China: Regulatory Reform 2.0 Changes the Game

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On October 8 2017, the General Office of the CPC (Communist Party of China) Central Committee and the State Council jointly released a document entitled ***The Opinions on Deepening the Reform of the Review and Approval Processes to Encourage Innovation of Drugs and Medical Devices***, unveiling a broader and deepened reform that will have game-changing impact on China's current drugs and medical devices administration system.

The blueprint covers six aspects with 36 measures to support the reform. This brief article will discuss key highlights relating to clinical trials, regulatory approval, and promoting innovation.

Reform Clinical Trial Administration

This measure will abolish the current clinical trial site certification system. The CFDA has issued a draft regulation on the filing procedures and management of clinical trial sites; medical institutions with proper facilities may conduct clinical trials after making a filing with the CFDA (China Food and Drug Administration).

Measures also include provisions to encourage medical institutions and clinical practitioners to conduct clinical trials. Physicians who focus on clinical trials will have the same opportunity for promotion as those who focus on practicing medicine. Investing private capital in clinical trial facilities is encouraged. These provisions may gradually address the shortage of clinical trial sites, a current bottleneck for drug development in China.

The Investigational New Drug (IND) process will be significantly revised to signify the importance of the clinical trial protocol. Sponsors are now required to have a communication meeting with the Center for Drug Evaluation (CDE) about their IND application. Ethics review and approval will precede IND submission. After the IND submission, the sponsor may proceed with the trial if there are no comments from the CDE after a specified period of time (currently proposed to be 60 business days). While IND review is set to accelerate, speeding up the overall clinical trial start-up will be a different matter and remains to be seen.

While streamlining the clinical trial review process, the CFDA will continue to enforce data integrity. Sponsors, clinical trial sites, and investigators are ultimately responsible for clinical trial data and will assume full legal responsibilities, the policy document states.

Accelerate Marketing Approval

The CFDA would grant “conditional” approvals, based on early promising clinical trial data, for drugs and medical devices that treat life-threatening diseases with no available effective therapies, and those that address unmet medical needs. Similar approval will be given to treatments for rare diseases if that therapy is already approved in another country, under the condition that post-approval commitment studies are required.

The CFDA may accept multiregional clinical trial data generated overseas to support product approval in China. This is the Chinese regulatory agency's first major step towards a more global view in reviewing clinical trial data. The CDE has released for comment a draft guideline on acceptance of foreign clinical data.

Additional Resources

Ropes and Gray Analysis: China's Central Government Unveils Final Policy for Drug and Device Regulatory Reform

CFDA Joins ICH, Seeks Public Comment on Further Reforms

China: Improving Reimbursement Level and Access to New Drugs

CFDA Town Hall: China Regulatory Reforms in Motion

Promote Drug Innovation

In addition to provisions such as priority review to promote the development of innovative medicines, the reform measures outline further steps to strengthen intellectual property protection and to facilitate market access for innovative drugs. These new policies include:

1. Explore establishing a patent linkage system: CDE's review of an application will be linked to the patent status of the product; if there is a patent dispute, CDE will "stay" its review.
2. Initiate a patent restoration pilot program: For certain new drugs, the patent term may be adjusted to reasonably compensate for delays in clinical trials and regulatory review.
3. Implement data protection system applicable to innovative drugs, orphan drugs, pediatric drugs, innovative therapeutic biologics, and successful patent challenge applications. More detailed regulations on this topic are expected in the near future.

The government will further clinical use of innovative drugs through more timely inclusion in the reimbursement system. Hospitals and medical institutions are encouraged to procure innovative drugs with demonstrated clinical value and a reasonable price.

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