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China Establishes "Blacklist" for Alleged Bribes in the Pharmaceutical Industry

Based upon a growing concern by the Chinese government that bribery of doctors is on the rise, on June 30, 2010 the Ministry Of Health (MOH) released the Notice on Further Combatting Commercial Bribery in the Area of Drug Purchase and Sales (Notice).

The Notice requires each MOH local office (including city and district offices) to establish, by year end 2010, a system to track alleged commercial bribery violations occurring in its jurisdiction in connection with the purchase and sale of pharmaceutical products. Drug manufacturers, distributors and their representatives confirmed of paying commercial bribes will be included on a "blacklist" that will be released to the public.

The Notice leaves unanswered various key questions. Does the imposition of an administrative penalty suffice to confirm violation, or could a company be blacklisted during the pendency of an investigation? Does the prohibition against commercial bribes apply only as related to bribes paid to doctors, or does it include other health officials?

More significant are the sales restrictions imposed upon "blacklisted" parties. For a period of two years, the applicable MOH provincial offices (which are responsible for centralized drug procurement in provinces; lower-level agencies do not have this authority) and all medical institutions within such provinces will be prohibited from purchasing drugs and other

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pharmaceutical products and devices from a blacklisted party. It is unclear at this point if the penalties apply to both the sales representative and the company for which he/she works.

Under these new rules, each MOH local office will be required to report to the applicable provincial-level MOH office any commercial bribery case where such local office has conducted an investigation and concluded improper behavior occurred. A troubling aspect of the Notice is that it does not clearly specify the degree of finality required with respect to the local office's conclusion. Presumably, some sort of implementation regulations or practice guidelines will be developed.

As stated in the Notice, following confirmation by the agency charged with implementing antibribery laws and regulations or Party policies, entities or individuals who are found to have offered bribes in connection with drug purchases and sales should be included on the blacklist. Given that several agencies in China are empowered to enforce antibribery laws and regulations, depending upon the circumstances, this casts further doubt as to the standards that will be used to determine whether a party should be included on the blacklist.

To date, even in advance of the issuance of the Notice, a number of provinces in China, including Fujian, Hunan and Sichuan, have begun to establish blacklist systems. For example, we understand that in 2008 and 2009 24 enterprises were prohibited from selling their products to state-owned medical institutions in Fujian Province for a period of two years.

In addition to the establishment of the blacklisting provisions, the Notice mandates that local counterparts of the MOH and medical institutions severely punish doctors or other persons in a medical institution who are accepting bribes. The punishments for those who accept bribes but do not invoke criminal liabilities may include administrative warnings, deprivation of qualification for promotion or professional title recognition, or termination. Disciplinary sanctions may also be imposed on Party members. In a serious case, an offender's medical license could be suspended.

In a situation whereby criminal liability is triggered, local counterparts of the MOH and medical institutions are obligated to promptly transfer the case to applicable judicial bodies. In other words, the MOH and medical institutions now have an obligation to notify prosecutors if they believe that criminal laws may have been violated. Under the PRC Criminal Law, criminal penalties for commercial bribery can be as low as \$1,500 to

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\$29,000, depending on the circumstances.

The issuance of the Notice reflects the Chinese government's determination to strike down commercial bribery in the pharmaceutical industry. With the progression of medical reform in China, it is likely that more stringent measures will be taken in an endeavor to build a clean, transparent and effective medical system.

For more information on the Notice or to discuss China's pharmaceutical industry in general, please contact your principal Squire Sanders lawyer or one of lawyers listed in this Alert.

The information in this bulletin was compiled by the China offices of Squire, Sanders & Dempsey L.L.P.

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