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REGIONAL RISK SPOTLIGHT

Managing Corruption Risks Facing Healthcare Companies in Eastern Europe

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The Eastern European market presents tremendous opportunities for healthcare and life sciences companies. Eastern European economies have been on a growth trajectory over the past decade and demographic changes and rising government and individual spending on healthcare have created a stable and growing market for healthcare goods and services. Their geographical proximity to the healthcare companies' Western European manufacturing bases and headquarters also makes them convenient markets to access.

But despite reform efforts, corruption continues to permeate the healthcare sectors of Eastern European countries, and a failure to address and mitigate sector-specific corruption risks can lead to enforcement action under local law or anti-corruption laws having extraterritorial effect, such as the U.K. Bribery Act and the FCPA, as well as reputational damage.

In this article, we discuss the key sector-specific risks facing healthcare companies operating or seeking to operate in Eastern Europe and outline mitigation steps for companies to consider.

See "[Canadian Health Science Company and Employee Settle Civil FCPA Charges in Failed Quest for Drug Distribution in Russia](#)" (Mar. 9, 2016).

Interactions With Healthcare Professionals

The relatively lower pay of healthcare professionals (HCPs) in Eastern Europe has always been a factor contributing to increased corruption risks in the region. Additionally, informal payments by patients to HCPs to ensure access to healthcare or preferential treatment appears to be an unshakable characteristic of the healthcare systems of many Eastern European countries.

Healthcare companies' improper interactions with HCPs have led to a number of high-profile enforcement actions in recent years. In 2014, Polish anti-corruption authorities charged 13 people (HCPs and a healthcare company's employees) in connection with the alleged bribery of HCPs to encourage promotion of the healthcare company's drug. The alleged bribes were recorded as payments for educational services, despite the HCPs clearly understanding that the payments were made to increase prescription of the healthcare company's drug. In 2013, Croatian authorities charged more than 350 people, including HCPs and a healthcare company's senior managers and employees, in connection with another alleged scheme to increase the prescription of the company's drugs. Alleged improper interactions with HCPs in Eastern Europe,

particularly Russia, Poland, Croatia, Bulgaria and the Czech Republic, have also been the basis for the DOJ and SEC bringing a number of FCPA enforcement actions against U.S.-based or U.S.-listed healthcare companies.

As in many jurisdictions, interactions with HCPs are often the cornerstone of healthcare companies' promotional and clinical research efforts. In Eastern Europe, a complex set of local laws and regulations (e.g., local advertising and anti-corruption laws), professional rules applicable to HCPs and codes adopted by industry associations, which cover activities such as sponsorships, research grants, advisory boards and other consultancy arrangements, regulate such interactions with HCPs. Recent national efforts by certain Eastern European countries to stamp out corruption have at times created contradictions within the regulatory regime.

For example, Ukraine's recently adopted anti-corruption law significantly restricts a healthcare company's ability to directly sponsor an HCP's attendance of a conference. In contrast, the code on pharmaceutical marketing practices of the local healthcare industry association adopts a more permissive attitude. Such compliance minefields of inconsistent rules can engender divergent market practices and different understandings of the "rules of the game" when it comes to interactions with HCPs.

Mitigation Steps

Healthcare companies should assess what corruption risks may arise from the nature of their specific interactions with HCPs in particular Eastern European countries. They should also obtain appropriate compliance advice on the international and

local regulatory regimes applicable to their interactions with HCPs in each Eastern European country in which they operate. The combination of the foregoing steps will allow healthcare companies to develop focused policies, procedures and internal controls to mitigate against the risk of corrupt misconduct by their local employees.

See "[A Guide to Identifying and Working With Quality Local Counsel](#)" (Apr. 4, 2018).

Distributors and Other Third-Party Relationships

The healthcare markets of Eastern European countries are fragmented. Differences in cultural approaches, languages, national currencies, regulatory regimes, market sizes and geographies necessitate reliance on local distributors, resellers, contract or toll manufacturers, consultants and other third parties. Third-party relationships are critical to a healthcare company's continued success in such markets. Absent a substantial and well-resourced local subsidiary, third parties are normally the conduit through which a healthcare company's critical interactions with local government agencies occur, including seeking product approvals or participating in government tenders.

