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China Further Eases Regulation on Human Genetic Resources: Key Takeaways from the New Implementation Rules

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Human Genetic Resources ("**HGR**") are an important strategic resource for national biosecurity and scientific and technological innovation. In recent years, driven by rapid advances in biotechnology and its expanding industrial applications, companies have increasingly sought to utilize HGR and engage in international collaboration in their research and development ("**R&D**") activities. How to facilitate the efficient and appropriate utilization of HGR while safeguarding their security has remained a key concern for the industry.

On May 8, 2026, the National Health Commission ("**NHC**") released the *Implementation Rules for the Regulations on the Administration of Human Genetic Resources (Draft for Comments)* ("**Draft for Comments**"), seeking public comments on amendments to the *Implementation Rules for the Regulations on the Administration of Human Genetic Resources* formulated by the Ministry of Science and Technology ("**MOST**") in 2023 ("**2023 Implementation Rules**"). On November 11, 2026, the NHC officially promulgated the revised *Implementation Rules for the Regulations on the Administration of Human Genetic Resources* ("**New Implementation Rules**"), which took effect on the date of promulgation, with the 2023 Implementation Rules repealed simultaneously. The HGR administration service system and related service guides have also been updated in parallel to support the implementation of the New Implementation Rules and facilitate the handling of relevant administrative procedures.

The amendments to the 2023 Implementation Rules, together with the updates to the supporting service guides and administration system, address both the need to ensure regulatory continuity following the adjustment of competent authorities and industry concerns arising in R&D practice. While maintaining security oversight, the New Implementation Rules reflect an approach that combines regulation with facilitation by clarifying the regulatory scope, refining regulatory requirements and optimizing regulatory procedures. These changes provide companies with clearer compliance guidance for R&D activities and collaboration. This article examines and analyzes the key provisions of the New Implementation Rules in comparison with the relevant provisions of the 2023 Implementation Rules, with a view to helping

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companies understand the implications of the new regulatory framework, plan their R&D activities and collaborations, and implement the relevant compliance requirements.

Refining Regulatory Requirements: Strengthening the Foundation for HGR Compliance

The New Implementation Rules further refine the regulatory framework in relation to the scope of HGR, application requirements and requirements governing HGR activities, institutional compliance responsibility and the emergency approval mechanism, providing clearer guidance for companies to identify compliance boundaries and plan project implementation. For companies, these requirements extend beyond the preparation of application materials to specific arrangements concerning collaboration agreements, information provision and internal management. They should be considered together during project design and implementation, with compliance requirements embedded throughout the entire R&D process.

I. Refining the Scope of HGR: Further Clarifying Regulatory Boundaries

The New Implementation Rules incorporate explanations of the scope of HGR set out in frequently asked questions and the previous service guides. By turning those explanations into express provisions of the New Implementation Rules, the amendments strengthen their regulatory effect and further refine the definitions of HGR materials and HGR information.

For HGR materials, the New Implementation Rules retain the description of the scope set out in the previous service guides and further specify that HGR materials **include genetic material derived from the listed substances**, such as all types of cells and whole blood, making the definition clearer. For HGR information, the previous service guides listed data and information relating to nucleic acid biomarkers as one type of HGR information, such as genes, genomes, transcriptomes, epigenomes and ctDNA. **The New Implementation Rules replace the phrase "data and information relating to nucleic acid biomarkers" in the previous service guides with "nucleic acid sequence information"**, making the definition of HGR information more focused and precise. In our view, these adjustments further clarify the regulatory boundaries for HGR and give companies a clearer basis for determining whether particular samples and data fall within the scope of HGR regulation.

II. Refining Application Materials and Regulatory Requirements: Enhancing Compliance Predictability for Companies

The New Implementation Rules both refine the application material requirements for various administrative procedures and adjust and clarify certain substantive regulatory requirements.

