Recent crackdown on medical rebates in Korea

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On 10 January 2013, the Seoul Central District Prosecutor's Office charged a Korean pharmaceutical company and its 12 employees for providing rebates of approximately KRW 4.8bn (US$4.8m) to hospitals. Some 100 doctors also have been subpoenaed for allegedly receiving rebates through third-party agencies.

This case is drawing substantial national attention, particularly because the rebates were paid by the market-leading pharmaceutical company on an unparalleled scale. This case illustrates how the scheme of providing rebates, or other illegal economic benefits, is becoming more sophisticated by the day. It also confirmed once again that, despite the aggressive enforcement action taken by the special joint investigation unit, which is specifically tasked with investigating medical rebates, the deeply entrenched rebate culture in the medical and pharmaceutical industry is still hard to eradicate in Korea.

One other recent rebate scandal uncovered last year by the special joint investigation unit resulted in indictment of 15 people, including the representative directors of two medical device agencies and officers of eight general hospitals, for violations of the Medical Device Act and the Medical Service Act. The special joint investigation unit unveiled a fraudulent rebate scheme for medical devices that defrauded the National Health Insurance Corporation of approximately KRW 1.7bn (US$1.5m). According to the prosecutors, the hospitals overcharged the National Health Insurance Corporation by deliberately inflating the prices of the medical devices sold by the agencies to the hospitals. The agencies took 40 per cent of the improper gains and the remaining 60 per cent were paid to the hospitals as rebates.

The foregoing cases bear great significance in many respects. Among other things, those cases are meaningful in that they mark two representative crackdowns on rebates after the introduction of the so-called 'dual punishment system'. In addition, it is noteworthy that the corporate entities were indicated for vicarious liability for the illegal rebates provided by its employees.

This article examines the dual punishment system and vicarious liability in criminal law context.

Dual punishment system

The dual punishment system is a new regulatory regime prohibiting and criminally penalising both the giver and recipient of rebates or other economic benefits provided for the purpose of promoting sales of drugs or medical devices. It was introduced in the recent amendments (which took effect as of 27 May 2010) to three major Korean laws governing medical and pharmaceutical affairs: the Medical Service Act; the Medical Device Act; and the Pharmaceutical Affairs Act.[1] These amendments essentially provide that medical professionals or pharmacists who receive any economic benefits for the purpose of promoting sale of a drug or medical device will be held criminally liable together with the givers of such economic benefits.

There are other Korean laws criminally punishing both the giver and recipient of rebates or other economic benefits, including the Korean Criminal Code which prohibits commercial private bribery as well as public official bribery. However, those other laws have limitations and loopholes in enforcement. For example, public official bribery is applicable only to persons who are, or are deemed as, public officials. Accordingly, doctors not working for, or employed by, a national hospital cannot be penalised for public official bribery under the Criminal Code. Such doctors can generally be punished for commercial private bribery under the Criminal Code; however, if a doctor is the sole proprietor of their medical practice, they would be off the hook from commercial private bribery. This is because one of the elements of private commercial bribery is that an improper payment be made to a person who is entrusted with conducting the business of another person. That is, a doctor who is a sole proprietor would not be viewed as a person entrusted with conducting the business of another person.

The recent amendments to the Medical Service Act, the Medical Device Act and the

Pharmaceutical Affairs Act introducing the dual punishment system have addressed the above limitations and loopholes in the legislation.

Not all rebates are illegal under the Medical Service Act, the Medical Device Act and the Pharmaceutical Affairs Act. Those laws provide a safe harbour for specifically enumerated economic benefits, including, among other things, sample products, support for academic seminars, support for clinical tests, product presentations, discount for costs in accordance with predefined payment terms and surveys after a product release. The safe harbour is similar to one of the affirmative defences provided for under the US Foreign Corrupt Practices Act.

Vicarious liability

It has been debated in Korea whether a corporate entity has capacity to commit a crime and, thus, could be criminally punished as a principal of a crime. The current majority view holds, and Korean courts have ruled, that a corporate entity cannot become a principal of a crime. This means that a corporate entity can be penalised only when vicarious liability is expressly provided for in the relevant criminal law.

The Korean Criminal Code is silent on the issue of vicarious liability and, therefore, a loophole exists in the Criminal Code which gets a corporate entity off the hook for its employee's illegal rebate. To fill the loophole, the legislature has enacted laws containing vicarious liability provisions. For instance, Article 97 of the Pharmaceutical Affairs Act and Article 55 of the Medical Device Act explicitly provide for corporate vicarious liability. Pursuant to such provisions, a medical device or pharmaceutical company could be criminally penalised for its employee's illegal rebate, and the two recent rebate scandals described in this article are cases in point.

A notable aspect about vicarious liability in Korea is that it is not strict liability. In this regard, the Korean Constitutional Court has held in recent cases that vicarious liability provisions themselves are not unconstitutional, while any vicarious liability provision imposing strict liability without requiring any specific fault on a corporate entity *is* unconstitutional. Based on the Constitutional Court's decisions, the Ministry of Justice amended many vicarious liability provisions to make them enforceable. Such measures include limiting the applicable scope of vicarious liability to cases where an employee committed a crime in the course of performing his or her duty, and exempting a corporate entity from vicarious liability if it is demonstrated that it has adequately supervised and fulfilled its duty of care over its employees. Consequently, a pharmaceutical company or medical device company can be held vicariously liable under the Pharmaceutical Affairs Act or the Medical Device Act for an illegal rebate provided by its employee in the course of performing their duty, unless the company could prove that it has discharged its duty to adequately supervise its employees.

Notes

1 Article 88-2 and 23-2 of the Medical Service Act, Articles 53, 13(3) and 18(2) of the Medical Device Act and Articles 94-2, 47(2) and 47(3) of the Pharmaceutical Affairs Act.