Middle East Life Sciences

2020 Industry compliance survey

March 2021

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Foreword

The advent of Covid-19 meant that regional Life Sciences business leaders have been forced to navigate a broad range of issues. These include employee and customer safety, shoring-up cash for liquidity, reorienting operations to ensure supplies, and navigating government support programs and regulatory changes.

In an effort to bring a degree of clarity to compliance issues emerging from the current environment, our inaugural compliance survey comprises interviews with Middle East based leaders from Life Sciences principals and large regional distributors.

We would like to thank those who participated in the survey. Their responses enabled us to uncover important trends and gain valuable insight.

Please contact us if you would like to discuss the topics explored within these pages.

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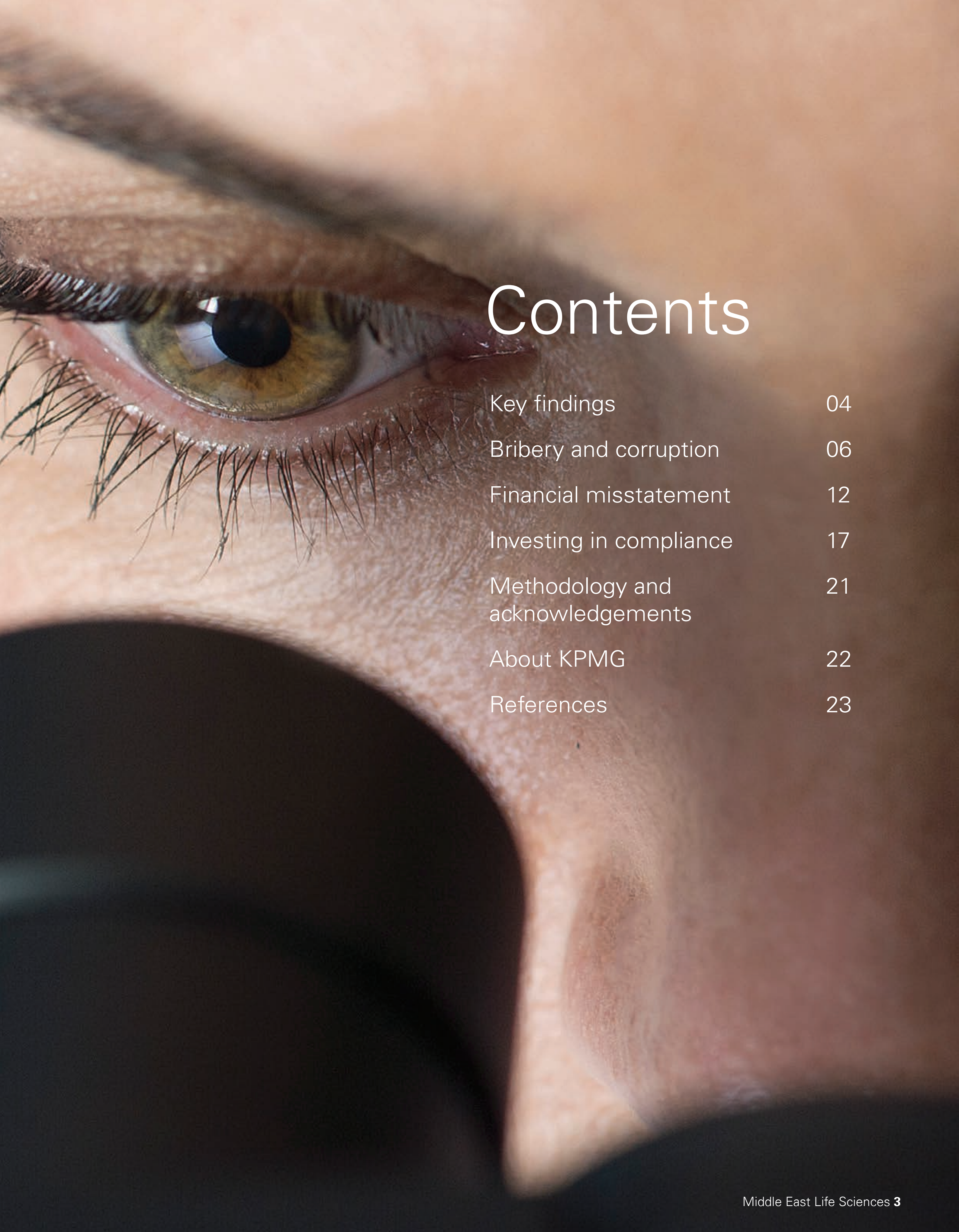
KPMG Lower Gulf



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Key findings

Our inaugural Middle East Life Sciences compliance survey provides a view on related practices in the sector. The purpose of the survey was to highlight compliance risks and associated trends, as well as identify mitigation strategies for Life Sciences companies.

Compliance risks:

'Bribery and corruption' was identified as the top compliance risk (rated 'high risk' by 38%), primarily due to the US Foreign Corrupt Practices Act's (FCPA) extra territorial regulations

Data privacy was rated as 'high risk' by 20%, related to an increase in the number of cyberattacks during the Covid-19 pandemic

Channel stuffing was acknowledged as a common financial statement risk (rated 'high risk' by 54%)

Future investment in compliance functions:

More than three-quarters (79%) of industry leaders are anticipating regulatory changes and increased regulatory focus in the next two years

Life Sciences companies are currently undergoing significant digital transformation, with more than half (57%) stating that they have already sanctioned digital and innovation projects to mitigate existing and anticipated compliance risks