On the one hand, the New Implementation Rules further refine application material requirements. For example, **agreements submitted in connection with applications for approvals of international collaboration scientific research or filings for international collaboration clinical trials (if applicable) shall include arrangements for ownership of research results, including intellectual property rights, and plans for the allocation of rights and interests**. This aligns with the requirement under the *Regulations on the Administration of Human Genetic Resources* that

international collaboration scientific research have "clear ownership of research results and a reasonable and clearly defined benefit-sharing plan", helping ensure that companies' rights and interests are adequately protected in practice. However, the specific criteria for assessing the "reasonableness" of a plan for the allocation of rights and interests remain to be clarified through regulatory practice.

On the other hand, the New Implementation Rules further clarify requirements governing the relevant HGR activities. For example, they prohibit reducing collection quantities or circumventing approval requirements through project splitting, fragmentation or similar arrangements. Preservation remains limited to scientific research purposes, but the word "future" has been removed from the description of those purposes. Preservation institutions shall also establish an open-access and sharing mechanism and describe sharing activities and results generated in their annual reports. In addition, the New Implementation Rules further clarify the specific conditions for exemption from separate prior reporting and submission of information backups when externally providing HGR information generated through international collaboration scientific research for which administrative approval has been obtained or international collaboration clinical trials for which filing has been completed: **the international collaboration agreement shall stipulate that the relevant information may be used by both collaborating parties, and the foreign entities shall be identified as recipients in the administrative approval or filing application information**. Accordingly, entities anticipating a need to provide relevant information to foreign collaborating parties are advised to identify the foreign recipient entities and specify the relevant information use arrangements at the initial application stage, so as to satisfy the exemption requirements and facilitate the efficient implementation of the project.

III. Strengthening Institutional Responsibility: Embedding Compliance at the Outset

The New Implementation Rules further embed HGR compliance requirements in institutions' internal management. **They expressly make the legal representative responsible for the institution's HGR management** and require relevant institutions to designate the department responsible for HGR management, establish and improve HGR management systems, and maintain records of HGR activities. The New Implementation Rules also retain the regulatory interview mechanism under the 2023 Implementation Rules: where regulators identify a risk that an institution subject to supervision and inspection may violate the *Regulations on the Administration of Human Genetic Resources*, they may interview its legal representative and other relevant personnel. Although the New Implementation Rules do not separately prescribe specific legal liability for a legal representative's management responsibilities, the *Regulations on the Administration of Human Genetic Resources* already provide for such liability in certain circumstances involving violations. Legal representatives should therefore remain attentive to their duties and related liability risks.

These provisions indicate that HGR compliance extends beyond preparing materials at the application stage and should form part of the day-to-day management of R&D activities. Companies may bring compliance review forward to the project design and initiation stages, clarify internal responsibilities and improve review and supervision mechanisms, assigning management requirements to specific roles and business processes. This can help mitigate HGR-related risks at the outset and build a sound compliance foundation for R&D activities.

IV. Improving the Emergency Approval Mechanism: Supporting Emergency R&D Activities

Article 17 of the 2023 Implementation Rules provided that administrative approval applications involving HGR for emergency response purposes should be processed on an expedited basis, while the specific circumstances, procedures, timelines and requirements for such expedited processing were not further specified. The New Implementation Rules further refine the emergency approval mechanism by specifying that, for HGR activities eligible for emergency approval mechanism, the application material requirements will be simplified and the approval procedures streamlined, **and an administrative approval decision shall be issued within five working days after all required application materials have been submitted**. In our view, this arrangement responds to the time-sensitive nature of emergency R&D activities and gives institutions clearer procedural expectations for rapidly initiating research during emergencies. It is also conducive to the timely mobilization of R&D resources and better serves public health emergency response needs.

Overall, by refining the regulatory scope and application requirements, strengthening institutional responsibility and specifying emergency approval timelines, the New Implementation Rules provide clearer guidance for companies conducting HGR activities. Companies should take the new requirements into account when planning their projects, structuring collaborations, and establishing internal management systems, and integrate compliance considerations from the outset and throughout the entire R&D process. This will enable them to advance R&D innovation and international collaboration more efficiently while safeguarding the HGR security.

Optimizing Regulatory Procedures: Improving Efficiency of HGR Utilization

The amendments to the 2023 Implementation Rules introduce several adjustments to international collaboration clinical trial filings, sample preservation, collection approvals and administrative penalty procedures, potentially reducing certain application steps and improving project efficiency. For companies, however, procedural simplification does not mean a relaxation of compliance requirements. The conditions for each facilitation measure should still be assessed against the specific business arrangements.

