Highlights on the Draft HGR Regulations Implementing Rules

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China began legislating the protection of human genetic resources in 1998, at which time the Ministry of Science and Technology (***MOST***) and the Ministry of Health jointly formulated the *Interim Measures for Administration of Human Genetic Resources*; however, there had been no corresponding implementing rules to implement it in practice. That was until 2015, when the Ministry of Science and Technology issued the *Service Guide for Administrative Licensing Items for the Collection, Collection, Trading, Export, and Exit of Human Genetic Resources*. This guidance caused the gradual application of the *Interim Measures for the Administration of Human Genetic Resources*, which had been dormant for many years. In 2019, the State Council promulgated the current *Regulations on the Administration of Human Genetic Resources* (the ***HGR Regulations***), which replaced the *Interim Measures for the Administration of Human Genetic Resources*. In 2020, the Standing Committee of the National People's Congress adopted the *Biosecurity Law of the PRC*, which officially came into force in 2021 and serves as the fundamental law in the field of biosecurity. So far, China's regulatory framework for the protection of human genetic resources has been established, but more implementing measures are needed to refine these laws and regulations.

On March 22, 2022, the MOST issued for public comments the *Rules for Implementation of the Regulations on Administration of Human Genetic Resources (Draft for Comments)* (the ***Draft Rules***). The Draft Rules contains certain highlights, such as the administrative system, subject qualifications (especially the recognition of foreign entities), international cooperation in intellectual property sharing, security reviews, and administrative enforcement procedures. This article aims to preliminarily interpret the Draft and analyze its potential impact.

Administration system

Article 3 of the Draft Rules **[Central management system]**: The MOST is responsible for the administration of human genetic resources approval, supervision, and sanction nationwide. Relevant institutions may be entrusted by the MOST to undertake specific support work in licensing acceptance, professional support, supervision and management, etc.

Article 4 of the Draft Rules **[Local management system]**: The science and technology departments (commissions and bureaus) of provinces, autonomous regions and municipalities directly under the Central Government, and the Science and Technology Bureau of Xinjiang Production and Construction Corps are responsible for the administration of human genetic resources in their respective administrative region:

- Routine management and supervision of human genetic resources;
- Accepting the entrustment of the MOST to organize the investigation of human genetic resources in the corresponding region;
- Investigation and sanction of violations in the scope of authority, and to organize and carry out the investigation of violations in the region as entrusted by the MOST;
- Accepting the entrustment of the MOST for implement matters related to human genetic resources.

The *Draft Rules* specify that the MOST is, once again, responsible for the national human genetic resources approval, supervision, sanction and other administration work, but further proposes that relevant institutions can be entrusted by the MOST to undertake part of the specific work of licensing and supervision. The administration of supervision and enforcement authorities at provincial level have been further refined. Notably, the MOST has not yet delegated the approval authority for human genetic resources to the provincial level.

Recognition of foreign entities

Article 12 of the Draft Rules **[Foreign Entity]:** "Foreign entity" refers to an institution established by overseas organization(s) or an institution which is actually controlled by overseas organization(s) or individual(s).

The above-mentioned "actually controlled" includes the following status:

- An overseas organization or an individual directly holds or indirectly holds more than 50% of the shares, equity, voting rights, property shares or other similar rights and interests of the institution;
- Although the shares, equities, voting rights, property shares or other similar rights and interests of the institutions directly held or indirectly held by an overseas organization or an individual do not reach 50%, the voting rights, other rights and interests of the decision-making bodies they owned are sufficient to have a significant impact on the resolution, decision-making and internal management of the institution;
- The agreement or other arrangement by the overseas organization(s) or individual(s) is sufficient to have a significant impact on the decision-making, operation and management and other major matters of the institution;
- Other status identified by the MOST.

Pursuant to the *HGR Regulations*, any foreign entity [foreign organizations and institutions that are established or actually controlled by foreign organization(s) or individual(s)] is prohibited from collecting or preserving China's human genetic resources within China. If the foreign entity does need China's human

genetic resources to conduct scientific research, it would be required to cooperate with Chinese entities (such as Chinese scientific research institutions, colleges and universities, medical institutions, enterprises) so as to conduct scientific research. Besides this, the above international cooperation would require approval by the MOST *Human Genetic Resources Office*.

As to the definition of foreign entities, there was a gap between the regulation and legal practice when China began to supervise and regulate related human genetic resources activities. The Interim Measures for Administration of Human Genetic Resources (1998) once used the terms "foreign cooperative entity" and "foreign (overseas) entity", but did not explain or distinguish them. However, in our experience, the MOST has always regarded entities with any foreign capital as foreign entities, not merely entities registered outside China. Although Article 21 of the current *HGR Regulations*, expressly defines a "foreign entity" as a "foreign organizations and institutions that are established or actually controlled by foreign organizations or individuals", the definition of "actual control" remains unclear.

