Chinese Government Publishes Comprehensive, Ambitious Plan for Drug System Reform, Calling for Significant Changes

On February 9, the State Council of China published a policy document titled “Opinions on Further Reform and Improvement of Drug Manufacturing and Distribution Policies” (Opinions). This document requires relevant government agencies to implement 17 action items to reform China’s drug system that cover almost all major aspects of the approval, manufacturing and distribution of drug products. Some of the requirements may apply to medical devices as well.

After its full implementation, the reform will significantly change the regulatory, compliance and commercial landscape of drug and device companies’ operations in China. However, significant uncertainties still exist, and companies should closely monitor subsequent developments.

Below are the summaries of the action items that are most relevant to multinational drug and medical device companies in China, as well as our analysis.

I. Tightened Regulation of “Medical Representatives”

The action item that will bring about the most uncertainty is the tightened regulation of “medical representatives” (MR). Specifically, the Opinions impose the following requirements:

- The China Food and Drug Administration (CFDA) is required to establish a Medical Representative Registration System, where companies need to register their MRs, and the registration information will be made available to the public.
- MRs are allowed to conduct only “academic promotion” and “technical consultancy,” and companies are prohibited from charging MRs with “drug sales responsibilities.”
- Noncompliant activities of MRs will be reflected in their “individual credit records.”
- However, the implementation of these requirements still has many uncertainties:
- First, the scope of “medical representatives” is unclear. In 2015, a document published by the Chinese government defined this term to cover both traditional “sales representatives” and also – likely – employees.

of the marketing function. It is unclear if “medical representatives” in the Opinions is also intended to include manager-level employees in companies’ sales function, such as district sales directors and regional sales directors.

- Second, it is unknown what information companies need to provide for registration of MRs.
- Third, most important, the exact meaning of “drug sales responsibilities,” which MRs are prohibited to undertake, is unknown. It seems that, at a minimum, drug/device companies should revise the KPI system for MRs and remove any sales volume/value-related KPIs, but it is unclear whether the government expects or will require companies to take any other actions in this regard.

Also, it is unknown what penalties, if any, will be imposed for failing to comply with both the MR registration requirement and the “drug sales responsibilities” ban. As a matter of fact, some people doubt the legitimacy of the last requirement because Chinese law does not authorize the government to regulate companies’ internal personnel management. In this regard, CFDA is expected to issue agency rules to implement these requirements, and more clarity should be provided then.

Last, though it is not explicit in its language of this clause, it seems that this clause applies to both drug companies and medical device companies, particularly because one of the two activities that MRs are allowed to undertake, “technical consultancy,” is a typical medical device MR activity, which drug MRs do not have.

II. Drug Launch Price Commitment

Another very controversial requirement the Opinions raise is that for patented drugs and off-patent drugs, relevant agencies should ensure that their launch prices in China are not higher than prices in the originating country and comparable neighboring countries. The Opinions authorize agencies to make use of a comprehensive set of tools to achieve this goal, including conditional drug approvals, drug price negotiations, centralized procurement programs and healthcare insurance coverage as levers, etc.

This is the second time since August 2015 that the State Council made a clear statement on this issue. Given the State Council’s increasing emphasis, it is very likely that CFDA will develop specific regulations to implement this requirement. However, the implementation still seems difficult, particularly considering that the CFDA is not authorized by law to condition drug approval on price commitment. In addition, the practicality of this requirement is also in doubt, such as whether companies will be prohibited to increase their drug prices after launch and whether companies will be allowed to adjust drug prices in China after launch when prices in overseas markets have changed.

III. Other Important Requirements

In addition to the above, the Opinions also raise a number of other requirements that may significantly affect most, or at least some, drug companies.

- Threat of compulsory licensing: The Opinions require CFDA to improve its drug approval procedures and at the same time state that patented drugs treating major diseases may be subject to compulsory licensing “when necessary.”

2 Opinions of the State Council on Reform of the Drug and Medical Device Evaluation and Approval System (国务院关于改革药品医疗器械审评审批制度的意见), issued Aug. 18, 2015.
• Enhanced Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) inspections: The Opinions require CFDA to heighten its GCP inspections, particularly data integrity inspections, as well as monitoring of GMP compliance.

• Expansion of the Market Authorization Holder (MAH) pilot program: The MAH program has been launched in 10 pilot provinces, and the Opinions require that CFDA make efforts to roll out the MAH program nationwide.

• Consolidation of drug manufacturers and distributors: The Opinions require relevant agencies to promote the consolidation of the drug manufacturing and distribution industry so as to form large flagship drug manufacturers and distributors. This may increase merger and acquisition activities in the pharmaceutical industry.

• Rollout of the two-invoice system: The State Council set the goal of nationwide implementation in 2018.

• Heightened drug price supervision: The government will penalize companies for providing false data on drug raw material prices and ex-works drug prices. The government will also heighten its supervision of ex-works prices and actual transaction prices for drugs “with insufficient competition” and conduct drug price inspections in case of abnormal price fluctuations or excessive price gaps with drugs of same types. These may result in more drug price inquiries by the government as well as more aggressive antitrust enforcement in the drug and medical device industry.

• Drug price information disclosure: Hospitals will make quarterly disclosures on drug prices, drug use amount and so on at hospital levels. It is unclear, however, whether such disclosure is for the public or only within the hospitals.

IV. Observation

The Opinions have demonstrated the Chinese government’s determination to deepen the reform of China’s drug system in a comprehensive and ambitious fashion. Some requirements in the Opinions are not entirely new, but reiteration of them indicates a strong desire of the Chinese government to implement these requirements expeditiously, despite suspicions and questioning from the industry.

The Opinions announced the work plan for relevant agencies. In the next step, these agencies need to issue rules to set forth implementation details for these requirements, which should provide more clarity. Companies are not directly governed by the requirements in the Opinions and should take time to watch the subsequent rule-making activities of relevant agencies.

It is particularly important to watch how the agencies will implement those requirements not explicitly authorized by Chinese laws. There will be intriguing legal issues if the agencies raise new, mandatory requirements, or even impose penalties, on these issues.

Though companies are not required to take any immediate actions, before implementation details are made available through agency rule-makings they nevertheless should start internal assessment and preparation, considering that the Chinese government has provided clear directions on certain key issues. Specifically, companies should carefully study the change of the regulatory environment in China as a result of this policy document, assess the effect of key requirements on them and start to make changes on those “unavoidable” requirements so as to smoothly transition to the new environment in China.
If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work or

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