China human genetic regulatory regime update

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Executive summary

Following the entering into effect of the Biosecurity Law, Data Security Law and Rules on Human Genetic Resources Administration ("**HGRA Rules**"), China is poised to issue the Implementation Regulation to Rules on Human Genetic Resources Administration ("**Implementation Regulation**") which will provide detailed requirements in relation to the collection, storage, use and outbound transfer from China of human genetic materials such as blood samples as well as the related data. The consultation paper of the Implementation Regulation allows companies to get prepared for when the Implementation Regulation is officially adopted. This paper highlights the detailed requirements set out in the consultation paper which are expected to be officially adopted soon.

Application and exemption

The China human genetic regulatory regime is applicable to the collection, storage, use, and outbound transfer from China of human genetic materials and data. Human genetic materials are defined as organs, tissues, cells and other genetic materials containing human genome, genes and other genetic material. Human genetic data are defined as human genes, genomic data and other information generated by the use of human genetic materials.

The regulatory regime is not applicable to clinical diagnosis or treatment, blood supply services, investigation and prosecution of crime, doping detection or funeral activities. Consequently, clinics and test labs handling blood, saliva, urine and other human samples for diagnosis or treatment purposes are exempt from the regulatory regime.

General requirements

The collection, storage, use, or outbound transfer of human genetic materials and data may only proceed after obtaining informed consents and ethics committee approvals in China, ensuring the protection of the privacy, health and other rights of the individuals.

The collection, storage, use, and outbound transfer of human genetic materials and data also need to comply with the relevant Chinese technical standards, such as General Requirements for the Quality and Functions of Biobanks《生物样本库质量与能力通用要求》(GB/T 37864) and Management Specifications for Human Biobanks《人类生物样本库管理规范》(GB/T39766-2021).

Prohibition against foreign involvements

The collection, storage, use and outbound transfer of human genetic materials and data may only be undertaken by Chinese parties. Foreign organisations, individuals or organisations established or controlled by foreign parties may not collect or store Chinese human genetic resources in China, and may not transfer human genetic materials or data outside of China.

The consultation paper specifies that certain Chinese parties are deemed foreign parties. If more than 50 percent (50%) of the shares, equity, voting rights, shares of property or other similar interests in Chinese organisations are held directly or indirectly by foreign organisations or individuals, then the Chinese organisations would be deemed foreign parties. If the voting rights or other interests enjoyed by foreign organisations or individuals in the decision-making body of the Chinese organisations or if the foreign organisation or individuals through agreements or other arrangements may have a significant impact on the resolution, decision-making or internal management of the Chinese organisations, then such Chinese organisations would also be deemed foreign parties. Hence, Chinese parties in variable interest entity structures would be considered foreign parties for the purposes of the regulatory regime. In addition, the Chinese government may additionally deem other companies to be foreign parties for the purposes of this regulatory regime.

Foreign collaborative research

Prior to proceeding with collaborative research by foreign and Chinese parties, the parties must enter into contracts stipulating their rights and obligations, and approvals from the Chinese ethics committee and the Chinese government must be obtained.

In addition, it should be ensured that the Chinese parties would meaningfully participate in the whole research and all records and data of the research would be provided to the Chinese parties.

If patents are to be obtained for the research results, the patent applications should be jointly filed and owned by the Chinese and foreign parties.

However, the associated works, data, standards, processes and other scientific and technological achievements, and the related right to use, transfer and co-own may be agreed to by the foreign and Chinese parties. If the parties did not enter into an agreement or if the agreement is unclear on these items, both parties have the right to use, but any transfer to a third party is subject to the agreement of the parties and the proceeds obtained are to be apportioned in accordance with the contributions of the parties.

Within six months after the completion of the collaborative research, both the foreign and Chinese parties must report the research to the Chinese Ministry of Science and Technology, including details on the use and disposal of the human genetic materials and data, the record, storage and use of the research data, and the research results.

Outbound transfer from China

Outbound transfer of human genetic data that may affect China's public health, national security or social public interest is subject to government approval (referred to as "security assessment"). Otherwise, mere recordal of the outbound transfer is sufficient. In addition, copies of the data should be submitted to the China Ministry of Science and Technology (Office for the Administration of Human Genetic Resources).

On the other hand, outbound transfer of human genetic samples and other such materials must be pre-approved by the China Ministry of Science and Technology.

Clinical trials of foreign sponsors

For clinical trials in China for obtaining drug or medical device market authorisation in China by foreign sponsors, as long as the clinical trial samples are not transferred outside of China, outbound transfer of clinical trial data to the foreign sponsors does not require Chinese government approval and the parties merely need to proceed with recordal as well as submitting copies of the data. The recordal must specify the types, quantities and purposes of the data to be transferred outside of China. On the other hand, outbound transfer of clinical trial samples must be pre-approved by the Ministry of Science and Technology.

In addition, if the clinical trials in China of foreign sponsors involve exploratory trials, the exploratory trials must be separately pre-approved as with collaborative researches.

Personal information protection

Besides the human genetic regulatory regime that is applicable to the handling of human genetic samples and data, other China regulatory regimes, including the clinical trial regulatory regime, are also applicable. Human genetic data also fall within the definition of sensitive personal information. The collection, use, sharing, and transfer within and outside of China of human genetic data therefore must also comply with China's data privacy regulatory regime. The key law in the data privacy regulatory regime, which is the Personal Information Protection Law which went into effect on 1 November 2021, sets out four permissible mechanisms for outbound transfer of personal information from China:

- Government approval (security assessment)
- Certification by professional institution
- Entering into a contract ("Chinese Standard Contractual Clauses") prescribed by the Chinese government with the overseas recipient
- Other permissible mechanisms as prescribed by the Chinese government

Detailed rules on the first three mechanisms have just been issued by the Chinese government. In addition, further requirements for the outbound transfer of human genetic data from China, including separate government approval needed from the China Cyberspace Administration in specified situations, standalone notices and consents (termed Separate Consents), and outbound data transfer impact assessment, must be complied with prior to outbound transfer of human genetic data from China.

Takeaways

The China human genetic regulatory regime has been robustly enforced by the regulator (the China Ministry of Science and Technology (Office for the Administration of Human Genetic Resources)). Both foreign and Chinese big pharma and biotech companies as well as an internationally well-known university have already been investigated and penalised. Further, the punishments are publicised. It is important for multinational companies to keep monitoring legal changes in this area so as to ensure compliance.

Let's talk

For a deeper discussion of how this impacts your business, please contact us.

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