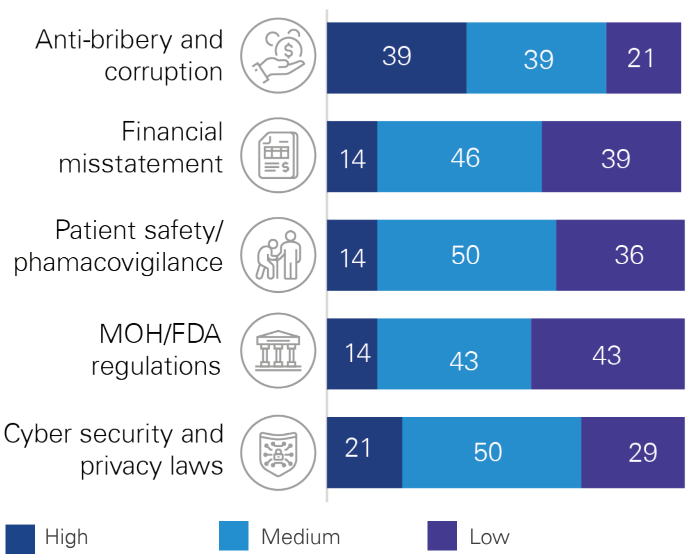
As a priority, about half (46%) of industry leaders are looking to increase the efficiency and effectiveness of their compliance programs using regional industry data points on fair market value (FMV) for high-risk expenditures

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 globe[i]—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.

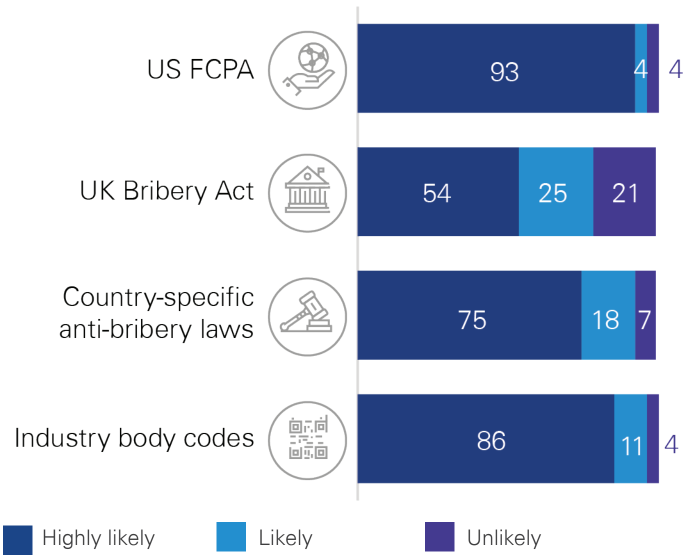
Please rate the below compliance risks for your company in the Middle East:



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.

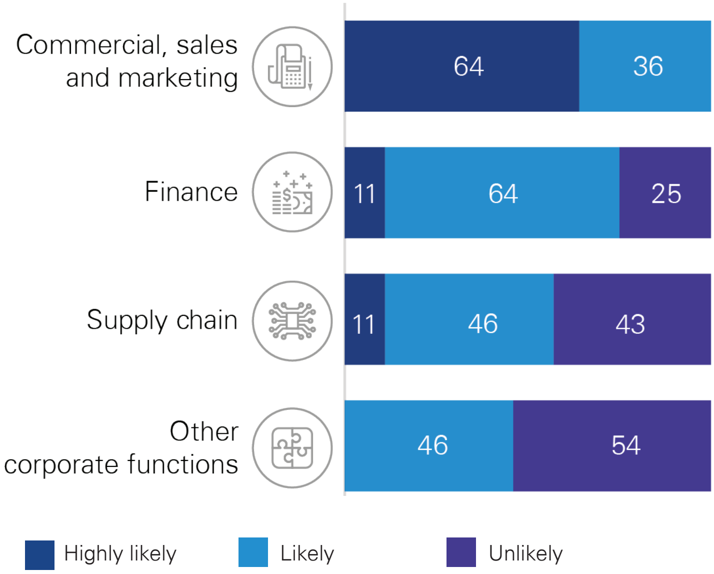
Likelihood of key regulatory laws driving compliance priorities in the Middle East:



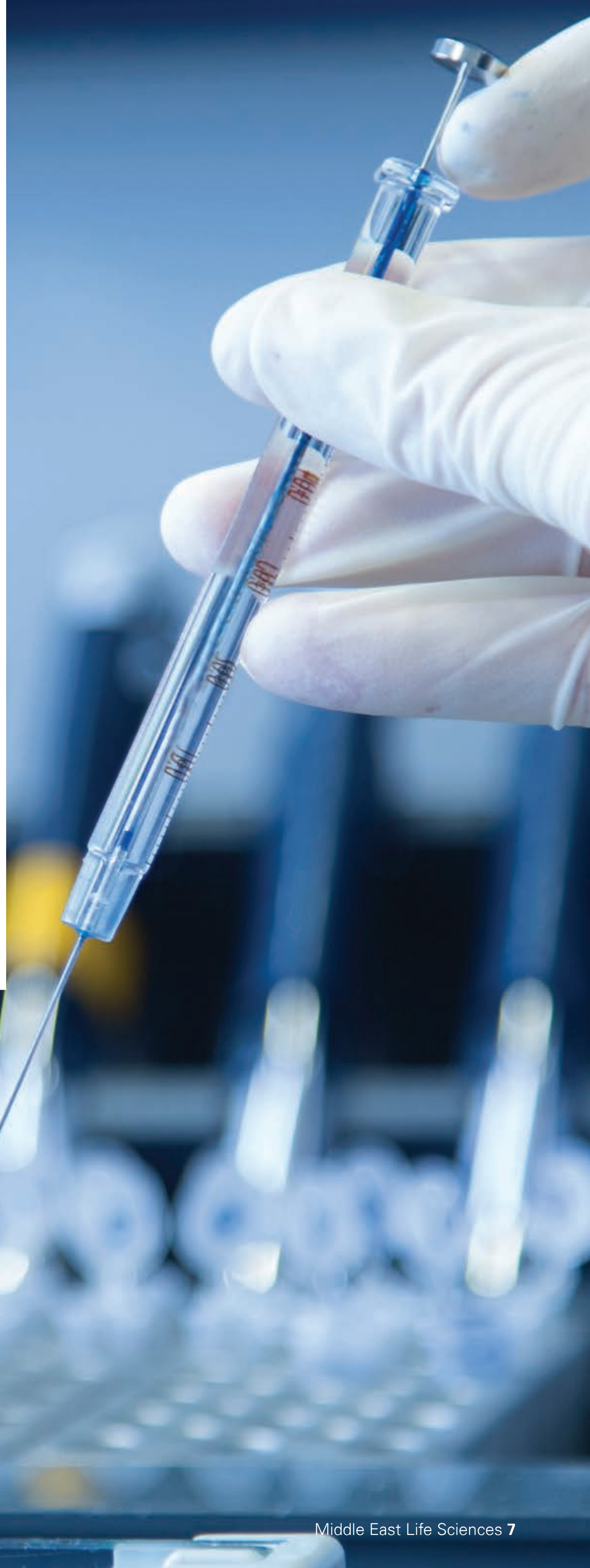
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