The definition of "actual control" has been controversial in practice, especially with use of the VIE structure. Some companies believe that the domestic companies in their VIE structure are not recognized as foreign entities as they do not hold any foreign capital in terms of equity, while some companies clearly disclose that domestic companies under their VIE structure still have risks to be recognized as foreign entities by the MOST in their prospectuses. Based on our experience, the MOST has already identified domestic companies in VIE structures as foreign entities in their approval practices. This regulatory practice is further clarified and confirmed in Article 12 of the Draft Rules which clearly includes the application of the VIE structure, that is, "agreements or other arrangements by an overseas organization(s) or individual(s) is sufficient to have a significant impact on the decision-making, operation and management and other major matters of the institution."

In contrast to the above-mentioned explicit incorporation of the VIE structure into supervision, another striking breakthrough in the *Draft Rules* is that the definition of foreign entities may be loosened. The Draft Rules clearly emphasize the concept of "50%" ratio for the first time, and stipulate that "actual control" includes "(1) an overseas organization or an individual directly holds or indirectly holds more than 50% of the shares, equity, voting rights, property shares or other similar rights and interests of the institution" or "(2) although the shares, equities, voting rights, property shares or other similar rights and interests of the institutions directly held or indirectly held by an overseas organization or an individual do not reach 50%, the voting rights, other rights and interests of decision-making bodies they owned are sufficient to have a significant impact on the resolution, decision-making and internal management of the institution". If the Draft Rules are finalized in this form, entities with less than 50% foreign shares which have no significant impact on their decision-making and internal management, may no longer be recognized as foreign entities. This would be advantageous for companies with only limited foreign ownership.

Additionally, interpreted literally, if an institution is **established** by an overseas organization or individual, it would be recognized as a foreign institution regardless of its shareholding ratio. In this way, there is a certain lack of logic in the disparity between the two types of enterprises in which foreign organizations and individuals hold minority ownership through establishment and **through share transfer**. The MOST should further clarify this issue.

International cooperation in intellectual property sharing

Article 16 of the Draft Rules **[International cooperative patent sharing]**: If the results of international cooperative scientific research by using China's human genetic resources could be used to apply for a patent, the patent application shall be jointly filed by both parties, and the patent shall be jointly owned by both parties.

Article 17 of the Draft Rules **[International cooperation rights and interests sharing]**: The use rights, transfer rights, and benefit sharing methods of *copyright, data, standards, technological processes and other scientific and technological achievements produced using China's human genetic resources in the international cooperative scientific research* are agreed by both parties through the cooperation agreement. If there is no agreement or the provisions in the agreement are not clear, both parties have the right to use, but transfers to a third party must be agreed by both parties, and the transfer-benefit will be shared according to each party's contribution; if each party's contribution cannot be determined, both parties share the benefit equally.

Regarding the sharing of patent rights, the Draft Rules are consistent with the *HGR Regulations*. That is, Chinese and foreign entities are required, under relevant laws and regulations on human genetic resources, to jointly apply for and share patents produced by using China's human genetic resources in international cooperation scientific research. Regarding IP rights other than patents, the *Draft Rules* firstly specify that rights to use, transfer and share benefits of "copyright, **data**, standards, technological processes and other scientific and technological achievements" resulting from international cooperative scientific research may be agreed through an agreement of both parties.

In the legal practice of human genetic resources, in addition to patents, the ownership of corresponding **data** was often required to be jointly owned by both Chinese and foreign parties. The provisions of Article 17 of the Draft Rules might change this situation and give more autonomy to both Chinese and foreign parties regarding the ownership of data.

Data backup

Article 30 of the Draft Rules **[Data backup]**: If the human genetic resources information will be provided to or be opened to overseas organizations, individuals and institutions for utilization, the backup information must be submitted to an information backup institution designated by the MOST, and it must be filed to the MOST.

According to the definition of "actual control" discussed above, in the future, it may not be necessary to go through the backup and filing process for data sharing if the human genetic resources information is provided or opened to entities with less than 50% foreign shares which have no significant impact on their decision-making and internal management, may no longer be recognized as foreign entities. However, this needs to be further confirmed by the MOST in practice.

International cooperation filing

Article 41 of the Draft Rules **[Conditions for International Cooperation filing]**: If the international

cooperation party wishes to obtain marketing authorization in China for relevant drugs and medical devices or to cooperate with a Chinese entity to conduct international cooperative clinical trials by using China's human genetic resources in clinical institutions, and the cooperation does not involve the exportation of human genetic resource materials and complies with the following requirements, the party shall file with the MOST the types, quantities and uses of human genetic resources that are desired to be used for each cooperation party; approval is not required in this case:

- The collection, testing, analysis and processing of remaining samples of the human genetic resources are carried out in clinical institutions;
- The human genetic resources are collected in a clinical institution, and the testing, analysis and remaining sample processing are conducted in the domestic entity designated by the clinical-trial-protocol in the relevant drug and medical device marketing authorization clinical trial.

Clinical institutions refer to medical institutions, disease prevention and control institutions, etc. that are registered with relevant departments and can carry out clinical research.