I. Optimizing Filing Procedures for International Collaboration Clinical Trials: Shorter Timelines and Integrated Applications

1. Clinical Trial Filings Involving No Cross-Border Transfer of HGR Information

Under Article 28 of the New Implementation Rules, where a filing application for an international collaboration clinical trial does not involve cross-border transfer of HGR information and the application materials are complete and meet the requirements, **the NHC shall confirm the filing on the day it receives the application**. Applications received after working hours or on statutory holidays shall be confirmed on the next working day. Compared with potential processing periods that could previously take one to two weeks in practice, this arrangement is expected to shorten initiation timelines for eligible projects.

Companies should **assess their needs for cross-border transfer of information over the full**

project lifecycle, rather than focusing solely on the efficiency of the initial filing. If the needs are not identified in the filing while subsequent collaboration requires cross-border transfer of HGR information, prior reporting to the NHC and submission of information backups will still be required. Companies should therefore consider subsequent R&D collaboration arrangements and balance the efficiency of the initial filing against the time and management costs of completing subsequent separate prior reporting procedures.

Notably, the New Implementation Rules **use the concept of "cross-border information transfer" in Article 28** while retaining the wording "external provision or access opening" in Chapter VI. The respective scope of, and relationship between, the two concepts remain to be clarified. For example, further regulatory interpretation is needed as to whether "cross-border information transfer" covers all of the following: overseas individuals physically present in China viewing, processing or using HGR information stored in China; domestic entities uploading such information to overseas servers owned and controlled by domestic organizations; and individuals in China carrying storage media containing such information from China to an overseas destination.

2. Joint Filing of Exploratory Research and the Main Clinical Trial

Article 27 of the New Implementation Rules clarifies that, for clinical trials conducted to obtain marketing authorization for drugs or medical devices in China, **the exploratory research part does not require a separate application for approval of international collaboration scientific research and may instead be included in the same filing as the main clinical trial**. This addresses longstanding industry concerns regarding the application pathway for exploratory research, helping reduce the procedural burden of making separate applications within the same project, lower compliance costs and facilitate exploratory research procedurally. However, whether the degree of connection between exploratory research and the main clinical trial affects eligibility for joint filing remains to be clarified through practice.

II. Adjusting Sample Preservation and Collection Management: Clarifying the Regulatory Scope and Adjusting Approval Thresholds

Article 21 of the New Implementation Rules clarifies that **sample storage for the manufacture of marketed drugs or medical devices falls outside the scope of preservation regulation**. For sample storage and analysis in contexts such as post-marketing research, safety event reporting and ongoing quality management, companies should consider its connection with the manufacture of marketed products to assess the application of the above arrangement. Companies should also pay attention to the environmental conditions for sample storage. For preservation entrusted to a laboratory or another institution, companies should verify its relevant qualifications and whether it constitutes a foreign entity, to avoid entrusting HGR samples to a foreign entity for preservation.

For collection approvals, the New Implementation Rules **raise the threshold for a collection administrative approval application to 10,000 individuals**. The *Service Guide for Administrative Licensing Matters on the Collection of Chinese Human Genetic Resources* issued by MOST in 2019 previously set the threshold at 500 individuals, which was increased to 3,000 individuals by the 2023 Implementation Rules. The latest adjustment is expected to reduce the application burden for

companies conducting large-scale population clinical studies and provide greater flexibility in determining study size.

Companies should also distinguish between collection activities that fall outside the regulatory scope and activities covered by combined approval applications. HGR collection activities in clinical trials conducted to obtain marketing authorization for the relevant drugs and medical devices in China fall outside the scope of collection regulation. For HGR preservation or international collaboration scientific research involving HGR collection, the collection part should be included in the application for approval of preservation or international collaboration scientific research, without a separate application for collection approval. Accordingly, **whether a separate collection approval application is required should be determined by the purpose of the activity and the applicable application pathway**, rather than sample quantity alone.

