

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

John Tan

Counsel, Shanghai
+86 (21) 6032 3188
jtan@reedsmith.com

Christine Liu

Associate, Washington, D.C.
+1 202 414 9200
ccliu@reedsmith.com

...or the Reed Smith lawyer with whom you regularly work.

China Life Sciences Regulatory Crackdown: September 10 Update

The regulatory enforcement environment in China remains tense, as both the Chinese government and media bring new actions and allegations against life sciences manufacturers in both the pharmaceutical and device sectors. We are seeing:

- Increased attention to medical device sector
- Enforcement actions spreading to smaller cities
- Continued pressure on pharmaceutical sector
- Reports of misconduct by local manufacturers
- Questionable vendors named

Reed Smith continues to monitor the life sciences regulatory and media environment in China and has prepared the following summary regarding recent developments.

Medical Devices

New Media Reports On September 6, *The 21st Century Business Herald*, a Guangdong newspaper, published a lengthy feature entitled **“The Underlying Causes of Excessive Medical Care,”** including an article entitled “The Artificially High Cost of Medical Devices: For Every Stent Implanted, Doctors Receive At Least 2000 RMB in Kickbacks.” *The 21st Century Business Herald* previously published anonymous allegations naming three multinational pharmaceutical companies as being engaged in the bribery of doctors in China.

The article alleges that medical devices are marked up 200 percent to 300 percent over their import price, with some being marked up as much as 1000+ percent. With respect to stents, the article claims that Chinese doctors frequently implant stents in patients who do not need them, or implant too many stents in patients in order to obtain kickbacks from manufacturers. The article claims that the import price of foreign manufacturers’ stents is 6000 RMB, which increases to 20,000 RMB when sold to the

consumer, of which the doctor receives 10 percent to 15 percent as a kickback.

The article also makes allegations regarding diagnostic tests and capital equipment. The article claims that a U.S. manufacturer's color blood flow imaging system was sold to a hospital for 980,000 RMB, of which up to 100,000 RMB was a kickback to the hospital director. The article alleges that although the Chinese government has implemented centralized purchasing for some medical supplies and devices, doctors are unwilling to use such products because they cannot receive kickbacks through the centralized purchasing process.

The article also alleges that hospitals systematically arrange CT scans and blood tests that are not necessary for patients, and that sometimes negatively impact patients' health, in order to generate more fees.

Enforcement Actions The Ministry of Commerce (MofCom) and National Development and Reform Commission (NDRC) may be gathering information on the medical device industry, potentially in preparation for an antitrust or anti-corruption investigation. On August 21, **Reuters reported** that the Chinese Association of Medical Device Industry (CAMDI)¹ is conducting a survey of member companies that asked for an unusual amount of detail regarding their pricing and business practices. One device manufacturer expressed concern that the survey was potentially being used to gather information for an investigation by authorities. CAMDI subsequently **issued a statement** acknowledging that it had received a questionnaire from MofCom and forwarded the questionnaire to some members, but denying that it had been formally entrusted by MofCom's antitrust division to do so. CAMDI also stated that the questionnaire focused on barriers to market entry, rather than on pricing and sales techniques. The NDRC and MofCom further **issued statements** denying that they were engaged in investigations specifically targeting the medical device industry, and denying that they had specifically entrusted CAMDI to conduct such investigations. The NDRC is currently conducting investigations of the automotive, jewelry, education, and pharmaceutical industries.

The NDRC appears to be becoming more aggressive in enforcing antitrust regulations. On August 21, **Reuters reported on a closed-door meeting between several U.S. multinational companies and the NDRC official.** According to anonymous sources who allegedly attended the meeting, an NDRC official pressured foreign companies' in-house lawyers to confess to violations and warned them against retaining counsel to defend against government investigations. The NDRC has targeted 60 pharmaceutical companies, including several multinationals, as part of an ongoing probe into pricing and cost-calculation issues in the industry. In August, the NDRC imposed a total \$110 million fine on six infant formula manufacturers, including five foreign manufacturers. This \$110 million total represents the largest fine in the history of Chinese anti-monopoly enforcement.

On August 29, **Kunming's local Ministry of Health announced** a special project to require Kunming hospitals to review the purchasing, quality, use, and tracking of implantable medical devices. This follows an August 15 **announcement** by the local Beijing Ministry of Health to conduct a similar review, as well as statements by the local Ministries of Health in **Xi'an** and **Shanghai** announcing reviews of the use of implantable medical devices and the quality management of physiotherapy medical devices, respectively.

Pharmaceuticals

New Media Reports *The 21st Century Business Herald* has published several articles on this topic, including the paper's previously mentioned **September 6 article** [<http://finance.sina.com.cn/china/20130907/043916693613.shtml>] on excessive medical care. This report also discussed the pharmaceutical sector, alleging that overprescription was caused in part by doctors supplementing their income with kickbacks from pharmaceutical companies. The article states that kickbacks on intravenous drip medications are higher than kickbacks on oral medications, leading to IV medication being a treatment of choice in Chinese hospitals. The article further alleges that if doctors prescribe medicines for a year or more, pharmaceutical companies will sponsor them on holidays or overseas trips. Finally, the article claims that kickbacks on formulated Chinese medicines are particularly common, at 20 percent to 30 percent, and that kickbacks on antibiotics are approximately 30 percent.

On September 10, *The 21st Century Business Herald* published allegations that a major local manufacturer of insulin paid close to 800 million RMB in bribes from 2008 to the present. Prior anonymous allegations published by *The 21st Century Business Herald* had focused on foreign pharmaceutical companies; this appears to be the first major media report of misconduct by a named local company.

Enforcement Actions On August 29, Kunming, the capital of Yunnan Province, **announced** an investigation into bribery and misconduct in the city's health care system. This announcement was notable for two reasons. First, prior enforcement actions had generally been focused on larger, coastal cities, whereas Kunming is a smaller, inland city. Additionally, the Kunming enforcement action involves the Public Security Bureau (PSB), or police. Prior investigations had mostly involved administrative, rather than criminal, enforcement agencies. (Chinese)

Previously, the local **Chengdu Ministry of Health and the Dalian Administration of Industry and Commerce (AIC)** had announced administrative actions targeting bribery in the pharmaceutical and medical services sectors.

Questionable Vendors During the course of media reporting on these matters, three travel agencies have been named as being potentially involved in misconduct: Linjiang Travel Agency; Kanghui Travel Agency; also known as China Comfort Travel Agency, and China Peace International Travel Agency. Media reports have also alleged that local pharmaceutical distributors have been involved in misconduct. Given the current enforcement environment, companies may wish to pro-actively review their vendor relationships.

This *Alert* is presented for informational purposes only and is not intended to constitute legal advice.

© Reed Smith LLP 2013.
All rights reserved. For additional information, visit <http://www.reedsmith.com/legal/>

1 The official name of the agency.