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Novartis AG Settles SEC FCPA Action Involving China Subsidiaries' Improper Gifts, Travel and Entertainment Payments to Healthcare Providers

Executive Summary

On March 23, 2016, the U.S. Securities and Exchange Commission ("SEC") announced a settlement with Novartis AG ("Novartis") regarding alleged violations of the books and records and internal accounting controls provisions of the Foreign Corrupt Practices Act ("FCPA"), arising from activities in two of Novartis's indirect subsidiaries operating in China, Shanghai Novartis Trading Ltd ("Sandoz China") and Beijing Novartis Pharma Co, Ltd ("Novartis China," and, collectively with Sandoz China, the "Novartis Subsidiaries").¹ Specifically, the SEC alleged that employees of the Novartis Subsidiaries provided payments and other things of value to healthcare providers ("HCPs") in order to induce them to prescribe Novartis pharmaceutical products, and concealed the true nature of the payments in company records. Novartis neither admitted nor denied the SEC's findings.

Under the SEC's Cease-and-Desist Order (the "Order"), Novartis agreed to pay disgorgement of approximately \$21.5 million, prejudgment interest of approximately \$1.5 million, and a civil penalty of \$2 million, for a total of over \$25 million.

This case follows closely on the heels of recent FCPA enforcement actions by the SEC against SciClone Pharmaceuticals, Inc. and Bristol-Myers Squibb Company, two other multi-national pharmaceutical companies operating in China, for providing improper payments or benefits to HCPs, as well as a recent enforcement action against PTC Inc., a technology company, which similarly concerned payments and benefits given to Chinese government officials.² The continued SEC enforcement in this area underscores the need for multi-national corporations operating in China to institute carefully crafted gift, travel, and entertainment policies, as well as systems designed to monitor compliance with such policies and detect potential violations. Furthermore, these actions highlight the importance of performing effective due

¹ In the Matter of Novartis Ag, Exchange Act Release No. 77431 (Mar. 23, 2016), 2016 WL 1130574.

² See In the Matter of SciClone Pharm., Inc., Exchange Act Release No. 77058 (Feb. 4, 2016), 2016 WL 683571; In the Matter of Bristol-Myers Squibb Co., Exchange Act Release No. 76073 (Oct. 5, 2015), 2015 WL 5782426. See also In the Matter of PTC Inc., Exchange Act Release No. 77145 (Feb. 16, 2016), 2016 WL 683594.

diligence on third-party vendors, such as travel agencies and event planners, which are often the mechanisms by which illicit payments and inducements to HCPs appear to have been made.

Factual Allegations

According to the Order, from at least 2009 to 2013, certain employees and agents of the Novartis Subsidiaries conducting business in China made payments and provided things of value to influence foreign officials, principally HCPs,³ in order to increase sales of Novartis pharmaceutical products.

With respect to Sandoz China, the SEC alleged that, between 2009 and 2011, employees, with the complicity of certain managers, provided HCPs with things of value including gifts, improper sightseeing and vacations, and entertainment for family members of HCPs. Such expenses were falsely reported in the general ledger as legitimate employee expenses, sponsorships, conferences, medical studies, and marketing costs.

Specifically, the SEC alleged:

- Several supposedly educational events paid for by Sandoz China, and organized by local travel companies, were predominantly or completely comprised of recreational activities unrelated to business, such as an excursion to Niagara Falls, travel expenses for the spouses of HCPs, “walking around” money, and cover charges at a strip club; and
- Sandoz China employees provided payments (totaling approximately \$522,000 between 2009 and 2010) to HCPs for the stated purpose of collecting and analyzing patient medical data regarding a drug, while in reality such funds were used to financially reward HCPs who had prescribed the drug.

The SEC alleged similar conduct against Novartis China, where between 2011 and 2013, employees and agents, with the aid of complicit vendors, improperly induced HCPs to prescribe or recommend Novartis products, by making payments disguised as legitimate selling and marketing costs.

