



# Regulation of Drug Promotion in China

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**D**rug promotion presents a challenging dilemma for regulatory authorities. On one hand, advertising and promotion are important sources of drug information. Physicians report that they often use promotion as a source of information about new drugs and this reliance increases the further along they are in their medical careers. In developing countries, drug promotion is particularly crucial. Drug company sales representatives are often the most important source of information about new medicines and studies have found that physicians rely heavily on industry-based sources of information.

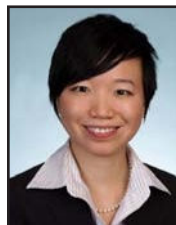
On the other hand, there are safety, public health and economic concerns over inappropriate promotion of drug

use. Studies have shown that heavy promotion of new drugs can lead to misprescribing and overprescribing of drugs and can cause serious safety concerns. The promotion of newer, more expensive drugs can also lead to the displacement of older, less costly drugs without any evidence that the newer drugs are more effective.

A regulator must balance between encouraging promotion as a valuable tool to disseminate drug information and policing it to ensure its reliability and honesty. Such a balance act presents several challenges. First, it can be difficult for a regulator to distinguish between reasonable and appropriate promotion and unethical and inappropriate promotion. Second, regulators often have limited authority, and correspondingly



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limited resources to regulate and enforce. Compared to the almost \$28 billion that was spent on promotion in 2010 in the United States alone,<sup>2</sup> government resources are limited. The regulator's task is made even more difficult by the diversity of forms in which promotion can occur, including sales representatives, samples, broadcast and print media, sponsorship of educational events and conferences, books, journal articles, magazine and newspaper stories, drug bulletins and newsletters, videos, and the internet. Finally, there is a variety of opinion on drug promotion, with different groups—manufacturers, advertisers, media, doctors and patients—having very different views and interests.

## Overview

China regulates the promotion and advertisement of drugs by two main statutes, the Advertisement Law (“AL”), promulgated in 1994, and the Drug Administration Law (“DAL”), promulgated in 2001, and the implementing and administrative regulations under these statutes. Similar to the roles of FDA and FTC in the United States, on the national level, the China Food and Drug Administration (“CFDA”) and the State Administration for Industry and Commerce (“SAIC”) have concurrent jurisdiction over drug promotion, though SAIC often defers to SFDA's greater scientific and pharmaceutical expertise. On the provincial level, the regulatory authorities are the provisional food and drug administrations (“PFDA”) and the local Administrations for Industry and Commerce (“AIC”).

Until recently, CFDA was under the Ministry of Health and was known as the State Food and Drug Administration (“SFDA”). As the result of the recent restructuring of the central government of China in March 2013, the Ministry of Health no longer exists. Instead,

the Chinese government has created a Commission for Health and Family Planning. CFDA is now a ministry-level agency headed by Mr. Zhang Yong, who was appointed on March 22.

The regulation of drug promotion is currently dichotomous. The government closely oversees drug advertisements with clear rules on forum and content and with established penalties for violations, but largely ignores non-advertising drug promotion. There are no regulations or standards for such promotion other than the general consumer protection requirement that promotion not be false and misleading, the violation of which carries limited administrative penalties.

China's biggest regulatory challenge is that it has a relatively underdeveloped regulatory regime, but is faced with a high degree of regulatory non-compliance. In 2012, CFDA found over 179,000 illegal drug advertisements. In comparison, FDA's Office of Prescription Drug Promotion issued 28 Warning Letters regarding unlawful promotion in 2012. Because non-advertising drug promotion is largely unregulated in China, few enforcement actions have been reported.

## Regulation of Advertising

One of the main differences between the United States and China with respect to the regulation of drug advertising is that China prohibits direct-to-consumer (“DTCA”) advertising for prescription drugs. Because there is a constitutional right to commercial free speech in the United States, pharmaceutical companies are allowed to advertise to consumers. Though such advertisements are subject to regulatory standards—including that the speech be neither false nor misleading—these standards are subject to “heightened” scrutiny review from U.S. courts. China, like most industrial nations, bans DTCA because of safety and

public health concerns over the effect of such advertising on consumer behavior.

