likely pain points when identifying and addressing ABC risks.

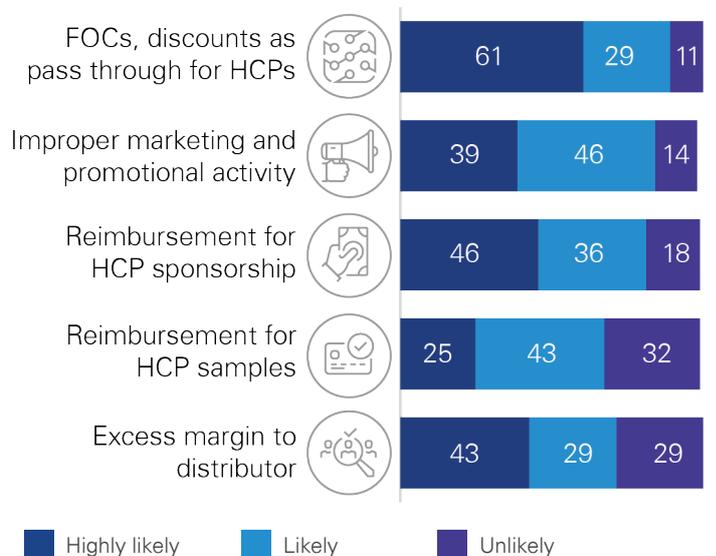
How likely is your organization to face the below challenges when identifying and assessing ABC risks:



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

To date, US FCPA violation enforcements within the Life Sciences sector were often related to improper payments to government officials by intermediaries. Whilst such payments were made with the knowledge of the Life Science companies in a few instances, violations were more often attributable to their inability to detect a third party’s unethical conduct.^{iv}

What is the likelihood of encountering bribery or corruption when managing third-party reimbursements:



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

How to mitigate ABC risks

Eighty-six percent of respondents believe an effective approach to mitigating ABC risk could be training and regular communication. Over the past few years, there has been an increased focus on educating third parties. Although Life Sciences companies obtain compliance training certifications from their distributors, there seems to be a gap in their understanding of related requirements.

Testing and monitoring were identified as the second most effective mitigation for bribery and corruption risk in the region (71%). Life Sciences companies conduct extensive reviews for all reimbursements made to their third parties. Review of distributor debit notes is often a time-consuming task for regional finance teams. Some stakeholders commented that there is room for improvement with respect to testing and monitoring based on past FCPA enforcements and internal investigations.

Recently, companies have started using data analytics and system tools for high-risk areas, such as HCP value transfers. This includes use of structured CRM tools for HCP event management, presenting management dashboards on compliance KPIs.

Rated most effective for mitigating ABC:



86%
Training and communication



71%
Testing and monitoring



57%
Third party due diligence



54%
Employee reporting of incidents



50%
Policies, procedures and SOPs

Source: KPMG Middle East Life Sciences 2020 Industry compliance survey



Contact us



Nicholas Cameron

Partner | Head of Forensic,
Middle East

KPMG Lower Gulf

m: +971 56 683 3019

e: nicholascameron@kpmg.com



Alexander Tuscano

Associate Director | Forensic

KPMG Lower Gulf

m: +971 55 109 3796

e: atuscano@kpmg.com

kpmg.com/ae

Follow us on:



The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavor to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

© 2021 KPMG Lower Gulf Limited, licensed in the United Arab Emirates, and a member firm of the KPMG global organization of independent member firms affiliated with KPMG

International Limited, a private English company limited by guarantee. All rights reserved.

The KPMG name and logo are registered trademarks or trademarks of KPMG International.

Designed by KPMG Lower Gulf Creative team.

Publication number: 3300

Publication date: March 2021