Alleged Violations and Resolution

The SEC alleged that Novartis, as a result of conduct perpetrated by the Novartis Subsidiaries, violated Section 13(b)(2)(A) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(A) by “failing to make and keep books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and disposition of assets of the issuer.” False entries initially recorded by the Novartis Subsidiaries were subsequently reported by Novartis in its consolidated financial statements.

³ As in prior enforcement actions, the SEC has—without discussion—characterized HCPs of state-owned hospitals and medical centers as “foreign officials,” in order to bring the alleged activity within the scope of the FCPA. *See, e.g.*, In the Matter of SciClone Pharm., Inc., Exchange Act Release No. 77058 (Feb. 4, 2016), 2016 WL 683571, at *1.

Further, the SEC alleged that Novartis violated Section 13(b)(2)(B) of the Exchange Act, 15 U.S.C. § 78m(b)(2)(B), because it “failed to maintain a system of internal accounting controls sufficient to provide reasonable assurances that within the China subsidiaries” assets were accessed and transactions were executed with management authorization, and that transactions were properly recorded. Specifically, the SEC found that Novartis did not employ sufficient internal accounting controls or anti-corruption compliance measures in connection with the use of vendors, failing to conduct sufficient training of its sales staff and managers to prevent and detect inappropriate payments, conduct proper due diligence on the vendors, and ensure adequate support for expenses.

The SEC noted that Novartis cooperated with the investigation and explained that Novartis had conducted its own “expansive review” of its relationships in China with travel and event planning vendors. That review revealed that a significant proportion of events for HCPs did not comply with existing Novartis company policies and procedures. Novartis also identified weaknesses in its internal controls over third-party vendor relationships and promptly took remedial action, including terminating and disciplining employees, suspending vendor relationships, overhauling its anti-corruption policies and procedures, reorganizing its compliance function, and eliminating the use of vendors to support external meetings.

In addition to the financial penalties, Novartis also agreed to issue non-public reports to the SEC, at no less than nine-month intervals during a two-year term, on the status of its remediation and the implementation of compliance measures.

Key Takeaways

This is the fourth settled enforcement action against a multi-national company operating in China announced in the last six months involving allegations of payments and inducements provided to foreign officials to increase product sales, under the guise of legitimate business expenses. Given the persistent regulatory interest in this area, multi-national companies should closely examine their anti-corruption compliance programs to ensure they have a robust systems of internal accounting controls, particularly in the areas of gifts, travel, and entertainment and the use of third-party vendors. While the use of third-party vendors can be entirely appropriate, policies and procedures should be designed to ensure that such vendors are not being used as a conduit for improper payments to government officials. Moreover, all such policies should be reinforced by periodic monitoring and auditing to ensure that the policies are working, and any violations are quickly detected and appropriately escalated.⁴

⁴ For additional details about these settlements and best practices in these areas, see *DOJ and SEC Pressure Test Accuracy of Self-Reporting and Cooperation in PTC FCPA Settlement*, Paul, Weiss, Rifkind, Wharton & Garrison LLP – Anti-Corruption & FCPA Practice Group Client Alert (Feb. 29, 2016), available at <https://www.paulweiss.com/media/3374177/29feb16fcpaalert.pdf>; *SEC Settlement Highlights Importance of Third-Party Agent Guidelines*, Paul, Weiss, Rifkind, Wharton & Garrison LLP – Anti-Corruption & FCPA Practice Group Client Alert (Feb. 25, 2016), available at <https://www.paulweiss.com/media/3365252/25feb16fcpaalert.pdf>; *SciClone Pharmaceuticals Settles FCPA Action Over China Business Practices*, Paul, Weiss, Rifkind, Wharton

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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& Garrison LLP – Anti-Corruption & FCPA Practice Group Client Alert (Feb. 16, 2016), available at <https://www.paulweiss.com/media/3351743/16feb16fcpaalert.pdf>; *SEC FCPA Action Against Bristol-Myers Squibb Highlights Importance of Addressing Red Flags and Compliance Gaps*, Paul, Weiss, Rifkind, Wharton & Garrison LLP – Anti-Corruption & FCPA Practice Group Client Alert (Oct. 8, 2015), available at <https://www.paulweiss.com/media/3188218/08oct15fcpaalert.pdf>.