China's rules on the advertisement of over-the-counter (“OTC”) drugs are more permissive. For example, OTC drug advertisements are permitted on any kind of media including the internet, although pre-approval is required.<sup>3</sup> CFDA has considered prohibiting DTCA of OTC drugs. In 2012, the agency prepared a proposal to amend the Measures for Drug Advertisements, but was strongly opposed by OTC drug manufacturers.<sup>4</sup> In light of this industry opposition, the fate of the proposal remains unclear.

Advertisements of prescription drugs are limited to state-approved medical and pharmaceutical professional publications. Two departments under the State Council—the administrative department for health (until recently, the Ministry of Health) and the drug regulatory department (currently, the CFDA)—jointly designate the list of approved publications. This joint administration is likely to change as a result of the recent promotion of CFDA into a ministry-level agency, with the new agency gaining full authority.

China also strictly regulates advertisement content and requires approval prior to launch. Under Section 60 of the DAL, drug advertisements, whether for prescription or OTC drugs, must be pre-approved by the PFDA of the province, autonomous region or municipality in which the applicant is located.

The main content requirement for drug advertisements is that the statements be true and legitimate and be based on information included in the approved package insert.<sup>5</sup> Prohibited statements include safety or efficacy comparisons with other drugs or descriptions of rates of effectiveness (e.g., cure rates).<sup>6</sup> In addition, advertisements must include the drug's

generic name, the advertisement approval number, the drug manufacturing approval number, and other specific statements. If the drug is a prescription drug, the advertisement is required to state that “this advertisement is only for medical or pharmaceutical professionals.”<sup>7</sup> If the drug is an OTC drug, the advertisement is required to state “please purchase and use in accordance with the drug instructions or under the guidance of pharmacist”<sup>8</sup> and to include the symbol for OTC.<sup>9</sup>

Even though advertising is strictly regulated, vague statutory language, relatively light penalties, and government resource constraints limit enforcement.

The term “advertisement” is not clearly defined in the AL, and not defined at all in the DAL. The AL defines the term as “commercial advertisements that publicize, directly or indirectly and through certain media or forms, some kind of commodities or services at the expense of the suppliers of the commodities or services.”<sup>10</sup> In addition to being self-referential, the definition provides no clear distinction between advertising and non-advertising promotion. Self-printed flyers have been regulated as drug advertisements.<sup>11</sup>

Under Chinese law, the administrative penalties for launching drug advertisements without pre-approval from the appropriate PFDA are limited to: (i) the issuance of an administrative order to stop advertising, (ii) the confiscation of funds or fees for the advertisement, (iii) the issuance of a fine of one to five times the advertisement fee,<sup>12</sup> (iv) the temporary suspension of drug sales regionally or nationally, and (v) the issuance of public notice about the violation.<sup>13</sup>

While the temporary suspension of sales can be a major deterrent, the sanction is only required—and in practice, is only imposed—when unapproved drug

advertisements promote off-label uses, seriously exaggerate efficacy or seriously mislead consumers.<sup>14</sup> Suspension of sales is typically lifted once the manufacturers or distributors make the required corrective statements on local television or in newspapers. For example, Jiangsu’s PFDA removed its sales suspension two months after the manufacturer made corrective statements in two newspapers.<sup>15</sup>

Penalties (i) to (iii) can be administered by the SAIC or the local AICs, while the remaining two penalties can only be issued by the CFDA or the PFDA. Because the CFDA and the PFDA have greater industry expertise and knowledge, in most cases, they investigate drug advertisement violations. Where the authority to implement the desired penalty rests with the AICs, the CFDA or PFDA will transfer the case to the local AIC to administer the penalty.

Criminal penalties can be imposed for “false advertisement” if manufacturers make a significant illegal profit or cause significant harm to consumers, or there are other serious circumstances.<sup>16</sup> Penalties under Article 222 of the Criminal Law include a criminal fine and/or up to two years of imprisonment. There have been few reported criminal prosecutions for false drug advertising, and even fewer reported convictions. For example, in 2012, three individuals were prosecuted in a case reported to be the first criminal prosecution for televised false drug advertising in China.<sup>17</sup> It is unclear whether there has been a conviction in that case.

