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China's HGR Draft Rules Signal Regulatory Easing: Key Takeaways from the Implementing Rules for the Administrative Regulation on Human Genetic Resources (Draft for Comments)

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On May 8, 2026, the National Health Commission ("**NHC**") released the *Implementing Rules for the Administrative Regulation on Human Genetic Resources (Draft for Comments)* ("**Draft for Comments**"), proposing amendments to the current *Implementing Rules for the Administrative Regulation on Human Genetic Resources* ("**Current Implementing Rules**") formulated by the Ministry of Science and Technology ("**MOST**") in 2023 (for our interpretation of the Current Implementing Rules, please see our previous article: *Han Kun Perspective | First Release: Key Takeaways from the Implementing Rules for the Administrative Regulation on Human Genetic Resources*), and is soliciting public comments.

The amendment is not merely a technical carryover of rules following the transfer of regulatory authority over human genetic resources ("**HGR**") management from MOST to the NHC (for our interpretation of the change in HGR regulatory authority, please see our previous article: *Han Kun Quick Comments | Further Amendments to the Regulations on the Administration of Human Genetic Resources*). Rather, guided by the regulatory principle of "strictly regulating what should be regulated while easing restrictions where appropriate", the Draft for Comments introduces a number of new regulatory mechanisms and requirements. Overall, while preserving the fundamental regulatory framework and security baseline for HGR regulation in China, the Draft for Comments reflects, as compared with the Current Implementing Rules, a trend toward greater facilitation, precision, and regulatory flexibility in areas including filings for international cooperative clinical trials, determination of foreign entities, scope of HGR collection approvals, external provision of HGR information in academic contexts, special procedures involving Hong Kong and Macau institutions, and integration with the administrative penalty procedures.

Drawing on the Current Implementing Rules and practical experience, this article analyzes several proposed amendments in the Draft for Comments that may materially affect pharmaceutical companies, medical institutions, research institutions, and related investors, for industry reference and discussion.

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Accelerated Filing for International Cooperative Clinical Trials: Introduction of Same-Day Confirmation for "No Cross-Border Information Transfer"

While retaining the filing mechanism for international cooperative clinical trials, the Draft for Comments further establishes an expedited confirmation mechanism for filings that do not involve cross-border transfer of HGR information. Under the current HGR regulatory framework, international cooperative clinical trials conducted for obtaining marketing authorization for drugs or medical devices in China are subject to a filing regime, provided that no HGR materials are transferred abroad, the relevant HGR are collected within qualified clinical medical institutions, and testing, analysis, and disposal of remaining materials are conducted within such institutions or domestic entities designated in the clinical trial protocol. Such international cooperative clinical trials must be filed with the NHC prior to commencement. Building on this existing filing mechanism, the Draft for Comments introduces a same-day confirmation mechanism for filings that do not involve cross-border transfer of HGR information. Specifically, where the filing does not involve cross-border transfer of HGR information, the NHC shall, in principle, confirm the filing on the same working day as receipt of the application; where the application is received after working hours or during statutory holidays, confirmation shall be completed on the next working day.

Under the current HGR regulatory framework, regulation of HGR information is generally described in terms of "providing" or "opening access to" it for foreign entities or overseas individuals. The Draft for Comments, for the first time, introduces the concept of "cross-border information transfer" in the context of utilizing HGR information.

In our view, if implemented, this mechanism would apply to registrational clinical trial projects under the international cooperative clinical trial filing regime where "neither materials nor information are transferred abroad". This arrangement would help further shorten filing timelines and improve project initiation efficiency. However, neither the current HGR regulations nor the Draft for Comments clearly defines "cross-border transfer of HGR information". In March 2024, the Cyberspace Administration of China ("**CAC**") issued the *Guidelines for Filing Data Export Security Assessment (Second Edition)* and the *Guidelines for Filing Standard Contracts for Cross-Border Transfer of Personal Information (Second Edition)*, which expressly define cross-border data and personal information transfer activities, including transmission abroad of data or personal information collected and generated during domestic operations, or situations where such data or personal information are stored domestically but can be queried, retrieved, downloaded, or exported by overseas entities, as well as other processing activities involving personal information of domestic individuals conducted overseas. With reference to the CAC rules, the concept of "cross-border transfer" may be broader than merely "providing or opening access to," as it may also encompass direct overseas processing of domestic information. Accordingly, the interpretation of "cross-border transfer of HGR information" — including whether factors such as server location, data access permissions, EDC systems, and remote access rights of foreign sponsors or CROs should be considered — remains to be clarified through future implementing rules and regulatory practice.

