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South Korea Fines Prominent Pharmaceutical Manufacturer in Latest Anti-Corruption Enforcement Efforts

In a sign that South Korea is ramping up its anti-corruption enforcement efforts, Korean authorities announced on April 27 that they plan to levy a $48 million fine against Swiss pharmaceutical giant Novartis International AG for allegedly bribing physicians to use its products. In addition to the fine, the Korean Ministry of Health and Welfare will also suspend state insurance reimbursements for several of Novartis' products. The fine and related penalties come eight months after Korean authorities indicted six current and former Novartis executives (along with over a dozen Korean doctors and editors of medical journals) for their role in the alleged kickback scheme, and seven months after South Korea implemented a sweeping new anti-corruption law.

Korean authorities allege that between 2011 and 2016, Novartis paid around $2.3 million in bribes to physicians, in the guise of funding of academic events, whereby Novartis would arrange for a scientific journal to host medical symposia and then would make cash "travel expense" payments to participating doctors. Novartis Korea was subject to a highly-publicized government raid last year, in which Korean prosecutors seized various documents and financial records from the company. Subsequently, Korean prosecutors criminally charged six current and former executives in August 2016, along with fifteen physicians and six medical journal publishers. Those individuals' criminal trials are currently underway. Novartis Korea issued a statement last week that it acknowledged and accepted the government's fine, further stating that "We do not tolerate misconduct and are continuing to invest significant efforts to fully embed a culture of compliance throughout our Korean organization."

This is not Novartis Korea's first domestic enforcement action. In 2011, Novartis and several other multinational pharmaceutical companies were fined by the Korea Fair Trade Commission ("KFTC") for providing travel, entertainment and gifts to medical professionals with the objective of increasing prescriptions. Novartis Korea paid a penalty of just over $2 million to resolve the KFTC action. However, in the aftermath of the KFTC's industry sweep, Korea introduced a "two-strike rule" intended to combat bribery in the health care sector: For a first violation, the South Korean Ministry of Health and Welfare ("MOHW") can delist a company's product from state reimbursement for up to one year, while a second violation can lead to permanent delisting. Per last week's announcement, MOHW has decided to suspend various formulations of Novartis' Alzheimer's Disease treatment Exelon and its chemotherapy drug Zometa for three months. The Ministry will continue to reimburse the company's other products, and it will announce its final decision on the penalty in May. In a parallel proceeding, the Korean Ministry of Food and Drug Safety had announced smaller fines and a similar three-month suspension of Exelon in March 2017. Media reports at the time suggested that the Korean government had responded to patient lobbying efforts to limit the number of suspended products, as adequate alternatives to some Novartis products did not exist in the Korean market.

Last week's announcement appears to be the most recent indication that South Korea is bolstering its anti-corruption enforcement efforts. In September 2016, Korea implemented an expansive new anti-corruption law, the Kim Young-ran Act, that is significantly broader than the U.S. Foreign Corrupt Practices Act in several respects. For example, the new Korean statute imposes strict liability for certain payments irrespective of corrupt intent; expands the definition of covered "public officials" to include journalists and private educators; and introduces corporate criminal liability for unlawful payments made by employees and agents.

In light of these recent initiatives, pharmaceutical, medical device, and other life sciences and health care companies operating in Korea are advised to: 1) Update their policies to reflect the changes in the Korean legal landscape; 2) Provide suitable training for personnel operating in South Korea or interacting with Korean public officials worldwide on the Kim Young-ran Act and associated health care compliance requirements; and 3) Continue to ensure they have adequate internal controls regarding the appropriate provision of gifts, hospitality, and educational support to health care professionals.

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