Because advertisement pre-approval and, to some extent, enforcement is conducted at the provincial rather than at the national level, differences in provincial resources and government competence result in disparate levels of regulation and enforcement. Generally speaking, however, regulators are

becoming more active. In the past five years, PFDA has suspended the sales of an increasing number of drugs for launching prohibited advertisements.<sup>18</sup>

## Regulation of Non-Advertising Promotion

Because DCTA is banned, and advertising in professional journals strictly regulated, most promotion of prescription drugs in China takes the form of non-advertising promotion.

Unlike in the United States, there are no specific legal requirements for non-advertising promotion of drugs. In the United States, there are detailed requirements for advertising and promotional labeling. They must: (1) not be false or misleading, (2) present a “fair balance” of information describing both the risks and benefits, (3) include facts that are “material” to the product’s uses, and (4) include a “brief summary” that mentions risks described in the product’s labeling.

In China, there is only a general requirement under consumer protection laws that promotion of any merchandise not be false *and* misleading.<sup>19</sup> Though this requirement appears similar on the surface to the U.S. requirements, they are not the same in practice. The main difference is that there is no law or regulation that requires promotional information to include material facts or to present balanced information.

While the SAIC has not issued any significant guidance on what constitutes “false *and* misleading,” China’s Supreme People’s Court has stated in a judicial interpretation that the following types of promotions may be considered false *and* misleading: (a) a one-sided promotional introduction of a product; (b) presentation of inconclusive scientific theories or phenomena as if they were conclusive; and (c) use of

any other misleading methods in a promotion.<sup>20</sup> The judicial interpretation also states that promotional information that is clearly exaggerated so as to not mislead the public is not considered misleading promotion.

In contrast to the high potential penalties that are available in the United States under the FDCA misbranding provisions, sanctions are limited for promotional violations in China. SAIC and the local AICs only have the power to levy an administrative fine of between RMB 10,000 to RMB 200,000 (about USD1,600 to USD32,000) for false *and* misleading promotion.<sup>21</sup> There is no criminal penalty for non-advertising promotion of drugs.

Faced with the lack of regulation, the industry group, R&D-based Pharmaceutical Association Committee in China (“RDPAC”), has drafted a voluntary self-regulatory code. The code imposes restrictions on “promotion,” defined as “any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply administration or consumption of its pharmaceutical products through all methods of communications, including the internet.”<sup>22</sup> Article 4.2 of the code states that promotional information should be “clear legible, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion of . . . therapeutic value . . .” Because the code is voluntary, and there are currently less than forty members in RDPAC, the self-regulation is unlikely to have a market impact.

## Conclusion

To curb inappropriate drug promotion, China relies on a blunt ban on DTCA for prescription drugs and a strict pre-approval requirement for all drug advertisement, but largely ignores non-advertising promotion. Review and

enforcement are mostly conducted at the provincial level, and not all provinces have the resources or expertise to monitor advertising activities. Because of these resource constraints, and the relatively light legal penalties available for advertising violations, illegal drug advertisements are common in China. Unethical non-advertising promotion is also common due to the lack of regulation. ▲