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?



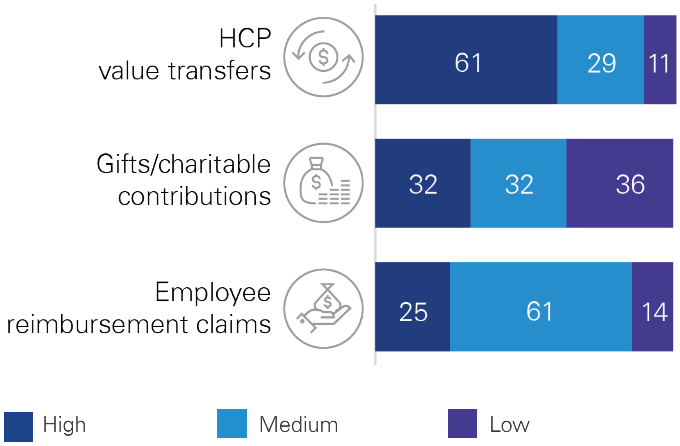
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey



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

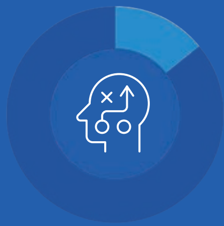
Anti-bribery awareness

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

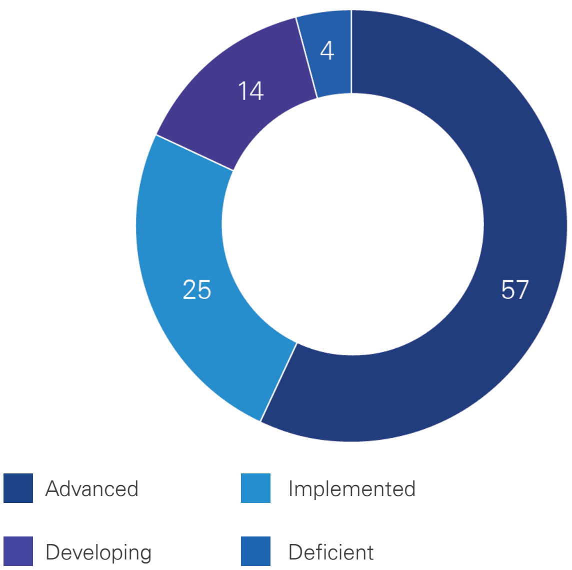
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

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:

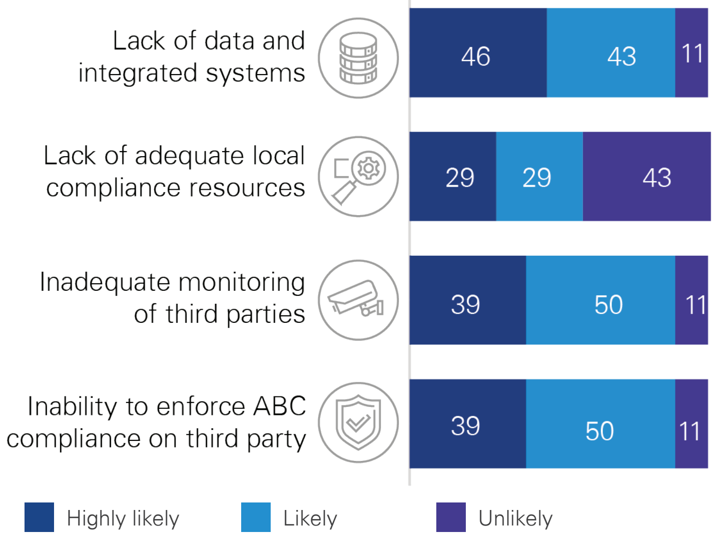


Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

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.