Misconduct by such third parties has been a basis for numerous anti-corruption enforcement actions against healthcare companies in the United States and the United Kingdom. For example, in 2016, the DOJ and SEC resolved an FCPA enforcement action arising from a healthcare company's alleged engagement of third parties with links to influential government officials in Russia and Ukraine. The officials were alleged to have

influence over the approval and purchase of the healthcare company's drugs in those markets.

However, healthcare companies cannot eschew third-party engagements because market forces and strategic government intervention continue to drive healthcare companies' need to rely on local third parties. For example, individual Eastern European markets have seen tremendous consolidation of healthcare market participants in recent years. In each of Hungary, Slovakia, the Czech Republic, Romania, Poland and Bulgaria, the three largest distributors combined dominate segments of the healthcare market. Partnering with a strong local distributor allows a healthcare company to seize a substantial market share quickly, but the healthcare company risks exposure to substantial corruption risks, if it fails to adequately assess its distributor's business practices.

Such risks are acute for healthcare companies operating in Russia, where the government has in recent years taken legislative steps to push international healthcare companies to localize production of healthcare products by partnering with local manufacturers. Companies that import healthcare products may struggle to participate in government tenders. Localization, however, can present operational and third-party corruption risks similar to a joint venture.

See [“Teva's \\$519 Million FCPA Settlement Highlights Hazards of Local Production Requirements”](#) (Jan. 18, 2017).

Mitigation Steps

Pre-retention due diligence and control of third parties can substantially mitigate risk

for healthcare companies. As part of their pre-retention procedures, companies should take steps to understand the third party's business practices, communicate their own anti-corruption compliance expectations and, where possible, secure contractual protections including compliance undertakings in their engagement documentation.

Enforcement authorities also expect that a healthcare company will adopt procedures that enable it to conduct regular and appropriate monitoring and oversight of the third party during the course of the business relationship. Such procedures could include regularly monitoring the company's transactions with the third party, exercising any audit rights secured in engagement documentation on a risk-assessed basis, or providing compliance training to the third party.

See the Anti-Corruption Report's three-part series on enforcing audit rights, the next third-party-management frontier: [“What to Do Before an Audit”](#) (Nov. 9, 2016); [“Conducting an Onsite Audit”](#) (Dec. 7, 2016); [“Forestalling Problems, Documenting the Audit and Responding Appropriately”](#) (Mar. 1, 2017).

Monetary and Equipment Donations

Despite benefiting from growth in government spending, the healthcare systems of Eastern European countries continue to experience funding pressures, in part due to post-financial crisis austerity or efficiency demands. State-owned hospitals, clinics and institutions of medical education rely on monetary and equipment donations from healthcare companies to plug funding gaps and modernize their services, presenting conflicts risks that

need to be carefully managed. Healthcare companies may also feel an obligation to support local charities as part of their local corporate social responsibility programs.

Without a robust procedure for conducting due diligence on donations, which, at the very least, seeks to understand the purpose of the donation and identifies its recipient, a healthcare company could face substantial corruption risks. A 2004 SEC enforcement action is a salient reminder that healthcare companies should tread carefully where government officials champion local charities and charitable causes. In that action, the SEC resolved FCPA charges with a healthcare company relating to donations that the company made to a bona fide charitable foundation in Poland, allegedly to influence the director of the charity, who was also a government official, operating within the Polish healthcare system. More recently, in 2017, Polish authorities commenced an investigation in connection with a healthcare company's donation of medical equipment to a government hospital that later ended up at a for-profit private clinic.

Monetary or equipment donations can also create a perception of significant conflicts of interest or bribery concerns. In 2018, the Lithuanian anti-corruption authorities revealed an investigation into allegations that at least 10 major Lithuanian government hospitals were rewarding healthcare companies that provided donations to the hospitals with government contracts.

