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China

China's Crackdown on Online Drug Sales Could Catch Device Companies by Surprise

BEIJING—Pharmaceutical and medical device companies in China could become unwitting targets of a recently launched campaign against the illegal sale and promotion of drugs over the internet if they are not properly qualified to post product information online, a practitioner told BNA Sept. 4.

The China Food and Drug Administration's Notice [2013] No. 123, dated July 29 and released on the CFDA's website Aug. 20, brings together the CFDA, the State Internet Information Office, the Ministry of Public Security, the Ministry of Industry and Information Technology (MIIT), and the State Administration for Industry and Commerce (SAIC) in a joint effort that runs through December.

While the main purpose of the five-ministry crackdown is to fight the illegal distribution of counterfeit drugs, companies that fail to comply with regulations about online sales or dissemination of drug and online medical device information also could face sanctions, said Nicolas Zhu, head of the life sciences sector of CMS China, a European law firm.

"These regulations are overlooked more often than not by in-house counsel and managers of companies," Zhu wrote in a law firm alert about the issue.

Medical Device Companies Unaware. The sale and distribution of drugs via the Internet is governed by a 2005 regulation, and the dissemination of online information about drugs falls under a 2004 regulation, Zhu told BNA.

CFDA's Circular [2005] No. 480, *Interim Provisions Regarding Pharmaceutical Transactions Over the Internet*, and Circular [2004] No. 9, *Measures Regarding the Management of Drug Information Services Over the Internet*, requires companies to obtain a qualification certificate from pharmaceutical regulators and register with internet authorities to either sell or disseminate drug information online, Zhu said.

Medical device companies in particular tend to be unaware of the two regulations because neither includes "medical devices" in the title, Zhu said. "The names of both of these regulations say only 'drug,' not 'medical device,'" Zhu told BNA, but the text of the regulations includes medical devices.

It logically follows that the recent crackdown also could encompass medical devices, Zhu said, adding that recent conversations he had in Shanghai with local regulatory officials confirmed that view.

Major Targets. There are 159 enterprises in China legitimately qualified to carry out online sales of pharmaceutical drugs, including 101 online enterprises that can sell directly to consumers, the CFDA said in a statement on its website Aug 26. However, due to the negative impact of illegal online drug sales, the legitimate online drug business is experiencing a crisis of consumer confidence, the CFDA statement said.

The campaign focuses on three categories of offenses: the online sale of counterfeit drugs, the sale or promotion of drugs online without proper qualifications, and using the internet to disseminate false information about pharmaceutical drugs, according to government statements. The crackdown phase of the campaign will run from September to November, and CFDA will seek to identify major cases and expose a number of illegal sites, the CFDA notice said.

"Major targets" include drugs for treating cancer, sexual dysfunction, heart disease, high blood pressure, and diabetes, according to the CFDA notice.

Diabetes is now more prevalent in China than in the United States, with 12 percent of adults having the disease, according to a study published in the *Journal of the American Medical Association* on Sept. 3.

Check for Compliance. In light of the crackdown and increased scrutiny from authorities, pharmaceutical and device companies should review their eligibility for online activities and make sure the qualifications and registrations they have match their business scope, Zhu said. Companies in serious violation of the regulations could have their websites closed.

Companies that display any type of information about a drug or medical device on their websites need to have a qualification certificate and must display the qualification certificate number online, Zhu said.

"We strongly advise pharmaceutical companies who are disseminating pharmaceutical information or selling pharmaceuticals on the Internet to immediately check whether they have duly obtained the relevant qualification certificates and also accomplished their ICP registrations," Zhu wrote in the law firm's alert. "Medical device companies should also take the precautionary step of checking their qualification certificates and eligibility even though medical device companies do not appear to be the priority target of the campaign."

By LESLIE A. PAPPAS

The Aug. 20 announcement from the agency, with a link to Notice [2013] No. 123 can be found in Chinese at <http://www.sfda.gov.cn/WS01/CL0050/83373.html>.

Circular [2005] No. 480, Interim Provisions Regarding Pharmaceutical Transactions Over the Internet, can be found in Chinese at <http://www.sfda.gov.cn/WS01/CL0060/9432.html>.

Circular [2004] No. 9, Measures Regarding the Management of Drug Information Services Over the Internet, can be found in Chinese at <http://www.sfda.gov.cn/WS01/CL0053/24486.html>.