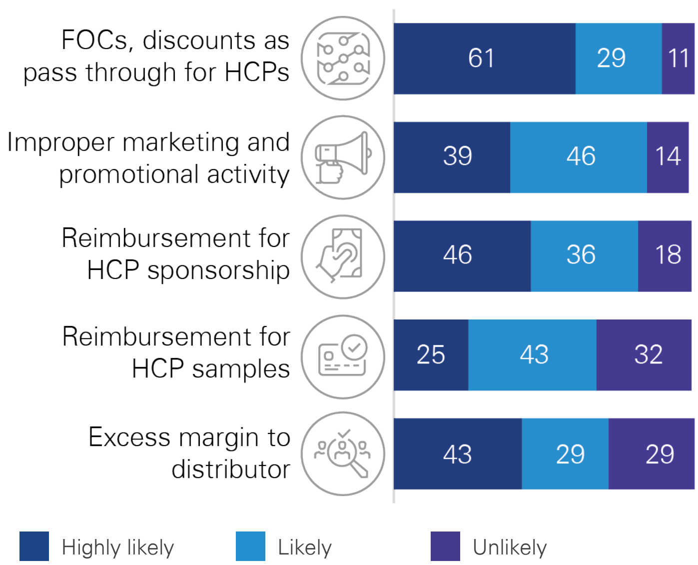
How likely is your organization to face the below challenges when identifying and assessing ABC risks:



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

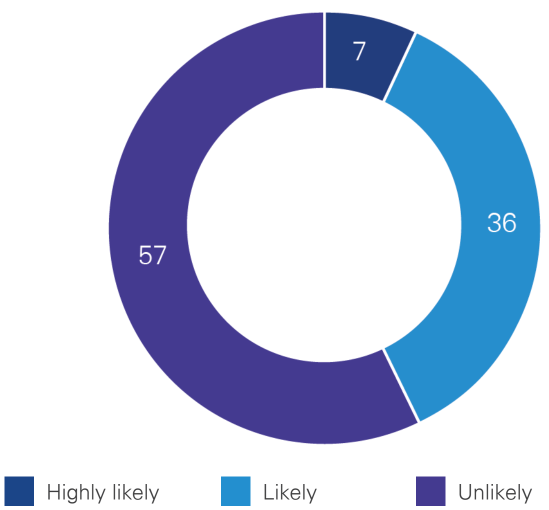
Financial misstatement

Generally accepted accounting principles (GAAP)[v], as well as the US FCPA[vi], require companies to make and maintain accurate books and records.

In our experience, the most common financial misstatement risks in the Life Sciences industry are accelerating revenue to meet business targets or delaying revenue if targets have already been met for a specific reporting period.

While more than a third (42%) of industry leaders stated that financial misstatement is likely, our survey finds that the majority of respondents (71%) average fewer than five internal investigations a year.

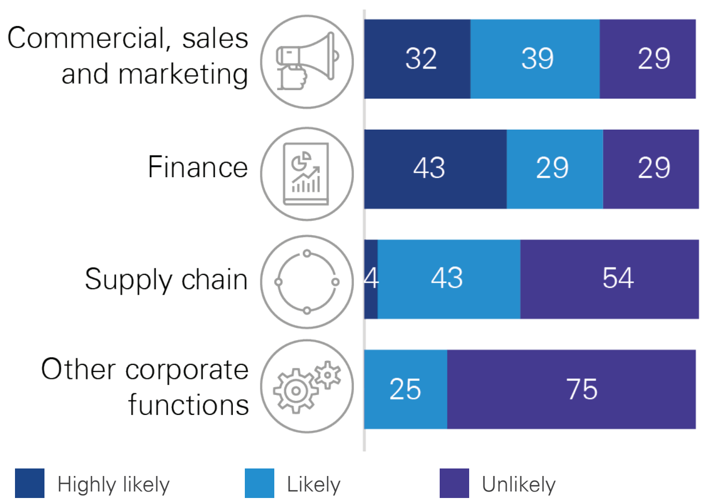
How likely is the risk of financial misstatement within your company?



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

When looking at various aspects of the business functions, those most likely to be exposed to the risk of financial misstatement of books and records are finance and commercial, sales and marketing.

For each department, how likely is there to be exposure to risk of financial misstatements?



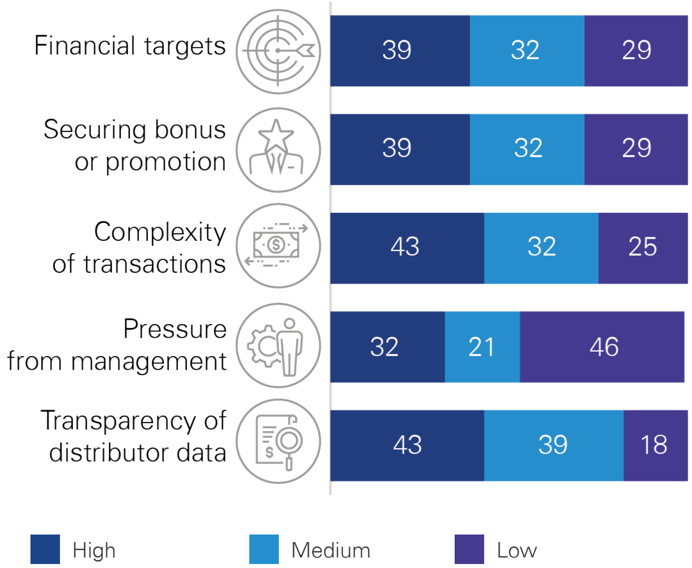
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Factors leading to financial statement fraud

In the Middle East, the Life Sciences industry is heavily reliant on public health care spending.[vii] With recent government budget cuts and the move towards generic and locally manufactured medication, regional business leaders are experiencing significant pressure to meet targets.

As per 43% of respondents, complexity of transactions and reduced transparency due to reliance on distributor data are the factors with a high likelihood of contributing to financial misstatements. These were followed by financial targets and securing performance bonuses and promotions (39%).

