

September 17, 2012



Crackdown on Medical Device Rebates

On July 13, 2012, the Seoul Central District Prosecutors' Office charged and indicted 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. A special joint investigation unit tasked with investigating medical rebates uncovered a fraudulent rebate scheme for medical devices that defrauded the National Health Insurance Corporation of approximately 1.7 billion Korean Won (US\$1.5 million).

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% of the improper gains and the remaining 60% were paid to the hospitals as rebates. The payments were falsely recorded in the hospitals' books as "information fees".

This case is significant as it is the first crackdown on medical device rebates after the introduction of the "dual punishment system". The dual punishment system is a new regulatory regime prohibiting and criminally penalizing both the giver and recipient of rebates or other economic benefits provided for the purpose of promoting sales of drugs or medical devices. The dual punishment system was introduced in the recent amendments to the Medical Service Act, the Medical Device Act and the Pharmaceutical Affairs Act that took effect as of May 27, 2010. Specifically, the statutes were amended as follows:

- Articles 88-2 and 23-2 of the Medical Service Act were amended to state that medical professionals shall be criminally liable and punished if they receive improper economic benefits in connection with the selection or prescription of drugs or selection or use of medical devices;
- Articles 53 and 13(3) of the Medical Device Act were amended such that medical device manufacturers and other persons shall be subject to criminal liability if they offer economic benefits to a medical professional for the purpose of promoting sales; and
- Articles 94-2, 47(2) and 47(3) of the Pharmaceutical Affairs Act were amended to criminally

punish both (i) pharmaceutical companies that offer economic benefits to a pharmacist or other medical professionals for the purpose of promoting sales and (ii) pharmacists or other persons who receive from a pharmaceutical company an economic benefit given for promoting sales.

There are other Korean laws criminally punishing both the giver and recipient of rebates or other economic benefits, including the Criminal Code prohibiting commercial private bribery as well as public official bribery and the Monopoly Regulation and Fair Trade Act regulating unfair trade practices.

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 penalized 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 his medical practice, he 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. Moreover, in order to prosecute a rebate as an unfair trade practice under the Monopoly Regulation and Fair Trade Act, it should be proven that the medical device manufacturer or agency was coerced into providing the rebate. Thus, in cases where a medical device manufacturer or agency voluntarily pays rebates, it is not possible to prosecute such rebates under the Monopoly Regulation and Fair Trade Act.

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.

We would like to note that not all rebates are illegal under the Medical Service Act, the Medical Device Act and the Pharmaceutical Affairs Act. Similar to the affirmative defenses under the U.S. Foreign Corrupt Practices Act, the laws provide a safe harbor for specifically enumerated economic benefits that are provided for medical devices or pharmaceutical products. These include, among other things, sample products, support for academic seminars, support for clinical tests, product presentations, discounts for costs in accordance with predefined payment terms, and surveys after a product release.

If there is any question regarding the above, please contact us as set out below.

-
- | | | |
|----------------------------|-------------------|--|
| ● Tak-Kyun Hong | TEL : 02 316 4085 | E-Mail: tkhong@shinkim.com |
| ● Myong-Hyon (Brandon) Ryu | TEL : 02 316 4276 | E-Mail: mhryu@shinkim.com |
-