III. Simplifying Prior Reporting Procedures in Academic Contexts: Completion upon Data Submission and Generation of a Registration Number

Article 40 of the New Implementation Rules and the relevant service guides clarify that, to externally provide or open access to HGR information for the purpose of paper publication or academic conference, **the data shall be submitted to the China National Center for Bioinformation before formal publication or the conference. Prior reporting is deemed completed upon successful submission and generation of a registration number**. This arrangement clarifies the manner in which the prior reporting obligation is fulfilled in academic contexts, facilitating paper publication and academic exchanges. Relevant institutions should incorporate data submission into publication and conference preparation workflows and coordinate research teams and internal management departments in advance to ensure completion of prior reporting procedures before the prescribed deadlines.

IV. Clarifying Administrative Penalty Procedures: Alignment with Health Administrative Penalty Procedures

Liability for HGR-related violations remains governed by Chapter V of the *Regulations on the Administration of Human Genetic Resources*. **The New Implementation Rules further clarify that administrative penalty procedures follow the *Provisions on Administrative Penalty Procedures for Health Authorities***. Effective from June 1, 2025, those provisions specify procedures for case initiation and investigation, decisions, enforcement and case closure, providing a clearer basis for companies to understand and respond to enforcement procedures. When facing potential administrative penalties, companies may refer to those provisions to understand procedural requirements, cooperate with regulatory investigations and provide timely feedback on the relevant facts and proposed measures.

Overall, by shortening filing timelines, integrating application matters, adjusting collection approval thresholds and clarifying enforcement procedures, the amendments give companies room to optimize HGR compliance arrangements. Companies should revisit their existing application pathways in light of project design, sample management and information flows, make appropriate use of relevant facilitative measures provided that the applicable requirements are met, and incorporate potential

subsequent reporting, information backup and approval requirements into full-lifecycle project management.

Optimizing Collaboration Rules: Promoting Openness and Collaboration in HGR Activities

The New Implementation Rules further optimize the regulatory framework for international collaboration involving HGR in relation to the determination of foreign-entity status, overseas marketing authorization applications and activities involving Hong Kong and Macau institutions. These adjustments should improve predictability in determining foreign-entity status, reduce the procedural burden in specified circumstances and improve processing efficiency through an expedited approval mechanism. At the same time, companies should carefully assess the scope of each facilitation measure in light of their specific ownership and governance arrangements, information provision pathways and forms of project participation.

I. Revising the Criteria for Determining Foreign-Entity Status: A 50% Interest Threshold and Removal of the "Control" or "Significant Influence" Standard

The determination of foreign-entity status directly affects a company's compliance pathway for HGR activities. Under the current regulatory rules, foreign entities may not collect or preserve China's HGR within China or provide China's HGR abroad, and shall cooperate with Chinese entities when utilizing China's HGR for scientific research. Article 59 of the New Implementation Rules defines foreign entities as overseas organizations and institutions established or actually controlled by overseas organizations or individuals, or in which such organizations or individuals hold, directly or indirectly, 50% or more of shares, equity interests, voting rights, property interests or other interests. It removes both the standard under the 2023 Implementation Rules covering institutions in which overseas organizations or individuals hold less than 50% of the relevant interests but can exercise "control" or exert "significant influence" through other rights and interests or investment relationships or other arrangements, and the catch-all provision.

In our view, this adjustment **expressly establishes a 50% interest threshold as the benchmark for determining foreign-entity status**. On that basis, entities previously deemed foreign entities because of veto arrangements or similar factors may not necessarily remain within the definition. If subsequent regulatory interpretations confirm this approach, Chinese-controlled companies that are nevertheless subject to foreign control or significant foreign influence over decision-making and management through veto rights or other contractual arrangements may no longer be deemed foreign entities and may therefore be exempt from HGR regulatory restrictions specifically applicable to foreign entities.