Rate the below factors for risk of financial misstatement:



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Common schemes of financial statement fraud for Life Sciences

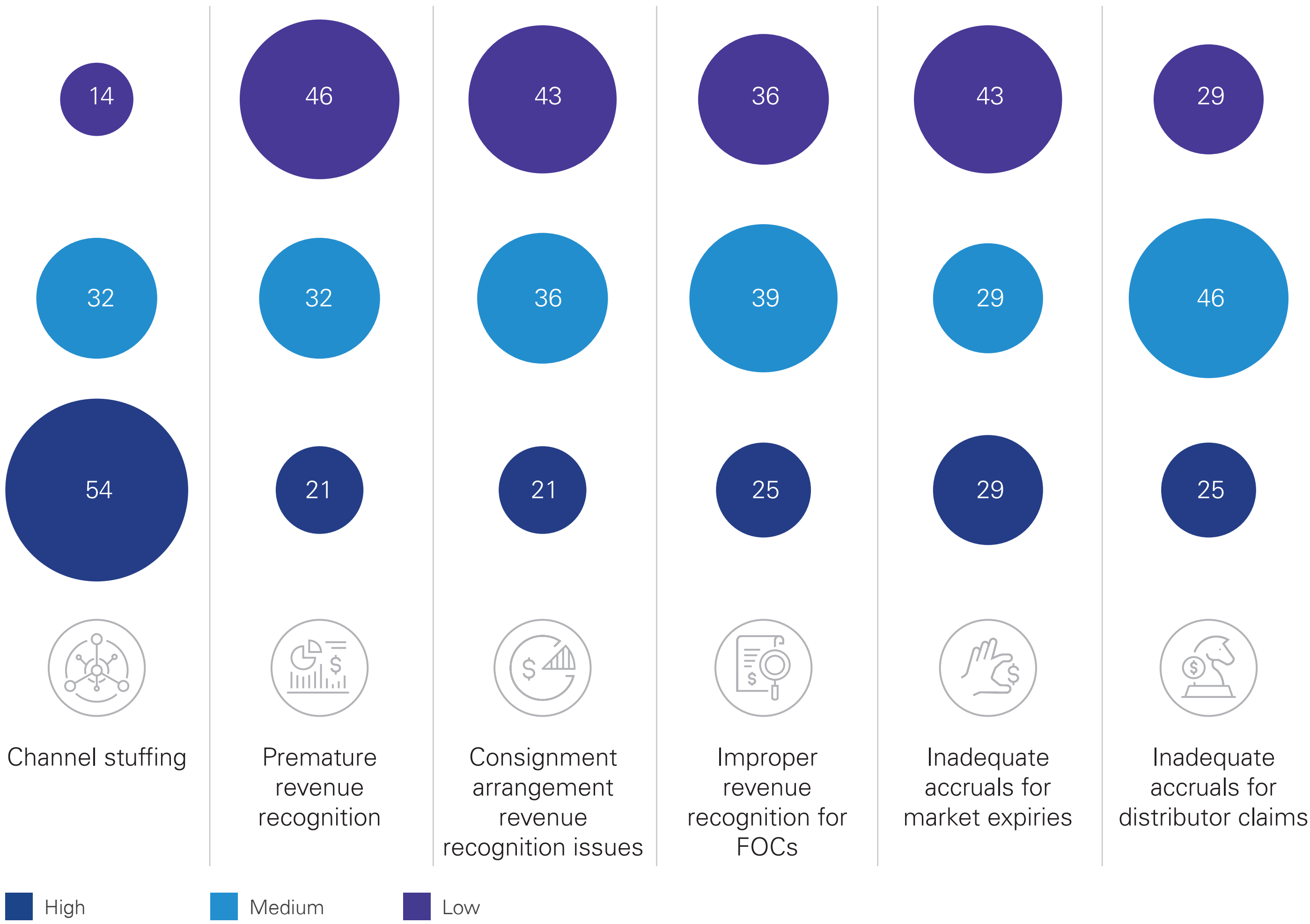
Based on our experience, channel stuffing is the most common accelerated revenue risk for Life Sciences companies globally. Our survey finds this is also the case in the Middle East, with 54% rating it 'high risk'. Middle East regulations do not allow a direct market authorization for Life Sciences companies and mandates the use of local distributors.

The recent trend of subsequent alteration of tender quantities by the government has further heightened the risk of excess quantities with distributors.

Product expiry is another area of concern. Life Sciences companies are frequently unable to make accurate accruals on the books for product expiries due to delayed and disputed claims from distributors. Sales teams work closely with distributors and customers in the field and are usually aware of product expiries in the market. However, this information is not always passed on to finance and regional management teams in time to make accruals for expiries and take corrective actions.

Further, certain stakeholders stated that whilst distribution agreements have clear clauses for expiry claims, informal agreements between commercial teams and distributors exist. These may further increase the risk of companies recording and paying for such claims—often in the subsequent reporting period without the required accruals.

Rate the likelihood of encountering the financial misstatement risks below:

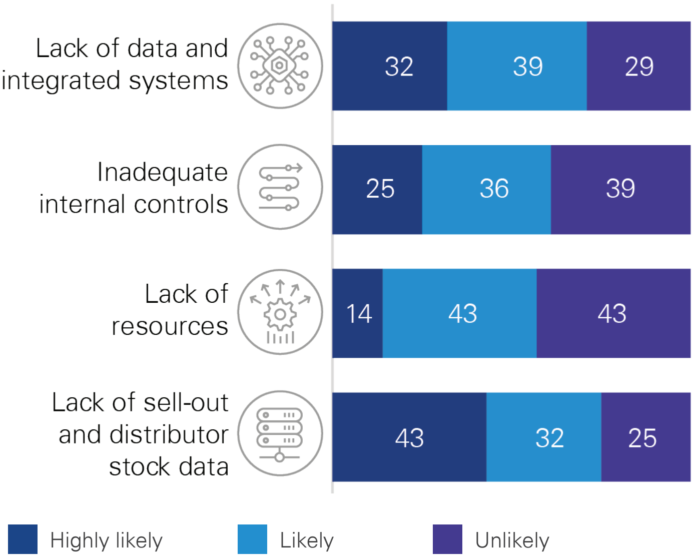


Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Challenges in identifying financial misstatement risks in the Middle East

Our survey identifies the lack of integrated systems and distributor data as two main challenges when seeking to identify financial misstatement risks. Life Sciences companies are dependent on distributors for timely and accurate reporting of financial data and supporting documentation for sales, marketing and promotional activities. This is coupled with the challenge of integrating non-standardized distributor reported financial data in their systems for monitoring.

