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CITELINE COMMERCIAL

09 Jul 2021 |

How Integrity Due Diligence In Lifesciences Is Changing Post COVID-19

Supply Chain Risk Management Now C-Suite Discussion

by Anju Ghangurde

Senior Kroll executive outlines sharp shifts in scope of integrity and reputational due diligence in the healthcare and life sciences sector post COVID-19, with investors now seeking "very micro" insights of target firms.

The pandemic may have brought with it growth opportunities for the healthcare and life sciences industry but it has also upped the intensity of a range of business risks, and investors are now looking at things via a different lens when it comes to integrity due diligence.

At a recent webinar, senior executives of Kroll, a leading global provider of services and digital products related to governance, risk and transparency, outlined the “massive shift” underway in the focus and questions being asked while undertaking such due diligence on a target entity as the “influencers” in the industry have evolved.

While questions were previously more “big picture”- around business practices, source of capital, R&D - post COVID-19 these have become “very micro,” said Tarun Bhatia, managing director and head of South Asia, Business Intelligence and Investigations for Kroll.

“And the type of questions and insights buyers and investors seek have become much more operational,” Bhatia indicated at the virtual event, entitled “Will the APAC Life Sciences Sector Get a Shot in the Arm in the Post-COVID-19 Era?” Earlier this year, Duff & Phelps announced plans to transition its company name to Kroll, which it acquired in 2018.

Reputation Risk

The Kroll executive recounted a recent engagement related to the diagnostics industry, where a client specifically wanted to know things such as the footfalls across key centers of the target firm and whether payments were happening in cash or through apps.

“They wanted to know if there was local influence to carry out lower RT-PCR tests, delay results or under-report [COVID-19] positive counts, because for the investor, if this was true, it would mean serious reputation risk,” Bhatia said.

Experts have previously noted how, amid the pandemic, things are at a watershed moment with respect to trust and expectations of investors - both governments as investors in health systems around the world and also private investors. Those investing in healthcare are seeking the prioritization of ethical business conduct, Andrew Blasi, director at law firm Crowell & Moring, had emphasized at an industry summit last year (*see side box).*

Pharma And Building Trust In The Healthcare Ecosystem

By Anju Ghangurde

22 Dec 2020

Biopharma and legal experts discuss at a recent summit the need for multi-stakeholder action to foster trust across the healthcare system. Capital is going to flow away from unethical organizations, one executive predicted.

Read the full article here

Meanwhile, addressing the Kroll webinar, *Cipla Limited*'s global chief financial officer, Kedar Upadhye, indicated that the firm’s broader objective is to improve its innovation index and investment opportunities have to be “margin-accretive and intelligent growth” and use an “intelligent” mix of organic and inorganic opportunities.

“If I do organic and margin-accretive innovation, then it’s a delight and value creation is very clear,” Upadhye said.

Inorganic opportunities may require firms to pay control premium, and also factor in synergies as well as competitive bidding for a target; the acquirer will have to leverage “goodwill” to generate synergies. “Cipla’s experience in this area [inorganic growth] is quite good. It’s not 10 out of 10 and every deal we’ve done has achieved its objective but we have done well especially in the tie-ups with global innovator firms,” the CFO added.

Social Media Activity

Strikingly, Kroll’s Bhatia also asserted that it is increasingly important for healthcare and life sciences companies to have a social media and a public relations response strategy, given that customers have become “very vocal and very real time” about their complaints. “It's important for corporates to now have a predefined response," Bhatia emphasized.

The scope of due diligence activity for a recent private equity deal, he indicated, included understanding how active the founder and the senior management was on social media, whether they were talking about things such as new drug launches and if their "communication was factual or was there mis-selling" and also the response time of the company if somebody raised a complaint or asked for access to a medicine.

"These are some new challenges in the digitized world that we are facing - a massive shift in how an investor today is looking at the industry," Bhatia added.

Other due diligence aspects in the fore in the post COVID-19 scenario include the "genuineness" of operations (the impact of the pandemic and on-ground validation of top-line and profitability), the dependence on third parties, potential regulatory risks and also the "comfort" with and migration towards technology.