Mitigation Steps

Healthcare companies should assess what corruption risks may arise from the nature of their specific charitable activities in

a particular Eastern European country. Proportionate to those risks, healthcare companies should develop procedures that scrutinize the nature, purpose and recipient of any future donations. Healthcare companies should ensure that any charitable donations receive adequate review (where possible, by non-commercial personnel) to avoid any perception of a *quid pro quo*.

See "[Checklist of FCPA Issues to Consider Before and After Making a Charitable Donation](#)" (Apr. 29, 2015).

Public Procurement

Eastern European countries have historically witnessed flagrant corruption in and abuse of healthcare product procurement processes. The European Commission's 2013 Study on Corruption in the Healthcare Sector suggested that corruption in healthcare product procurement was most severe in the Czech Republic, Latvia, Croatia, Slovakia, Romania and Bulgaria. A number of pharmaceutical companies have faced FCPA enforcement actions in connection with alleged corrupt misconduct in state procurement of healthcare products in Eastern Europe.

Over the past decade, Eastern European countries have taken steps to bolster or centralize their procurement processes and increase transparency. Substantial corruption risks, however, remain, as these processes have not been universally successful. For example, a 2018 investigation by the Hungarian Audit Office discovered that several state hospitals and clinics flagrantly breached public procurement regulations applicable to them.

The local procurement authority's reliance on healthcare companies' product expertise

when formulating tender specifications further exacerbates corruption risks in tender activities. The European Commission's 2017 Updated Study on Corruption in the Healthcare Sector observed that such practices were particularly prevalent in smaller hospitals in Poland. Such close pre-tender interactions create a strong incentive for the healthcare company to take all possible steps to influence the drafting of the specifications and may also be perceived as creating an improper conflict of interest.

In certain Eastern European countries, corruption in the public procurement of healthcare services has been so endemic as to cripple the entire healthcare system. In Ukraine, the so-called "pharma mafia," a gang of private distributors and corrupt public officials, allegedly had such a strong grip on the healthcare distribution channel that kickbacks and corrupt payments devoured more than 40 percent of the government's healthcare purchasing spend, forcing Ukraine to outsource the procurement of certain healthcare products to international development agencies in 2015. Learning from Ukraine's experience, Moldova and Bosnia and Herzegovina subsequently entered into similar arrangement with international development agencies. In the meantime, the European Commission's 2017 Updated Study observed that the Romanian government's healthcare product procurement process showed signs of pervasive "state capture."

Mitigation Steps

The foregoing examples underscore the need for healthcare companies to take time to understand the public procurement processes in the Eastern European countries in which they operate and to assess the corruption risks

posed by them. A healthcare company should also consider how its local employees' targets and incentives interact with those risks. Even if the healthcare company participates in a tender indirectly, *e.g.*, through a distributor, the healthcare company should critically evaluate its distributors' business practices and commitment to anti-corruption compliance.

See the Anti-Corruption Report's three-part series on detecting and mitigating corruption risk when participating in public procurements: "[Understanding the Procurement Process](#)" (May 13, 2015); "[Steps to Take Prior to Entering into a Procurement Process](#)" (May 27, 2015); and "[Seven Steps to Take During and After a Procurement Process](#)" (Jun. 10, 2015).

Concluding Considerations

Healthcare companies should proactively address compliance risks for their subsidiaries and operations in Eastern European countries. In particular, despite genuine efforts over recent years to bolster anti-corruption legislation and enforcement, these countries continue to struggle with corruption issues. A culturally more permissive attitude toward corruption in the healthcare sector, reflected in the normalcy and prevalence of informal payments to HCPs to secure access to national healthcare systems, further exacerbates corruption risks.

While there are some commonalities in certain key anti-corruption risk areas presented by these countries, each country ultimately presents its own unique corruption risk profile. Healthcare companies should take time to assess those risk profiles through discussions with its employees on the ground. Replicating global compliance manuals and procedures

is an important first step in developing a compliance culture in a particular local operation. Embedding a corporate compliance program requires taking a proactive approach in understanding the incentives of, and business pressures and corruption risks faced by, the local teams.

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