2018 outlook for drugs and medical devices in China: regulatory reform fueled by innovation

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The year 2017 ended with a central government directive to reform the regulatory approval system for drugs and medical devices and a subsequent flood of CFDA changes and proposed changes to the system, and we should see further regulatory reform in 2018 as the Chinese government continues to encourage domestic innovation in this sector.

On October 8, 2017, the Central Committee of the Chinese Communist Party and the State Council jointly promulgated the *Opinion on Deepening the Reform of the Regulatory Approval System to Encourage Innovation in Drugs and Medical Devices* ("Innovation Opinion"). The Innovation Opinion signaled the central government's commitment to address long-standing issues in China's regulatory approval system for drugs and medical devices and make advanced medicines and medical technology more quickly and widely available in China, and triggered an unprecedented flurry of activity by the China Food and Drug Administration (CFDA) to implement its mandates, including draft amendments to the laws and regulations governing drug and medical device approvals. These developments set the stage for 2018 to be a milestone year for reform in the drug and medical device sector. One issue to watch in 2018 is regulatory reform on who can hold marketing authorization for drugs and medical devices. Other sector issues to monitor in 2018 include wider acceptance of clinical trial data and strengthened protection of intellectual property.

Legislative Developments in 2017

The Innovation Opinion's release in October 2017 caught the attention of all stakeholders in the healthcare industry, domestic and foreign alike. The Innovation Opinion set forth the Chinese government's agenda for reforming the industry to be more efficient and innovative and touched on such issues as clinical trials, the review and approval process, drug innovation and generics, and the marketing authorization scheme.

We did not have to wait long to see the Innovation Opinion being implemented. On October 10, 2017, just two days after the Innovation Opinion was issued, the CFDA issued the *Decision to Adjust Relevant Items concerning Imported Drug Registration* ("Imported Drug Decision"). The Imported Drug Decision implemented changes to facilitate the review and approval process for imported drugs, particularly for innovative imported drugs.

Other legislative action quickly followed the Imported Drug Decision:

- On October 23, 2017, the CFDA published *draft amendments to the Drug Administration Law* ("Draft Amendments to Drug Law"). A majority of the proposed amendments focus on full implementation of the marketing authorization regime, which is an important agenda item in the Innovation Opinion
- Also on October 23, 2017, the CFDA published *draft amendments to the Provisions for Drug Registration* ("Draft Amendments to Drug Provisions"). The proposed amendments seek changes to the regulatory review and approval

process relating to clinical trials, marketing authorization and the efficiency of the approval process

- On October 31, 2017, the CFDA published *draft amendments to the Regulations for the Supervision and Administration of Medical Devices* ("Draft Amendments to Medical Device Regulations"). The proposed changes aim to improve the marketing authorization regime for medical devices, reform clinical trial management and facilitate the approval process, all of which are goals outlined in the Innovation Opinion
- On December 28, 2017, the CFDA issued a *Notice concerning Publication of the China Marketed Drug Catalogue* ("Drug Catalogue Notice"). The Marketed Drug Catalogue is similar to the "Orange Book" in the U.S. and was issued to encourage drug R&D and innovation in China

Regulatory Reform in 2018

The Innovation Opinion and other legislative developments in late 2017 signal what might lie ahead for us in 2018. However, regulatory reform is notoriously slow in China, and what will actually be accomplished this year is uncertain.

1. Marketing Authorization Holder

We could see an easing of the restrictions on who can be a Marketing Authorization Holder (MAH), which is the entity that receives and holds the approval from the CFDA needed to sell a drug or medical device in China. Under the current regulatory regime, only organizations with manufacturing capability can be a MAH. Under the Draft Amendments to Drug Law and Draft Amendments to Medical Device Regulations, R&D organizations and academic research institutions, which are powerhouses for medical technology innovations, can be a MAH even if they don't possess manufacturing capability. R&D organizations and research institutes are frequent drivers of pre-marketing activities, such as pre-clinical studies and clinical studies, and enabling them to own and market the products themselves is expected to incentivize innovation.

2. Foreign Clinical Trial Data

Foreign companies seeking drug or medical device approval in China have long lobbied for the acceptance of foreign clinical trial data, and this appears to have become a reality this year in certain circumstances. The Draft Amendments to Medical Device Regulations explicitly allow foreign clinical trial data to be used for registration of medical devices, and on January 11, 2017, the CFDA published the *Technical Guidelines for Accepting Foreign Clinical Trial Data for Medical Devices*, which set forth the requirements for submitting foreign clinical trial data. On the drug side, the CFDA has indicated that it will accept foreign clinical trial data as part of international multi-center clinical trials. Furthermore, the Imported Drug Decision provides that an overseas applicant intending to conduct an international multi-center clinical trial in China can simultaneously conduct a Phase I clinical trial inside and outside China, which essentially means foreign Phase I clinical trial data can be used for the approval application of imported drugs.

3. Chinese "Orange Book"

2018 will also be the first year China has implemented its equivalent of the U.S.-styled "Orange Book," and we're monitoring the situation to see how the *Chinese Orange Book* will be used and to what effect. The Chinese Orange Book includes a list of originator drugs and their generic substitutes for reference by medical practitioners and the public. The list, which is published on the CFDA's website, currently includes 131 drugs and will be updated as new drugs are approved. The Chinese Orange Book also includes links to other databases with more information about the drugs and related patents. According to the Drug Catalogue Notice, the purpose of the Chinese Orange Book is to encourage the R&D and innovation of drugs, promote access to medicine and reduce drug costs.

4. Patent Linkage

We also anticipate more progress this year introducing patent linkage into China's regulatory approval process. Under the Draft Amendments to Drug Provisions, drug applicants must identify relevant Chinese invention patents and notify the patentees of their drug application. While the draft amendments don't give many details, they do provide that rules for implementing the patent linkage system and data exclusivity will be separately issued. Similarly, the CFDA stated in its explanations for the proposed amendments that it will seek to codify the patent linkage system and the patent term compensation regime, which are concepts favorably mentioned in the Innovation Opinion. Thus, the question now seems to be not *if* patent linkage will be adopted but when and in what form.

Final Observation

The Innovation Opinion and other legislative developments at the end of 2017 provide a blueprint for what regulatory reforms to expect in the pharmaceutical and medical device sector in 2018 and beyond. These developments also reflect a broader plan for healthcare reform taking place in China as the central government tries to meet the healthcare needs of an aging and more demanding population and increase innovation of and access to cutting-edge drugs and medical technology. We expect to witness more legislative and regulatory developments in the sector in 2018 and will report on them as they arise.

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