If the exploratory research part is involved in the clinical research in order to obtain the marketing authorization of the relevant drugs and medical devices in China, it shall be submitted separately in accordance with the requirements of the administrative license for international cooperative scientific research.

Compared with the *HGR Regulations*, the Draft Rules expand the scope of application of international cooperation filing. In addition to the two conditions for clinical trials that "is to obtain marketing authorization for related drugs and medical devices in China" and "does not involve exportation of human genetic resources materials", the Draft Rules expand the scope of the other condition, "**utilization (samples) in clinical institutions**" to "testing, analysis and processing of remaining **samples in domestic entities designated by the clinical-trial-protocol** in the relevant drug and medical device marketing authorization clinical trials."

We understand that the **scope of domestic entities** (i.e. third-party laboratories) that are designated by the clinical-trial-protocol **will not be limited to** the "**entities** entrusted by clinical institutions to conduct testing, analysis and processing of remaining samples" and "**entities** that clinical institutions shall sign formal agreements with" stipulated in the current administrative guidelines issued by the MOST, **rather**, the "domestic entities" in the Draft Rules would more likely refer to current practices in actual operations in the clinical trial industry.

Security review

Article 48 of the Draft Rules **[Security Review System]**: The provision or open utilization of human genetic resources information to overseas organizations, individuals and institutions that they have established or actually control which might affect China's public health, national security and social public interests shall pass a security review organized by the MOST.

Article 49 of the Draft Rules [**Scope of Security Review]**: The circumstances of security review include the provision or open utilization of the following information:

- Information on human genetic resources of important genetic families;
- Information on human genetic resources in a specific area;
- Human exome sequencing and genome sequencing information resources of more than 500 individuals;
- Other information that might affect public health, national security and public interests of China.

Since the *HGR Regulations*, China has established the security review system for the external provision or open utilization of human genetic resources information, but we have not yet observed relevant practices of such security review from official announcements or public reports. Given that the Draft Rules specify the provision of the security review and clearly mention the application of "human exome sequencing and genome sequencing information resources of more than 500 individuals", we expect that the MOST is likely to impose a security review in the near future. However, this security review has yet to be implemented; we will continue to observe as the review develops.

Major changes/non-major changes in the license for international cooperation

Article 62 of the Draft Rules **[Non-major changes to the license for international cooperation]**: During the process of using China's human genetic resources to conduct international cooperative scientific research, the party does not need to apply for a change-license in the following circumstances, but it should submit relevant documents to the MOST for illustration and filing:

- It only involves a change in which the cumulative number of cases does not exceed 10% of the approved number while the research protocol remains unchanged;
- Participating parties other than the cooperative parties, and the names of the legal entities of all participating parties listed in the first paragraph of Article 61;
- The research plan changes, but it does not involve changes in the type, quantity, and use of human genetic resources, or the changed content still falls into the approved scope.

Before the Draft Rules, the *HGR Regulations* did not delineate a specific scope for non-major changes of the international cooperation approval. The Draft Rules offers relevant standards, particularly specifying that "change-license is not needed when it only involves a change in which the cumulative number of cases does not exceed 10% of the approved number while the research protocol remains unchanged"; the party need only submit relevant documents to the MOST for clarification and notification. This provision has significant value for practice.

Administrative sanction

Article 83 of the Draft Rules **[Subjects of administrative sanction]**: The MOST, the science and technology departments (commissions, bureaus) of provinces, autonomous regions, and municipalities directly under the Central Government, and the Science and Technology Bureau of Xinjiang Production and Construction Corps shall, in accordance with statutory authorities and procedures, impose administrative penalties on natural persons, legal persons or other organizations pursuant to these Rules

if they violate laws and/or regulations in the administration of human genetic resources. Except as otherwise provided by laws and administrative regulations.

Article 117 of the Draft Rules **[Determination of illegal income]**: Illegal income is calculated according to the value of human genetic resources that are illegally collected, illegal preserved, human genetic resources illegally used while participating in international cooperation, and illegally provided foreign entities. Or, the illegal income is calculated as the amount of money invested in human genetic resource.

Lastly, the Draft Rules detail the procedural requirements for administrative sanction, such as jurisdiction, filing, hearing opinions and hearings, review, decision-making, and enforcement. This is also in line with the increased supervision and enforcement of human genetic resources compliance by the MOST in recent years.

In addition, it is worth mentioning that the current *HGR Regulations* do not give a specific definition of "illegal income", while the Draft Rules refine this and use "the value of human genetic resources" as one of the calculation methods for illegal income. At the beginning of this article, we mentioned the *Biosecurity Law of the PRC*, which stipulates that "the state shall have sovereignty over China's human genetic resources and biological resources". We speculate that the value of human genetic resources is "immeasurable", from the perspective that China attaches great importance to human genetic resources. Therefore, in the future, it would be another major focus and questions will arise such as: Who *should assess the value of these resources in practice? How are they to be assessed?* In any case, it is foreseeable that if this provision is implemented, the potential risks and fines may greatly increase.

Important Announcement

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