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China's Newly Launched Medical Representative Registration System: Interim Compliance Recommendations for Multinational Pharmaceutical Companies

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On September 30, 2020, the National Medical Products Administration released its *Administrative Measures for the Registration of Medical Representatives (for Trial Implementation)* (the "Measures"), which will become effective on December 1, 2020. The long awaited release of the Measures constitutes China's most recent step in reforming the country's nationwide medical and health framework, since those efforts began in 2009.

Significantly, these new Measures impose obligations on drug marketing authorization holders ("MAHs") and their designated domestic agents to register and manage all medical representatives acting on their behalf, including their own employees and those employed by contract sales organizations ("CSOs"). The Measures also explicitly prohibit medical representatives from engaging in certain activities that may be undertaken by sales representatives employed by, or acting on behalf of, multinational pharmaceutical companies operating in China. Pharmaceutical companies operating within mainland China will need to evaluate how these Measures may affect their sales and marketing activities in the country, and may need to adjust their promotional practices and relationships with CSOs going forward to comply with the new requirements.

Background

In February 2017, the General Office of the State Council released the *Several Opinions on Furtherance of Reform and Improvement of Drug Production, Circulation and Use*

Policies (the “Opinions”). At the national level, the Opinions proposed three reforms related to the activities of medical representatives, including: (1) requiring food and drug supervisory and regulatory authorities to enhance their oversight of medical representatives and to establish a medical representative registration and filing system; (2) separating academic promotional activities from sales activities; and (3) reflecting illegal promotional activities in the individual credit records of implicated medical representatives.

Following the release of the Opinions, the China Food and Drug Administration and National Health and Family Planning Commission (both of which have now been consolidated under China’s State Administration for Market Regulation) published a first draft of the Measures for public comment in December 2017, and a second draft in June 2020. At the local level, cities such as Shanghai and Tianjin also issued their own draft requirements suggesting that a local medical representative registration system would soon be created.

The final draft Measures, which are due to take effect on December 1, represent a milestone in implementing a system to regulate the activities of medical representatives.

The Scope of the Measures

Medical representatives are broadly defined as professionals who act on behalf of MAHs by transmitting, communicating, or collecting feedback information about drugs. Under the Drug Administration Law, MAHs include companies or drug research and development institutions that have obtained a drug registration certificate.

The Measures further specify that “medical representatives” includes all individuals involved in academic promotional activities on behalf of any MAHs, including those who: (1) create plans and strategies for the promotion of medical products; (2) transmit medical product information to health care providers (“HCPs”); (3) assist HCPs in using medical products; and (4) collect feedback on the clinical use of the products and information regarding supply demand at hospitals.

As discussed above, the new Measures explicitly prohibit all medical representatives from "undertaking drug sales tasks and engaging in sales activities". The Measures do not provide clear definitions for "sales tasks" or “sales activities”. However, the Measures provide examples of prohibited “sales activities”, including collecting payment and dealing with purchase/sales invoices. The regulation is also silent on

whether MAHs may use sales-related key performance indicators ("KPIs") to evaluate the performance of medical representatives. Enforcement agencies are expected to clarify these ambiguities in the near future.

Additional Requirements for MAHs

The Measures impose several requirements on MAHs, including that they register and manage the personal information of medical representatives on the China Pharmaceutical Association's platform. The Measures specifically emphasize that a foreign MAH (*e.g.*, a *multinational* pharmaceutical company) must comply with these requirements through its designed domestic agent and provide that a foreign MAH and its domestic agent will be jointly and severally liable for failure to fulfill the obligations.

Importantly, the Measures require MAHs to register medical representatives employed by third parties, including contract sales organizations ("CSOs"), who are authorized by MAHs to act on their behalf. Extending this registration requirement beyond medical representatives directly employed by MAHs is a significant additional requirement for multinational pharmaceutical companies operating in China. It is yet unclear how MAHs will comply with this requirement. Nevertheless, pharmaceutical companies should evaluate the monitoring and management of CSO employees acting on their behalf.

Finally, the Measures also require MAHs take action if they discover that a medical representative working on their behalf engages in prohibited conduct. The required action includes remediation; suspension of the representatives' authorization to work on behalf of the MAH; enhanced employee training; and a requirement that affected employees pass a re-evaluation before authorizing them to work on behalf of the MAH again.

Permitted Academic Promotional Activities

The Measures provide that medical representatives may carry out academic promotional activities through (1) in-person meetings with HCPs at medical institutions, (2) organizing academic meetings and lectures, (3) providing academic materials, (4) communications through the Internet or telephone, and (5) other activities agreed to by individual medical institutions.