II. Introducing an Exemption for Overseas Marketing Authorization Applications: Linking Clinical Trial Filings with Overseas Registration Applications

Article 41 of the New Implementation Rules introduces **an exemption from separate prior reporting and submission of information backups** where HGR information generated in clinical trials is provided to overseas drug regulatory authorities for the purpose of obtaining overseas marketing

authorization for the relevant drugs and medical devices, provided that the relevant matters have been identified in the application for filing an international collaboration clinical trial involving HGR and the filing has been completed. This arrangement should reduce the procedural burden at the subsequent overseas registration application stage, lower the costs of coordinating HGR applications with overseas registration applications, and facilitate global registration using clinical trial data generated in China.

This exemption is conditional on the relevant matters having been identified in the international collaboration clinical trial application and the filing having been completed; **it is not a general exemption for external provision of HGR information.** Companies should assess whether the matters identified in their initial applications cover the information actually provided abroad and subsequent registration arrangements. For example, if an overseas drug regulatory authority requests additional HGR information beyond the scope of the original application, or a company subsequently seeks registration in additional countries or regions, whether the original filing remains sufficient for the exemption should be assessed against the original application and subsequent regulatory interpretations.

III. Improving Facilitation for Activities Involving Hong Kong and Macau Institutions: Concurrent Applications and Better Coordination of Approval Procedures

Article 52 of the New Implementation Rules expressly establishes **an expedited approval mechanism for HGR activities involving Hong Kong and Macau institutions**. Unlike the standard regulatory procedure, which requires applicants to submit proof of ethics review approval as part of the application materials, entities eligible for this expedited approval mechanism may submit HGR approval applications while ethics review or clinical trial applications are in progress. The competent authority will make an approval decision or process the filing once the relevant ethics approval, clinical trial approval or other required materials have been submitted to supplement the application. The mechanism allows eligible projects to pursue applications in parallel rather than in the previously required sequence, helping reduce waiting time between procedures and improve project preparation and implementation efficiency.

Notably, compared with the Draft for Comments, the New Implementation Rules change the treatment following supplementary submission of materials from “directly granting approval or processing the filing” to “making an approval decision or processing the filing”. In our view, this wording indicates that supplementary submission of the relevant materials is a condition for continuing the approval or filing process, rather than a guarantee of obtaining approval or completing the filing. In particular, for matters requiring approval, the competent authority shall still conduct its review and make a decision in accordance with law. The mechanism therefore primarily **optimizes application sequencing and coordination between procedures**; it should not be understood as relaxing substantive review standards.

The precise scope of this mechanism also warrants attention. First, Article 60 of the New Implementation Rules expressly provides that institutions established in Hong Kong or Macau and actually controlled by domestic investors are to be regulated by reference to the rules applicable to

Chinese entities. In our view, Hong Kong and Macau institutions not actually controlled by domestic investors may remain subject to the activity restrictions applicable to foreign entities. How "Hong Kong and Macau institutions" are to be identified awaits regulatory interpretation. Second, the degree of participation required for activities to be considered "involving Hong Kong and Macau institutions" remains unclear: whether those institutions should participate substantively as contract research organizations, sponsors or in another capacity, or whether general services or ancillary participation suffice, remains to be clarified. Finally, whether the HGR activities covered by this expedited approval mechanism extend to the full process of collection, preservation, utilization and external provision, and which specific activities qualify for this expedited approval mechanism, should be assessed in light of supporting rules and subsequent regulatory practice. When planning project timelines, companies should first verify the eligibility of the institutions concerned and the scope of matters covered by the facilitation mechanism, rather than treating procedural facilitation as an exemption from entity eligibility requirements or activity restrictions.

Overall, while maintaining security oversight, the New Implementation Rules address a range of practical concerns arising in companies' R&D activities and collaborations by refining compliance requirements, optimizing regulatory procedures and improving international collaboration rules. They also provide a clearer framework for the compliant and efficient utilization of HGR. For companies, procedural facilitation does not mean a relaxation of compliance requirements. Companies should still carefully assess the conditions for each measure against their own structures and project arrangements and adjust their application strategies in a timely manner. The specific application of certain new rules remains subject to further clarification through supporting guidance and regulatory practice. We look forward to these arrangements better supporting R&D innovation and international collaboration while safeguarding HGR security as the New Implementation Rules take effect and regulatory interpretations become clearer. We will continue to monitor developments and provide guidance to help companies understand and implement the new requirements.

Important Announcement

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