Haiwen Insights on Recent Updates on Chinese HGRs Regulation

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HGRAO allows a parallel review of a clinical study to accelerate the approval process

In response to the industry's call for an expedited review of clinical studies by the Chinese Human Genetic Resources Administration Office ("**HGRAO**"), on October 21, the HGRAO announced to optimize the application process for collecting human genetic resources ("**HGRs**") and conducting clinical studies. This optimized process aims to accelerate the clinical study process by allowing a parallel review of a clinical study by (i) Chinese National Medical Products Administration ("**NMPA**"), (ii) Ethics Committees ("**EC**"); and (iii) the HGRAO.

Previously, the sponsor and the investigator of a clinical study involving a foreign party have to obtain (i) the NMPA's approval as well as (ii) the EC's approval before they can submit online applications to the HGRAO. Under the optimized process, applicants can submit online applications to the HGRAO right after the relevant IND applications have been accepted by the NMPA. After the HGRAO grants a green light to the online applications, the applicants may then make paper submissions together with the NMPA's and EC's approvals. This means, the HGRAO's online review could be proceeded in parallel with the NMPA's and EC's review, which would save around 2 weeks.

Expansion of the HGRAO's abbreviated review process

This is the second time for the HGRAO to streamline its application process within 3 months. On August 20, the HGRAO just announced to expand its abbreviated review process to numerous amendment applications, such as (i) change of the name of a study collaborating entity or a collecting entity, (ii) change of an HGR collecting entity; (iii) extension of an HGR collection term, or (iv) other non-HGRs related changes to a collection plan.

Previously, applicants have to re-file the applications to the HGRAO for these changes and the refiled applications would be subject to expert penal review. The whole process would take around 1.5 to 2 months. The abbreviated review process skips the expert panel review step, and may save around 2-3 weeks.

Implication of Chinese Biosafety Law on HGR regulation

On a related point, the PRC National People's Congress (**"NPC"**) passed the Chinese Biosafety Law on 17 October, which will become effective on April 15, 2021. The Chinese Biosafety Law presents Chinese government's clear intent to position bio-resources (including HGRs) as one of its national security priorities.

Though Chinese Biosafety Law generally codifies and echoes the principles under the current HGR Regulation, it highlights national security as a critical rationale for regulating HGR-related activity in China. It is foreseeable that HGR-related R&D activities (including exploitation, transmission and sharing of HGR data) would face increasing scrutiny by Chinese regulator.

Potential criminal liabilities for HGR-related violations

Coupled with Chinese Biosafety Law, one of the increasing enforcement actions taken by Chinese regulator is to criminalize certain HGR-related violations. On October 21, the NPC published the draft amendments to China's Criminal Law ("**Draft Amendment**"). Among others, the Draft Amendment creates new crimes specifically for (i) illegally collecting Chinese HGRs in China, (ii) illegally transporting, shipping or exporting Chinese HGR materials; (iii) providing or disclosing Chinese HGR data to foreign entities without a security review. Serious violations would be subject to up to seven-year imprisonment.

In addition to this HGR-specific provision, other HGR-related criminal charges under the current PRC Criminal Law include crimes of espionage, spying, divulging state secrets, illegally collecting or supplying blood or blood products, etc.

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In light of the above legislative and enforcement trends, we advise life sciences and healthcare companies, especially foreign-invested companies, to closely and systematically review and evaluate the compliance level of their current HGR-related projects and take corrective or remedial actions where necessary.