Rate the likelihood of encountering the following when identifying financial misstatement risks:



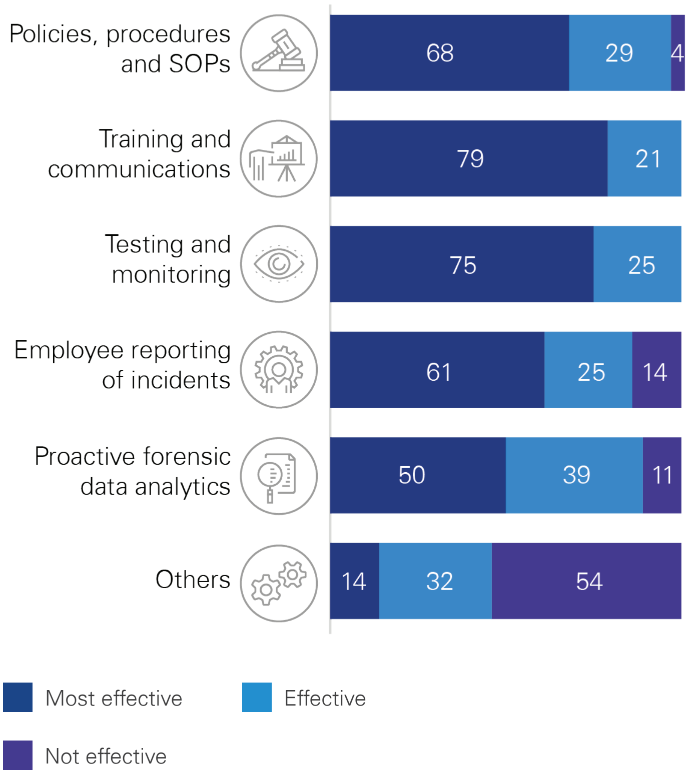
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

How to mitigate financial statement risks

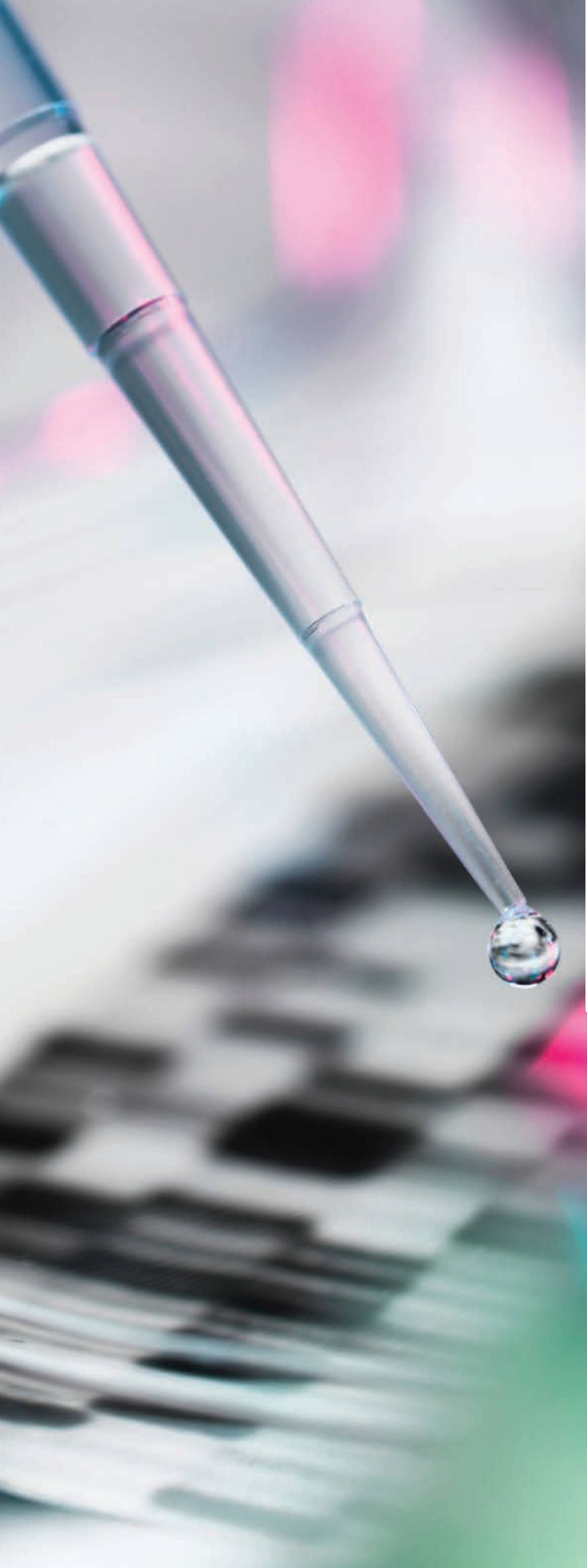
From our experience, Life Sciences companies have global accounting policies and procedures to mitigate financial statement risks such as channel stuffing, accelerated revenue recognition and delaying accruals for distributor claims. Our survey finds that regional SOPs and guidance, trainings and transaction monitoring are most effective to mitigate financial misstatement risks.