Narrowed Criteria for Determining Foreign Entities: From "Actual Control" to "50% Equity Interest" Threshold

The Draft for Comments retains the fundamental framework under the Current Implementing Rules restricting activities of foreign entities, namely that foreign entities may not collect or preserve China's HGR within China, or provide China's HGR abroad, and foreign entities utilizing China's HGR for scientific research must cooperate with Chinese entities. Notably, however, compared with the Current Implementing Rules, the Draft for Comments revises the criteria for determining "foreign entities". Article 58 significantly narrows the scope of foreign entities, creating interpretive room for certain joint ventures, enterprises in which foreign investors hold minority equity interests, and contractually controlled entities (VIE-structured entities) to potentially fall outside this scope.

Specifically, the Current Implementing Rules adopt an "actual control" standard for determining foreign entities. In addition to circumstances where foreign entities directly or indirectly hold 50% or more of equity interests, the Current Implementing Rules also cover situations where foreign entities exert "significant influence" over corporate decision-making or management through veto rights, investment relationships, contractual arrangements, or other mechanisms. By contrast, the Draft for Comments retains only the clear and quantifiable standard of foreign entities "directly or indirectly holding 50% or more of equity interests", without looking through to the influence arising from complex contractual control arrangements or minority shareholdings.

If this proposed amendment is ultimately adopted, compared with the current rules, certain entities — such as companies under Chinese majority shareholding but subject to significant foreign influence through veto rights or other contractual arrangements, including domestic operating entities under VIE structures — may no longer be deemed foreign entities and therefore may be relieved from certain HGR regulatory restrictions. By replacing the broad wording of "being able to control or exert significant influence over an institution's decision-making or management" with a clear equity interest threshold, the Draft for Comments enhances predictability for joint ventures, enterprises in which foreign investors hold minority equity interests, and entities with special structures in assessing HGR compliance. Nevertheless, whether strong veto arrangements, VIE structures, or other contractual arrangements may still be taken into account in determining foreign-entity status on a case-by-case basis remains to be clarified in the final rules, supporting regulations, and future regulatory practice.

Furthermore, it is noteworthy that Article 58 of the Draft for Comments does not appear to contemplate offshore entities controlled by Mainland Chinese entities or individuals (e.g., Cayman Islands vehicles controlled by Chinese shareholders or wholly-owned NewCo subsidiaries established in the U.S. by Chinese domestic enterprises). Consequently, this may result in an inconsistency regarding the scope of "foreign entities" between Article 58 and Article 9 of the Draft for Comments. We understand that such discrepancy will be rectified in the final rules.

Further Increase in Collection Approval Population Thresholds

The *Service Guide for Administrative Licensing Matters on the Collection of Chinese Human Genetic Resources* issued by MOST in 2019 set the population threshold for large-scale population studies

requiring collection approval at 500 individuals. The Current Implementing Rules increased the threshold to 3,000 cases, while Article 16 of the Draft for Comments further raises the threshold to 10,000 cases. For large-scale population studies such as cohort studies, cross-sectional studies, clinical studies, and anthropometric studies, this adjustment narrows the scope of collection approval requirements and helps reduce the upfront administrative approval burden for certain medium-sized research projects.

At the same time, with respect to HGR involving important genetic pedigrees and specific regions, the Draft for Comments further implements the catalog mechanism established under the Current Implementing Rules by linking collection approval obligations to officially published catalogs. Only collection of HGR included in such catalogs would require approval, helping companies, medical institutions, and research institutions more clearly determine whether application procedures are necessary. We will continue to closely monitor how such catalogs will be formulated, published, and dynamically updated.

However, while increasing the approval population threshold, the Draft for Comments also prohibits reducing collection quantities or circumventing administrative approval requirements through project splitting or other fragmented arrangements. In our view, future large-scale population studies will still need to adopt reasonable project designs, sample size arrangements, and implementation pathways to avoid being deemed as "circumventing collection approvals" due to project segmentation, thereby triggering compliance risks.

Simplified Procedures for External Provision of Information in Academic Contexts

Under the current HGR regulatory framework, regardless of the usage scenario — including academic exchanges and publication of papers — providing or opening access to HGR information externally generally requires completion of prior reporting procedures and submission of information backups. In practice, such procedures may take one to two weeks to complete. The existing prior reporting obligation is substantively similar to an administrative filing and still applies in academic exchange and publication contexts.

In light of the special circumstances and needs of academic exchanges and publication activities, the Draft for Comments proposes that where HGR information is provided externally or opened for use for the purpose of paper publication or academic conference exchanges, submission of the relevant data to the China National Center for Bioinformation prior to formal publication or the conference shall be deemed completion of the prior reporting obligation, without the need to await approval. This simplification would significantly reduce the compliance burden on relevant parties, including physicians and scholars, when using HGR information in international lectures, exchanges, or publications in international journals, greatly accelerating the process. The "submission equals compliance" approach also more closely aligns with the ordinary meaning of "reporting".