Emerging Risks

The Kroll executive also highlighted a series of risks that have emerged for the healthcare and life sciences industry as it focused on solutions and maximizing opportunities that the pandemic presented, though in some instances it also lead to "losing control" on processes/people, which can have a far reaching impact on businesses, including on reputation.

While the pharmaceutical industry has typically had very strong processes around good manufacturing practices/storage practices, he referred to multiple assignments that his firm engaged in where "all of this went out of the window" and there were companies with "serious compromises" in the process.

"We have seen incidences where expired goods have been mixed with live goods and reused, destruction of expired batches took much longer because of the lock-down and storage of goods which need a particular setup was not available and companies had to live with it. And there are going to be regulatory implications because of this, which we have already started seeing for some companies."

Risks of counterfeits, third party fraud, breach of data privacy are some of the other emerging risks that firms are having to deal with.

Fake Online Pharmacies

Kroll's Bhatia also referred to the recent major operation by Interpol related to COVID-19 testing kits in Asia and Africa, where a large number of bogus online pharmacies were closed and hundreds of arrests were made and almost millions of dollars worth of counterfeits were tracked down.

> *"Greed tends to come into play whenever there are opportunities. We saw that in the financial crisis in 2007 and we've seen it in some form in 2020." - Tarun Bhatia, managing director and head of South Asia, Business Intelligence and Investigations, Kroll.*

Last month an operation coordinated by Interpol which involved police, customs and health regulatory authorities from 92 countries led to the closure or removal of 113,020 web links, including websites and online marketplaces that were targeting the sale of counterfeit and illicit medicines and medical products.

Fake and unauthorized COVID-19 testing kits accounted for over half of all medical devices seized during the week of action (18-25 May), which resulted in 277 arrests worldwide and the seizure of potentially dangerous pharmaceuticals worth more than $23m, Interpol said at the time.

"Greed tends to come into play whenever there are opportunities. We saw that in the financial crisis in 2007 and we've seen it in some form in 2020; especially when it happens ...because of health you feel much more worse about it," Bhatia noted, also referring to exploitative practices in India around supplies of the antiviral remdesivir. (Also see "*Gilead Keeps Close Eye On Stormy Remdesivir Situation In India*" - Scrip, 19 Apr, 2021.)

Last year, there were several instances of black-marketing by alleged middlemen cashing in on the situation as demand outstripped supply for remdesivir in India, while fake vials of the antiviral were another issue that enforcement agencies had to deal with.

Bhatia warned that many of these risks are emerging even as the bandwith of management of companies is stretched. "There's so much

India Remdesivir Black Market: Supply Gap May Normalize Soon, But No End To Greed

By Anju Ghangurde

20 Jul 2020

India generic remdesivir supply situation seen improving soon, with existing players Cipla and Hetero ramping up the antiviral and the arrival of new entrant Mylan. But will that be enough to control black marketing of the investigational COVID-19 therapy? The government is also keeping a close watch on the goings on.

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happening, where does the senior management, the board spend its time and many of these risks are slowly brewing underneath and could come and haunt some of the companies."

Supply Chain Now A C-Suite Topic

The post COVID-19 environment has also put the spotlight on supply chain risk management, which has "really come of age," Bhatia declared.

Clients now indicate that supply chain is has become a C-suite board level topic and is no longer an "operational discussion" anymore.

"That's a big shift that has happened. Prior to COVID-19, most companies really looked at their immediate set of partners; people would meet the top few vendors but that is changing," he added.

An uptick in contract disputes with force majeure clauses being enacted because of disruption and the economic downturn causing supplier financial risks which could lead to bankruptcy-led closure, are among a string of supply chain vulnerabilities that the executive listed in a presentation.

Merck & Co, Indian Firms On Tackling Supply Chain Risks And A Hijack

By Anju Ghangurde

26 Feb 2021

Merck & Co. executive outlines how the company could sustain a "compliant supply performance" amid the pandemic, while senior officials from Sun Pharma, Cipla, Zydus Cadila and Biocon shared insights on coping with supply chain turbulence and moving away from over-dependence on China for starting materials.

Read the full article here

Force majeure clauses in a contract typically absolve firms from liability in the event it cannot fulfill the terms of a contract for reasons beyond its control.