1. Rachel Kornfield, *et al.*, *Promotion of Prescription Drugs to Consumers and Providers, 2001-2010*, PLoS ONE (2013), available at <http://10.1371/journal.pone.0055504>.
2. See Huijianwang yaopin xinxi fuwu guanli banfa [Measures Regarding Internet Information Services for Drugs] (promulgated by CFDA, May 28, 2004, effective July 8, 2004), art. 10 (P.R.C.), available at <http://www.sfda.gov.cn/WS01/CL0053/24486.html>.
3. See [http://www.cnma.org.cn/sy\\_Infos.asp?id=973](http://www.cnma.org.cn/sy_Infos.asp?id=973).
4. Yaopin guanli fa [Drug Administration Law] (promulgated by Standing Comm. Nat'l People's Congr., Feb. 28, 2001, effective Dec. 1, 2001), art. 61 (P.R.C.), available at <http://former.sfda.gov.cn/cmsweb/webportal/W45649037/A48335975.html>.
5. *Id.* See also Guanggao fa [Advertisement Law] (promulgated by Standing Comm. Nat'l People's Congr., Oct. 27, 1994, effective Feb. 1, 1995, art. 14, LAWINFOCHINA (last visited March 3, 2013) (P.R.C.).
6. Yaopin Guanggao Shencha Fabu Biaochun [Standards of Review of Applications for Drug Advertisements], art. 8.
7. *Id.*
8. *Id.* art. 7.
9. Advertisement Law, *supra* note 4, art. 2.
10. See Bulletin Publicizing Violations of Rules on Advertisements for Health Food, Drug and Medical Device, available at <http://www.sfda.gov.cn/WS01/CL0085/>.
11. Advertisement Law, *supra* note 5, art. 43.
12. Weifa guanggao gongshi zhidu [Establishment of the Publicity System for Illegal Advertisements] (promulgated jointly by CFDA, SAIC, the Ministry of Health and a number of other government agencies, Nov. 21, 2006), available at [http://www.law-lib.com/law/law\\_view.asp?id=181703](http://www.law-lib.com/law/law_view.asp?id=181703).
13. Yaopin guanggao shencha banfa [Measures for Review of Applications for Drug Advertisements] (promulgated by CFDA, May 1, 2007), art. 21, available at <http://eng.sfda.gov.cn/WS03/CL0768/61649.html>.
14. See Jiechu zanting xiaoshou yi qi congming wan de gonggao [Notice of removal of sales suspension of “yiqi conming” pills] (promulgated by Jiangsu PFDA, Jan. 31, 2012), available at [http://www.jsfda.gov.cn/art/2012/2/1/art\\_325\\_95908.html](http://www.jsfda.gov.cn/art/2012/2/1/art_325_95908.html).
15. See Criminal Law, Art. 222; see also Zuigao renmin jianchayuan, gongan bu guanyu gongan jiguan guanxia de xingshi anjian lian zhuisu biaozhun di guiding [Supreme People's Procuratorate and the Ministry of Public Security's Prosecution Standards for Criminal Cases under the Jurisdiction of the Public Security Organs], art. 75, available at <http://www.mps.gov.cn/n16/n1282/n3493/n3778/n4303/2417768.html>.
16. See [http://zqb.cyoil.com/html/2012-06/28/nw.D110000zqgnb\\_20120628\\_1-08.htm](http://zqb.cyoil.com/html/2012-06/28/nw.D110000zqgnb_20120628_1-08.htm).
17. See Jiangsu zanting xiaoshou “nu jin dan wan” deng qi zhong weifa guanggao yaopin (Jiangsu suspends sales of seven drugs that violate drug advertisement laws), CHINA MED. REP., available at <http://www.chinamsr.com/2012/0703/52820.shtml>.
18. Xiaofei zhe quanyi baohu fa [Law on the Protection of Rights and Interests of Consumers] (promulgated by the Standing Comm. Nat'l People's Congr., Oct. 31, 1993, effective Jan. 1, 1994), arts. 19, 50, LAWINFOCHINA (last visited March 3, 2013); see also Fan bu zhengdang jingzheng fa [Anti-unfair Competition Law] (promulgated by the Standing Comm. Nat'l People's Congr., Sept. 2, 1993), art. 9, LAWINFOCHINA (last visited March 3, 2013).
19. 20 Guanyu shenli bu zhengdang jingzheng minshi anjian yingyong falu ruogan wenti de jieshi [Judicial Interpretation on Application of Anti-Unfair Competition Law at Trials] (issued by Sup. People's Ct., Jan. 12, 2007), art. 8, available at [http://www.court.gov.cn/qwfb/sfjs/201006/t20100609\\_5953.htm](http://www.court.gov.cn/qwfb/sfjs/201006/t20100609_5953.htm).
20. See Anti-unfair Competition Law, *supra* note 18, art. 24.
21. RDPAC Code, art. 1.2