Cooley

China Issues New Policy for Drug and Medical Device Approvals

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On October 8, 2017, the General Office of the CPC Central Committee and the General Office of China's State Council jointly issued Opinions of the State Council on Promulgating the Reform of Review and Approval System for Drugs and Medical Devices to Encourage Innovation (the Opinion). This alert is to provide you with a high-level summary of the latest Opinion on Reform of the Review and Approval System for Drugs and Medical Devices and its implications.

Background

China's efforts to reform the drug and medical device approval system started seriously in 2015 when China's State Council issued the Opinions on Reforming the Review and Approval System for Drugs and Medical Devices. The efforts culminated in the issuance of four important policy pronouncements by the China Food and Drug Administration (CFDA) for comments in May of this year, which mainly touched upon four key areas: encouragement and protection of innovators, lifecycle management, clinical trial management, and acceleration of review and approval of new drugs and medical devices.

The Opinion officially adopted the four draft policies issued by the CFDA for comments, and represents a significant milestone in China's efforts to reform its drug and medical device approval system.

Summary of the opinion and its implications

Clinical trial management

The Opinion seeks to streamline the clinical trial process and shorten the time line by providing that (i) once the ethics committee of the lead investigation site completes its ethics review for a clinical trial, no review by other clinical sites is necessary, (ii) after a clinical trial application is filed, if the CFDA or its local counterparts fails to raise any issues or reject the application within a certain period (which is not specified in the Opinion), the application is deemed to be approved and the applicant may proceed with the trials, and (iii) clinical trial samples could be tested by the applicant itself or a third party testing lab entrusted by the applicant, rather than being required to go through testing by government accredited testing labs.

The Opinion eliminates the requirement for the qualification of clinical sites, which will significantly increase the number of organizations available to conduct clinical trials. Currently there are only around 600 qualified clinical trial organizations in China. The Opinion also encourages private sectors to establish clinical trial organizations but no details are provided, e.g., on method of involvement, or limit on percentage of private ownership or foreign ownership.

One of the most significant aspects of the Opinion to foreign drug or device manufacturers is that data from overseas multi-center clinical trials can be used for applications in China if the data meets the relevant standards in China. However, the applicant must provide data on ethnic differences if the drug or device has never been launched in China. This will significantly lower the costs and reduce the timeline for clinical trials in China for imported drug or device manufacturers.

Acceleration of review and approval process

The Opinion provides for special fast-track approval for two kinds of drugs and medical devices: (i) new drugs and devices in urgent clinical need; and (ii) drugs and devices for rare diseases. The new drug or device in urgent clinical need can be approved for marketing with conditions if the data in early or mid-stage trials shows its clinical value. The drug or device for rare diseases can be approved for marketing with conditions if it has

been approved for marketing overseas. In addition, new drugs and devices in urgent clinical need which are major national science and technology projects and financed by key national development plans, as well as those recognized by the relevant departments and with clinical trials conducted in national clinical research centers will be given priority in the review and approval process.

Please note that approval of injectable drug products will be strictly controlled.

Protection of innovators

The Opinion seeks to encourage innovation and protect innovators through (i) the adoption of a patent linkage system, (ii) restoration of patent term, and (iii) protection of innovator's data.

Under the proposed patent linkage system, when the applicant filed the applications, the applicant shall describe the relevant patents and the status of the patents, and relevant patentees will be notified of the application and may file a lawsuit against the applicant at court. If no valid judgment or ruling is rendered within a certain period (which is not specified in the Opinion), the CFDA or its local departments can approve the drug or device for marketing.

The Opinion also provides that the patent term may be extended if marketing approval is delayed by the review and approval process. However, no details are provided in the Opinion.

The Opinion provides that the clinical trial data and other data developed by applicants of innovative drugs, drugs for rare diseases, pediatric drugs, innovative therapeutic biologics, and applicants for generic drugs that succeeded in patent challenges will be protected during the data protection period, during which the same kind of drugs by other applicants will not be approved unless those other applicants develop data themselves or obtain consent from the owner of such data. The Opinion states that the data protection period starts from the date the drug is approved for marketing, but it does not specify the length of protection. Under the Implementing Regulations of the Drug Administration Law, a developer of a new drug which contains a new chemical entity is entitled to six years of data protection starting from the date of approval.

Lifecycle management of drugs and medical devices

China started to implement a pilot program on Marketing Authorization Holder (MAH) System in ten provinces in 2015. The Opinion states that the MAH system will be implemented throughout China and the Drug Administration Law of the People's Republic of China will be amended accordingly.

Under the Opinion, a research and development organization or its personnel can be an MAH.

The MAH will be fully responsible for the liabilities with respect to the drug during the lifecycle. The parties authorized by the MAH to conduct relevant work, including research and production, will bear liabilities in accordance with law and the relevant contracts. In addition, the MAH will also be required to establish a system to directly report adverse drug reactions or adverse drug events.

The Opinion also imposes requirement for reassessment for both injectable and medical devices. For approved injectables, the reassessment process will aim to be completed within 5 to 10 years.

The Opinion imposes strict requirements on the conduct of pharmaceutical representatives. Pharmaceutical representatives are only allowed to take part in academic promotion of the drugs but are not allowed to participate in the direct sale of the drugs. The list of pharmaceutical representatives shall be filed and publicized by MAH and academic promotion events by pharmaceutical representatives shall also be filed with the specified website.

Conclusion

China has made great strides in its efforts to encourage innovation as well as to improve the quality of drugs and medical devices available in-country in recent years. The Opinion incorporates components of the recent pilot programs and policy pronouncements and is a significant step in China's reform efforts.

However, this Opinion is not a formal law or regulation. To fully implement the Opinion, the relevant laws and regulations, including the Drug Administration Law of the People's Republic of China, will need to be amended. In addition, the Opinion lacks many details with respect to the reform, and thus, the actual effects of the reform contemplated in the Opinion have yet to be seen. We expect that the relevant amendments to laws and regulations and the implementing regulations will be issued soon.