Regional business leaders have been focusing on early detection measures to mitigate financial statement fraud. Proactive data analytics is one such approach, recently implemented in the Middle East. Companies are also increasingly demanding that distributors upscale their systems and provide direct, automated reporting on a daily basis to monitor and review distributor sell-out and stock positions.

Rate the below elements effectiveness for mitigating financial misstatement risks:



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey



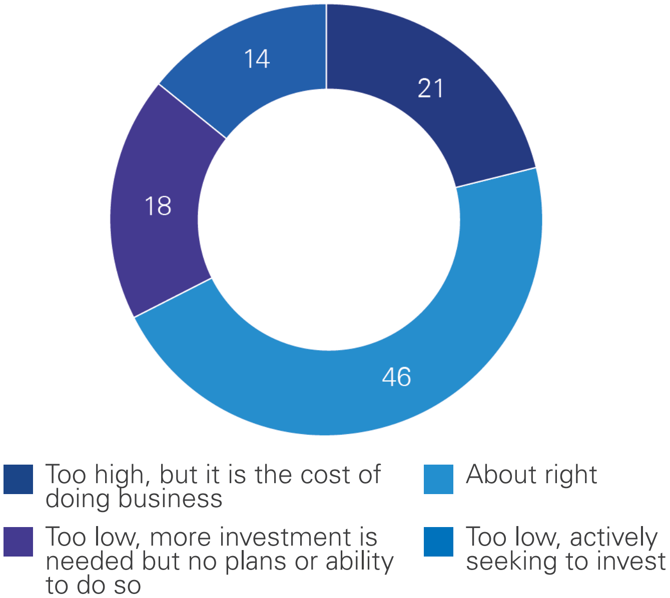
Investing in compliance

Working through the pandemic

The Life Sciences industry is at the center of the Covid-19 pandemic and has experienced accelerated growth as a result. Whilst corporate functions have largely worked remotely during this period, front-end sales and distribution teams have been active in the field in order to meet patient demand and maintain HCP interactions. In parallel, compliance monitoring appears to be reduced. For example, on-site review of third parties slowed during the pandemic, largely due to travel restrictions.

Life Sciences companies need to prepare for potential compliance risks associated with reduced monitoring activities during the pandemic, using technology

What is your current opinion about the cost of compliance for your organization in the Middle East region?



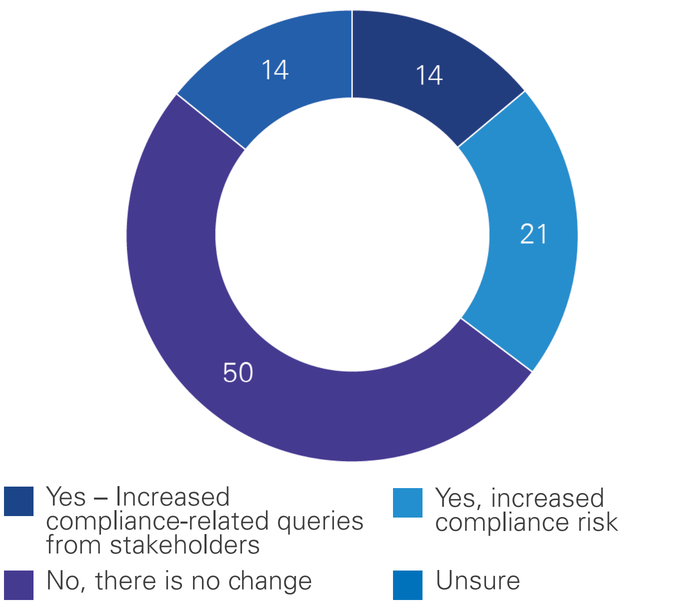
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Compliance costs in the Middle East

While 46% of stakeholders felt that their organization's compliance functions are adequately staffed and their overall compliance cost is about right, one-third (32%) believed additional investment is required.

For 21% of respondents, Covid-19 has increased their compliance costs, however half (50%) indicate no change in spend. This may indicate the presence of strong compliance frameworks prior to the pandemic.

Has Covid-19 impacted your compliance costs?



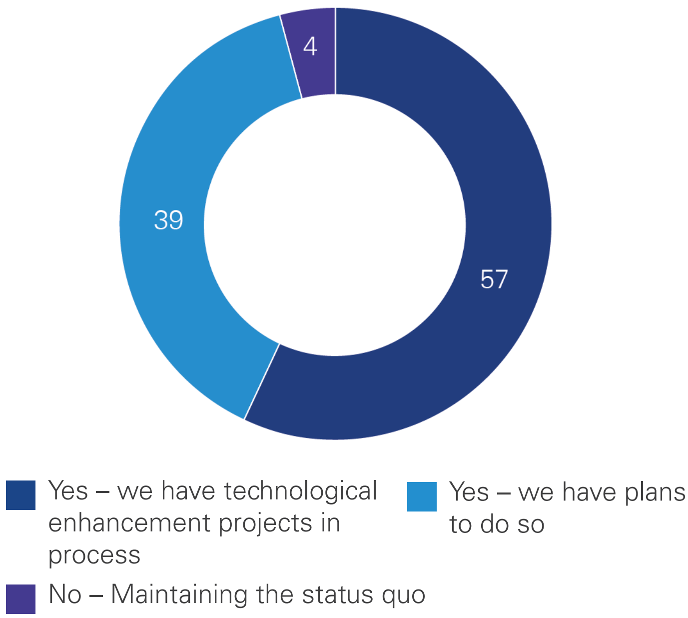
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Seventy-eight percent of respondents anticipate increased regulatory focus that may, in turn, increase compliance cost over the next two years.[1] For example, Abu Dhabi recently announced the launch of a new group purchasing organization (GPO) to manage and develop the procurement of healthcare-related products and services, including pharmaceuticals, equipment and consumables.[viii] Further, from our conversation with industry professionals, it is anticipated that the UAE will enact HCP transparency reporting

Ways to improve effectiveness in compliance

Nearly all (96%) industry professionals are investing in technology to support compliance and monitoring activities—a reflection of the fast pace of change and innovation in the region. More than half (57%) have projects in the works, while the remainder are in the planning stage.

