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China's Ministry of Science and Technology Publishes Draft Rules on the Administration of Human Genetic Resources

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China's Ministry of Science and Technology (MOST) issued the Draft Implementing Rules on the Administrative Regulations on Human Genetic Resources for public comment (the "Draft Implementing Rules") on March 22, 2022. The MOST is soliciting public comments until April 21, 2022.

The Administrative Regulations on Human Genetic Resources (the "HGRs Regulation") closely scrutinizes all HGRs-related activity from upstream collection of HGR materials to downstream exploitation and sharing of the HGR materials and data derived therefrom ("HGR data"). The Draft Implementing Rules are intended to provide operational details and clarify questions that have emerged in the past few years after the HGRs Regulation became effective. Given the growing need for using biological materials and related data from Chinese patients in basic research and clinical development, we advise that life sciences companies closely review the Draft Implementing Rules and consider their potential impact on their cross-border research initiatives.

Highlights of the Draft Implementing Rules are summarized below.

1. Clarifying the definition of "foreign entities"

Under the HGRs Regulation, foreign entities are prohibited from collecting, preserving or transferring Chinese HGRs outbound. HGRs include HGR materials and HGR data.

The HGRs Regulation defines foreign entities as foreign organizations or PRC-domiciled entities that are established or controlled by a foreign organization or individual. In practice, controversy exists as to whether a VIE that is contractually controlled by a foreign organization or individual would be deemed a foreign entity.

The Draft Implementing Rules provide guidance on what constitutes control. In summary, a foreign organization that holds more than 50% of shares, equity, voting rights, or other similar rights and interests, directly or indirectly, in a PRC-domiciled entity will be deemed to have control. Besides, a foreign organization or individual that can exert control or decisive influence over the strategic matters of a PRC-domiciled entity, such as decision-making, operation and management, will also be deemed to have control, even if such control is achieved by contractual arrangement. This means that a PRC-domiciled company adopting the VIE structure will be deemed as a foreign entity.

To avoid any doubt, foreign entities can also be interpreted to include a PRC-domiciled joint venture company whose registered shareholders include a foreign shareholder, regardless of its shareholding position.

2. Relaxing control over disclosure and sharing of "HGR data"

The Draft Implementing Rules limit the definition of HGR data to human genes or genome data derived from HGR materials, which include organs, tissues, cells or other genetic materials that contain human genome or genes. Data related to clinical practices, patient demographics, lab tests, medical images, etc. that do not carry genetic attributes will not be regulated as HGR data.

The HGRs Regulation requires a Chinese entity to notify the Human Genetic Resources Administration of China ("HGRAC") of its disclosure or sharing of any HGR data to a foreign entity. A security review by the HGRAC is mandatory if such disclosure or sharing may affect national security, public interests or the public health. The HGRAC has discretion to interpret what circumstances would be deemed "affecting" these interests and to prohibit disclosure and sharing of HGR data. The Draft Implementing Rules enumerate situations where a security review is required for disclosure or sharing of HGR data, such as disclosure or sharing of HGR data about important genetic pedigrees, HGR data from specific regions, and exome sequencing and genome sequencing information of over 500 individuals. In addition, the HGRAC must retain experts in the security review process.

3. Clarifying IP ownership requirements

Pursuant to the HGRs Regulation, foreign entities seeking access to China's HGRs can only do so through collaborations with Chinese partners, and an advance approval from the HGRAC is required for such collaborations. Any patents derived from such collaboration must be co-owned by the Chinese partners and the foreign entities. The HGRs Regulation further emphasizes that Chinese parties have the right to be substantially involved in the collaboration and shall have access to all the data generated from them.

The Draft Implementing Rules provide clearer guidance on how to allocate the intellectual property derived from a Sino-foreign cooperative research utilizing Chinese HGRs. While patents must be co-owned, the Draft Implementing Rules allow foreign entities and their Chinese research partners to agree by contract to the ownership and profit-sharing of other IP covering the work products, data, standards, or processes. In other words, the foreign entity is not prohibited to seek sole ownership of such non-patentable intellectual properties, but must provide the Chinese partners with access to all the data generated from the research collaborations.

4. Streamlining regulatory process for registration studies

Under the Draft Implementing Rules, clinical studies conducted for purpose of obtaining marketing authorization for drugs and medical devices in China, if not involving the export of HGRs, will be eligible for a recordation filing (as opposed to a pre-approval) if the HGR materials are collected by sites, and processed by sites or an onshore third-party lab specified in the study protocol. This streamlined regulatory process does not apply to exploratory studies or studies where samples will be exported for processing by an offshore third-party lab.

The Implementing Rules further clarify that for clinical studies conducted for purposes of obtaining marketing authorization for drugs and medical devices in China, the recordation filing should be made after receiving clinical trial approval from the NMPA or provincial MPA, and a separate collection permit from the HGRAC will no longer be required even if the biospecimens to be collected exceeds the 3000-sample size limit previously set by the HGRAC.

5. Providing clearer standards for law enforcement

Various measures have been introduced in the Draft Implementing Rules to enhance law enforcement against potential violations. The Ministry of Science and Technology and their local counterparts will conduct periodic inspections and for-cause investigations to ensure compliance. Entities that were sanctioned in the most recent three-year period, failed to take timely corrective actions, or were blacklisted will face more frequent inspections.

The HGRs Regulation sets up penalties for a variety of violations. For example, a foreign entity that violates the HGRs Regulation could be subject to fines up to RMB 10 million ($1.44 million), or five to ten times any illegal gains that exceed RMB 1 million. Responsible corporate officers of such entities are subject to fines up to RMB 500,000 and lifetime debarment in serious cases.

The Draft Implementing Rules elaborate the factors that law enforcement authorities need to consider when setting administrative penalties, which include but are not limited to whether the parties involved are at fault, whether the violation at issue is the first-time offense and whether any corrective measures have been taken to reduce the adverse effects. The Draft Implementing Rules further clarify that illegal gains shall be calculated based on the value of HGRs collected and funds invested in the relevant research projects.

A key outstanding issue that was not fully addressed by the Draft Implementing Rules is the HGRs Regulation's scope of application. The HGRs Regulation exempts certain collection and preservation activities of HGRs from its regulatory scrutiny, e.g., clinical diagnosis and treatment, blood banking, crime investigation, anti-doping and funeral services. However, companies can have legitimate needs for using HGRs to conduct QA/QC control to manufacture their diagnostic equipment or instruments that are approved by the regulatory authorities. This QA/QC-driven use is not clearly exempted in the HGRs Regulation or the Draft Implementing Rules. It will be helpful if the Draft Implementing Rules can clarify this issue and provide a possible solution to answer legitimate needs of life sciences manufacturers.