ROPES & GRAY

FOCUS ON GLOBAL HEALTH CARE COMPLIANCE

March 28, 2018

Spotlight on Korea

Introduction

Attorneys
Mimi Yang
Karen Oddo

Although historically U.S. regulators have not focused FCPA enforcement efforts in Korea to the same extent as other Asian jurisdictions such as China and India, multinational companies doing business in Korea, particularly in the life sciences space, should remain vigilant. In addition to the possibility of increased enforcement by U.S. regulators going forward, domestically, Korea has pursued an increasingly stringent and aggressive anti-corruption regime, marked by several high-profile enforcement actions as well as Korea's implementation of an expansive new anti-corruption law, the Kim Young-ran Act, in September 2016.

In its latest effort to battle corruption and increase transparency, Korea implemented the Sunshine Act, which requires pharmaceutical and medical device companies to establish and maintain an expense reporting system to track economic benefits provided to healthcare professionals ("HCPs") during a fiscal year. The obligation to implement the reporting system took effect on January 1, 2018, following adoption of the law in June 2017.

With the roll-out of the Sunshine Act marking a further uptick in Korea's efforts to strengthen its anti-corruption efforts, companies operating in the life sciences space in Korea should take appropriate steps to ensure compliance with local requirements, such as localizing their compliance policies and programs.

The Sunshine Act

Under Korea's Sunshine Act, pharmaceutical and medical device companies must collect and maintain records of economic benefits provided to HCPs, and prepare an aggregated expense report detailing the economic benefits provided during each fiscal year. Companies must generate aggregated expense reports within three months following the conclusion of its fiscal year, and retain expense reports for at least five years. Expense reports and relevant supporting documentation must be provided, if requested, to the Ministry of Health and Welfare ("MHW"), which may use such materials to investigate whether illegal kickbacks have been paid. There is no requirement that such reports be made public.

The MHW identified seven reporting categories: (1) samples; (2) clinical trials; (3) post-market surveillance; (4) product presentations to multiple medical institutions; (5) product presentations to a single medical institution; (6) academic conferences; and (7) price discounts. For product presentations, food, drinks, and souvenirs exceeding US$9 require reporting, while those under US$9 do not. However, no minimum threshold is required to trigger the reporting obligation for other economic benefits.

Regarding covered persons, companies must collect and keep records of economic benefits provided to a broad range of health care professionals, including physicians, pharmacists, dentists, traditional Korean medicine practitioners, nurses, midwives, founders of medical institutions, and individuals working with medical institutions for purposes of sales promotion.

Enforcement Trends

Signaling a continuing focus on domestic anti-corruption efforts, particularly in the life sciences industry, the Sunshine Act follows on the heels of several high-profile anti-corruption enforcement actions by Korean regulators. Such efforts include a US$48 million fine against Novartis International AG for allegedly bribing doctors to use its products in May 2017, and the criminal conviction of the top executive of one of the largest Korean companies.

It also follows the September 2016 implementation of the Kim Young-ran Act, which significantly expanded the scope of Korea's anti-corruption laws, imposing requirements that exceed the scope of the FCPA. Specifically, the Kim Young-ran Act criminalized the provision of "benefits" to any "public official" exceeding KRW 1 million (about USD $900) in a single instance, or KRW 3 million (about $2,500) in aggregate over a one-year period, regardless of whether benefits are provided in exchange for any particular business favor or in connection with the public official's duties. The Kim Young-ran Act also expanded the definition of public officials to cover a broader range of persons, including private educators and employees of state-owned enterprises, extended criminal liability to corporations for employee misconduct, and set caps on certain benefits offered for promotion of normal business and social relationships (KRW 30,000 (approximately US$25) for meals/drinks, KRW 50,000 (approximately US$41) for gifts, and KRW 100,000 (approximately US$82) for congratulatory or condolence payments at festive occasions and funerals).

While the Kim-Young-ran Act does not specifically target the pharmaceutical and medical device industry, it indicates that Korea is committed to eliminating corruption and improper payments. Korean regulators have long focused on potential corruption within the life sciences sector. In addition to the $US48mm fine levied against Novartis in May 2017, from 2007 to 2011, the Korea Fair Trade Commission ("KFTC") took extensive enforcement actions against the pharmaceutical industry, including global companies, and imposed numerous fines for "rebate" incentives provided to HCPs such as cash payments, lecture fees, and overseas sponsorships, which were deemed to be illegal incentives for increased prescriptions. The KFTC, and other Korean regulators, continue to investigate pharmaceutical and medical device companies for illegal rebates, improper payments, and related potential violations.

Given Korea's continued focus on rooting out improper payments and potential corruption, particularly in the life sciences sector, domestic enforcement actions are likely to increase.

Recommendations

To navigate through an increasingly difficult anti-corruption regime in Korea, pharmaceutical and medical device companies doing business in Korea should assess and update their policies, procedures, and internal controls to ensure they are localized to address Korean concerns, particularly with respect to travel, gifts and entertainment, and expense controls.

As part of this process, with respect to the Sunshine Act in particular, companies should ensure that their systems carefully and effectively track spend and other relevant data, and analyze their categories of spend and persons to which they provide economic benefits, to determine which expenditures and persons trigger a reporting obligation under the Sunshine Act. In addition, companies should ensure that they have robust internal controls in place, particularly with respect to the seven reportable categories of support for healthcare professionals, and the use of corporate credit cards in connection with such support. Finally, companies should provide training to appropriate personnel on the Sunshine Act, and monitor compliance on an ongoing basis.