Are you looking to increase the effectiveness of compliance in your organization through better use of technology?



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

More than two-thirds of respondents identified taking a proactive approach as an import element of improving the effectiveness of a compliance framework by:

enhancing data analytics for demand forecast

improving distributor stock management

analyzing distributor sell-out data

More than two-thirds of respondents agreed that industry data points on FMV for high-risk activities and key compliance risk trends is lacking in the Middle East region.

What do you feel are priorities in order to increase the efficiency and effectiveness of your compliance program regionally?

46% Regional industry-wide statistics to measure FMV in high risk spending areas

43% Auditing distributor debit notes and recharges

36% Enhancement of demand and stock management forecasting

29% Enhanced data modelling and monitoring of sell-out and distributor's customer profiling

21% Regional industry-wide statistics on other key financial metrics related to compliance

21% Automating compliance dashboards

7% Reducing audit footprint and associated cost

7% Outsourcing of compliance resources

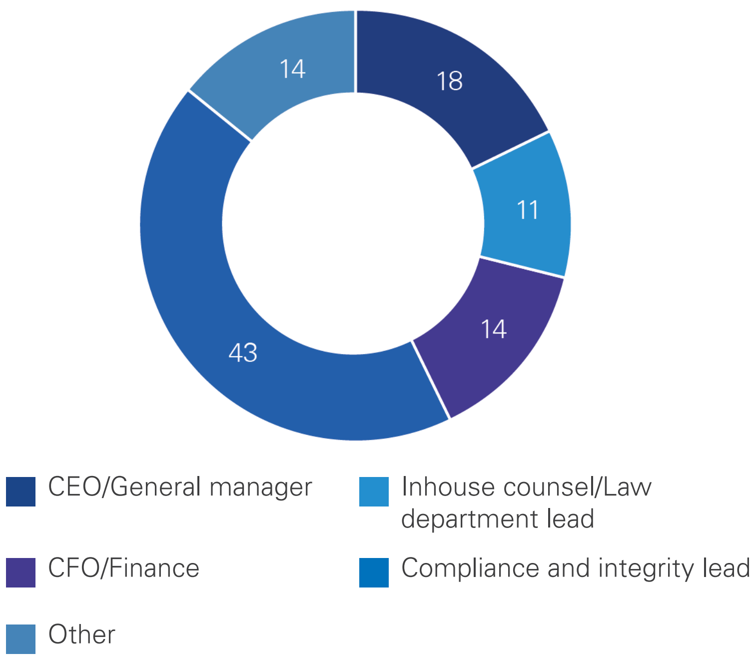
Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

Methodology and acknowledgements

In July 2020, KPMG launched the 2020 Middle East Life Sciences industry compliance survey on an online portal. Through October 2020, KPMG interviewed and/or obtained online responses from 28 regional industry leaders. Our sample predominantly comrpised multinational Life Sciences companies, as well as large regional manufacturors and distributors.

We would like to thank all business leaders for taking the time to participate in the survey.

Which of the following best describes your role?



Source: KPMG Middle East Life Sciences 2020 Industry compliance survey

About KPMG

For almost 50 years, KPMG Lower Gulf Limited has been providing audit, tax and advisory services to a broad range of domestic and international, public and private sector clients across all major aspects of business and the economy in the United Arab Emirates and in the Sultanate of Oman. We work alongside our clients by building trust, mitigating risks and identifying business opportunities.

KPMG Lower Gulf is part of KPMG International Cooperative's global network of professional member firms. The KPMG network includes approximately 227,000 professionals in over 146 countries. KPMG in the UAE and Oman is well connected with its global member network and combines its local knowledge with international expertise, providing the sector and specialist skills required by our clients.

KPMG is widely represented in the Middle East: along with offices in the UAE and Oman, the firm is well established in Saudi Arabia, Bahrain, Kuwait, Qatar, Egypt, Jordan and the Lebanon. Established in 1973, KPMG in the UAE and Oman employs 1,485 people across four offices, including about 100 partners and directors.

Our latest initiative, KPMG IMPACT, aims to help clients future-proof their businesses amid times of increasing focus towards issues such as climate change and social inequality. The goal is to help them achieve success across 17 major Sustainable Development Goals (SDGs) and become more resilient and socially conscious. For FY21, the firm has earmarked a global budget of USD 1.43 million for the initiative.

As we continue to grow, we aim to evolve and progress, striving for the highest levels of public trust in our work. Our values are:

Integrity: We do what is right.

Excellence: We never stop learning and improving.

Courage: We think and act boldly.

Together: We respect each other and draw strength from our differences.

For Better: We do what matters.

To meet the changing needs of our clients, we have adopted an approach aligned with our global purpose: Inspiring Confidence, Empowering Change. Our three pillars – exceptional quality of service, an unwavering commitment to the public interest, and building empowered teams – are the foundation of our firm.

Sources

i. *https://www.sec.gov/spotlight/fcpa/fcpacases.shtml*

ii *https://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml*

iii *KPMG Middle East Life Sciences 2020Industry compliance survey*

iv *https://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml*

v *https://asc.fasb.org/*

vi *https://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act*

vii *https://www.oatext.com/future-of-the-pharmaceutical-industry-in-the-gcc-countries.php#gsc.tab=0*

viii *https://gulfnews.com/business/abu-dhabis-adq-launches-healthcare-procurement-platform-rafed-1.1598971904345*

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Publication number: 3300

Publication date: March 2021