China issues new draft regulation on human genetic resources

Global Life Sciences: China Update
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China’s State Council published a draft Regulation on Administration of Human Genetic Resources on October 30, 2012 soliciting public comments by November 29, 2012. The draft is intended to replace the current Interim Measures for the Administration of Human Genetic Resources (1998) ("Interim Measures") issued by the PRC Ministry of Sciences and Technology ("MOST"). The new draft tightens regulations relating to the collection, storage, import and export, and R&D of Chinese human genetic resources.

By redefining human genetic resources as “resources and materials, such as human organs, tissues, cells, nucleic acid and nucleic acid products which contain human genome, genes or gene products, as well as any information derived from such resources and materials,” this draft encompasses any material containing information derived from physical human genetic materials. Also, as a sign of the government’s increasing awareness of cross-border electronic data transmission in R&D activities involving Chinese human genetic resources, the draft specifically emphasizes that any form of cross-border movement of Chinese human genetic resources cannot be done without prior approval from the government.

A new system to regulate the collection and storage of human genetic resources is also created by the draft; an institution conducting this type of work must be a legal "person" established in China and licensed by the government. If the draft is finalized as is, these licensed institutions will be the only entities that legally can collect, store and provide human genetic resources in China.

With regard to Sino-foreign R&D activities involving Chinese human genetic resources, the draft imposes an additional set of new requirements. First, foreign companies must collaborate with legal persons established in China. Second, while Sino-foreign R&D projects will continue to be subject to prior approvals, several new restrictions proposed in the draft will authorize the government to decline approvals, for reasons including: (1) the genetic materials are derived from illegal sources; (2) the project may endanger national or public security or damage the nation’s interests; or (3) the project may “cause discrimination.”

The current Interim Measures are particularly protective of Chinese partners in Sino-foreign collaboration projects, requiring the ownership of Chinese human genetic resources to be vested in the Chinese partner and mandating joint ownership of any intellectual property ("IP") rights arising from the collaboration. The draft removes such protective requirements but encourages Chinese partners to actively pursue IP protections for the collaborations.

Multinational pharmaceutical companies that are conducting R&D activities involving Chinese human genetic resources should carefully review this draft and consider providing comments either individually or as part of a group.

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