However, as discussed in more detail below, the Measures emphasize that medical representatives who are not registered, as required under the Measures, are not allowed to carry out even these approved categories of academic promotional activities. Further, registered medical representatives are required to obtain consent from each medical institution before conducting any promotional activities with that institution's HCPs. The Measures do not provide specifics regarding how MAHs should obtain consent from medical institutions to conduct promotional activities and is silent on whether implicit consent is permissible.

Prohibited Activities by Individual Medical Representatives

The Measures explicitly prohibit individual medical representatives from engaging in seven categories of activities. These prohibited activities include some of the common job responsibilities of sales representatives in China. The Measures specifically prohibit medical representatives from:

1. Engaging in academic promotional activities conducted by medical representatives who are not registered and filed as required by the Measures;
2. Engaging in academic promotional activities carried out without the consent of the relevant medical institution;
3. Undertaking drug sales tasks, engaging in sales activities or conduct, including collecting payment and dealing with purchase/sales invoices;
4. Counting the number of prescriptions issued by individual HCPs;
5. Directly providing donations, financial aid, or sponsorships to individual HCPs or internal departments of medical institutions;
6. Misleading HCPs about the use of drugs; exaggerating or misleading HCPs about a drug's curative effects; concealing a drug's known adverse effects; or concealing adverse event information from HCPs; and
7. Other conduct that interferes or influences the proper clinical use of drugs.

Two of these prohibited activities are particularly notable for multinational companies operating in China. *First*, although various previous laws and regulations have prohibited giving direct benefits to HCPs, the Measures *explicitly* prohibit medical representatives from directly giving *sponsorships* to individual HCPs. Similarly, the Measures clarify that donations, financial aid, or sponsorships may not be offered to internal departments at medical institutions in addition to individual HCPs or individuals in charge of procurement. By prohibiting the direct giving of sponsorships to internal departments as well as individual HCPs, the Measures may require some pharmaceutical companies to adjust their sponsorship procedures.

Second, the Measures explicitly prohibit medical representatives from participating in the counting of prescription data for individual HCPs. In 2013, China's National Health and Family Planning Commission previously prohibited HCPs from collecting prescription data for commercial purposes, or assisting pharmaceutical companies in collecting such data. However, the 2013 law did not directly proscribe data collection activities by medical representatives or pharmaceutical companies. The Measures now appear to shut the door on medical representatives collecting such data on their own.

Prohibited Corporate Activities

Relatedly, the Measures also explicitly prohibit all MAHs from engaging in five specific activities, including:

1. Failing to register information regarding their medical representatives, or failing to modify or delete such information in a timely manner;
2. Encouraging or suggesting that medical representatives engage in conduct that violates laws and regulations;
3. Assigning sales tasks to or requiring medical representatives to engage in sales activities such as collecting payment or handling purchase and sale involves;
4. Asking medical representatives or other personnel to count the number of prescriptions issued by individual HCPs; and
5. Providing false information during the registration and filing information related to their medical representatives.

The most notable of these prohibited activities is how "assigning sales tasks" is defined. Further, it remains unclear whether MAHs also may be prohibited from using sales-related KPIs to evaluate the performance of medical representatives. Authorities are expected to clarify these ambiguities in the near future.

In addition, as with the prohibitions on individual medical representatives, MAHs now are prohibited from requiring medical representatives to count the number of prescriptions issued by individual HCPs. Again, this is the first Chinese regulation that has specifically prohibited companies (as opposed to HCPs) from collecting such prescription information.

Potential Liability

The Measures make it clear that unregistered medical representatives are prohibited from carrying out academic promotional activities, which means that, in practice, unregistered medical representatives likely will be prohibited from communicating with HCPs. However, the Measures do not impose new liabilities on companies that engage in prohibited conduct. Instead, the Measures reiterate that manufacturers may be held liable under the Drug Management Law and Anti-Unfair Competition Law for acts by a medical representative who provides improper payments or benefits to HCPs or who otherwise engages in prohibited activity. In other words, companies may be exposed to civil or criminal liability under other Chinese laws for the failure of their employees and/or authorized CSO medical representatives to comply with the Measures.

The potentially sweeping consequences of violating the Measures behooves multinational pharmaceutical manufacturers operating in China to re-examine their sales and marketing practices in the country, and make any necessary conforming changes prior to December 1, 2020, while authorities clarify certain ambiguities in the Measures.

Kirkland & Ellis is continuing to monitor developments related to the trial implementation of the Administrative Measures for the Filing of Medical Representatives. If you have any questions concerning the material discussed in this client alert, please contact:

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