At the same time, it should be noted that under the simplified rules, relevant parties must still ensure that the HGR data submitted in each case are complete in scope and accurate in content, and that such submission is completed before formal publication of the paper or the occurrence of the conference. Accordingly, this remains a form of "prior reporting", unlike certain post-event obligations under other

regulatory regimes (such as filing standard contracts for cross-border transfer of personal information).

Emergency Approval and Expedited Approval Mechanisms for Hong Kong and Macau Institutions

With respect to emergency responses to public health incidents and other emergencies, the Draft for Comments is consistent with various regulations and policies issued by regulators in recent years and establishes an emergency approval mechanism for HGR licensing. In the event of a public health emergency, relevant HGR administrative applications may benefit from streamlined application materials and simplified approval procedures, enabling administrative approval to be obtained within as few as five working days.

Meanwhile, in light of the increasingly close cooperation between Mainland China and Hong Kong and Macau in the pharmaceutical and medical device sectors, the Draft for Comments introduces, for the first time, an expedited approval mechanism for HGR activities involving Hong Kong and Macau institutions. This mechanism allows HGR approval or filing applications involving Hong Kong and Macau institutions to be submitted concurrently with ethics review or clinical trial application procedures, with HGR approval or filing to be granted directly upon the subsequent supplementary submission of ethics approvals, clinical trial approvals, or other required materials. This expedited mechanism may accelerate HGR approval procedures for projects involving Hong Kong and Macau institutions, although relevant parties must still ensure that all required ethics and clinical approvals or supporting documents are obtained.

Notably, the Draft for Comments does not yet clearly define the scope of "HGR activities involving Hong Kong and Macau institutions". First, it remains unclear whether Hong Kong and Macau institutions include Mainland-controlled institutions established in Hong Kong or Macau as referenced in Article 59 of the Draft for Comments, and whether Hong Kong and Macau institutions not Mainland-controlled would still be subject to restrictions applicable to foreign entities. Second, the scope of "HGR activities" may cover the full lifecycle from collection and preservation to utilization and external provision. Finally, whether "involving" Hong Kong and Macau institutions requires such institutions to act as major collaborators or principal recipients of information, or whether a lower level of connection would suffice, remains to be clarified through the final rules, supporting regulations, and future regulatory practice.

Alignment with the Provisions on Administrative Penalty Procedures for Health Authorities: Standardization of the Enforcement Framework

Following the institutional reform under the 2024 amendments to the *Regulations on the Administration of Human Genetic Resources of the People's Republic of China*, which transferred HGR management responsibilities from MOST to the NHC, the Draft for Comments compresses the standalone chapter on administrative penalties under the Current Implementing Rules into a single principle-based provision in Article 57. Rather than enumerating specific enforcement procedures, the Draft for Comments provides that penalty procedures shall directly follow the *Provisions on Administrative Penalty Procedures for Health Authorities*.

This adjustment does not add or remove any categories of unlawful conduct or alter penalty severity at the

substantive level (penalties for HGR-related violations remain governed by the *Regulations on the Administration of Human Genetic Resources* and the *Biosecurity Law*), and the core purpose of this adjustment is to enhance consistency within the legal framework. The adjustment indicates that HGR regulation will become more deeply integrated into the existing healthcare supervision system, further strengthening the systematic nature and transparency of enforcement. For enterprises, leveraging the NHC's well-established administrative enforcement mechanisms, regulation will become more systematic and rigorous, with standardized procedures covering the entire process from case filing, investigation and evidence collection, and legal review to hearings, service, and enforcement. Whether such integration will further promote practical enforcement of HGR regulations and whether penalty information will be publicly disclosed remain subject to further regulatory practice.

Conclusion

Overall, while preserving the fundamental framework for safeguarding HGR security in China, the Draft for Comments is consistent with the stated principle of "strictly regulating what should be regulated while easing restrictions where appropriate", demonstrating a pragmatic shift in regulatory philosophy from "strict control" to "precision governance". Measures such as accelerating filing procedures for international cooperative clinical trials, narrowing the criteria for determining foreign entities, raising collection approval population thresholds, simplifying procedures for external provision of information in academic contexts, and introducing expedited approval mechanisms for Hong Kong and Macau institutions are intended to reduce industry compliance burdens and support scientific research and industrial innovation.

Although many key adjustments proposed in the Draft for Comments may still be subject to change before promulgation of the final rules, the Draft for Comments overall sends a clear signal that regulation is moving toward a more precise, pragmatic, and business-friendly direction. We look forward to the final rules achieving an appropriate balance between security and development, and providing the industry with clearer legislative guidance.

Important Announcement

This Legal Commentary has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

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