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China's State Council Publishes New Regulations on the Management of Human Genetic Resources

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China's State Council, the country's top administrative authority, released a new Regulation of Human Genetic Resources[1] (the "Regulation") on May 28, 2019, to replace the tentative rules issued in 1998. The Regulation, which will take effect on July 1, 2019, illustrates the Chinese government's clear intent to position the regulation of HGRs as one of its national security priorities. Specifically, the Regulation closely scrutinizes all HGR-related activity from upstream collection of human biospecimens to downstream exploitation and sharing of the material and any data obtained from it. It formalizes the approval requirements pertinent to research collaborations between Chinese and foreign-owned (including both partially and wholly foreign-owned) entities to avoid uncertainty during the approval process. It also significantly increases and expands penalties for various violations of the Regulation.

Increasing national security concerns

The Regulation highlights national security as a critical rationale for regulating HGR-related activity in China, Including the collection, storage, exploitation and sharing of HGRs. In particular, the Regulation requires that a Chinese entity notify the HGR regulator of its disclosure or sharing of any HGR-derived data to foreign–owned entities. A security review by the HGR regulator is mandatory if such disclosure or sharing may affect national security, public interests or the public health. The HGR regulator has discretion to interpret what circumstances would be deemed "affecting" these interests and HGR-related activity will be prohibited if such a determination is made.

The Regulation also incorporates China's evolving regulations governing data security and privacy. Consequently, companies that process HGR-derived data should comply with China's data security and privacy laws.

Simplified process for drug and medical device registration studies

Under the tentative HGR rules that preceded the Regulation, the HGR regulator required drug and device companies to obtain an advance approval for any registration studies in China that involved the collection of biospecimens. The life sciences industry expressed serious concern about this requirement because it had the potential to delay market access for new products by several months to years. To address these concerns, the Regulation replaced the advance approval requirement with a notification process for any studies not involving the export of HGRs outside of China, though the advance approval requirement still applies to studies involving the export of HGRs. It is unclear how this notification process will be implemented in practice and to what extent companies will benefit from it.

Formalized restrictions for Sino-foreign HGR-related collaboration projects

The Regulation formalizes the long-standing practice that foreign-owned entities seeking access to China's HGRs do so only through collaborations with Chinese partners. Such entities are also prohibited from collecting, preserving or supplying outbound Chinese HGRs. Under the Regulation, Chinese HGRs must be collected and stored by Chinese entities with an advance approval from the HGR regulator. If any foreign--owned entity wishes to export HGRs under a research collaboration with a Chinese partner, it must apply for an advance export permit with the HGR regulator. A Chinese party that provides a foreign—owned party with access to Chinese HGRs must also provide duplicate copies of the HGRs to the HGR regulator for the record. Any patents derived from scientific research collaborations must be co-owned by the Chinese and foreign-controlled partners. The Regulation further emphasizes that Chinese parties have the

[1] Human genetic resources (HGRs) refer to biospecimens that contain human genome information. Under the new Regulation, HGRs include physical biospecimens as well as any data derived therefrom.

right to be substantially involved in collaboration projects that involve HGRs and shall have access to all the data generated from them.

Increasing penalties for violations

The Regulation grants the HGR regulator more power to inspect HGR-related activities on-site. It also significantly expands and increases penalties for a variety of violations. For example, a foreign-owned entity that violates the Regulation could be subject to fines up to RMB 10 million ($1.44 million), or 5-10 times any illegal gains that exceed RMB 1 million. The Regulation also imposes personal liability on responsible corporate officers of such entities now subject to fines up to RMB 500,000 and lifetime debarment in serious cases.

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With the implementation of the Regulation, multinational companies will face intense scrutiny and enforcement by the Chinese government for their HGR-related activities within China. We advise life sciences companies to immediately initiate an internal review of current HGR-related projects in light of the Regulation and take corrective or remedial action as necessary.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.