

# Legal Commentary

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## China New Biomedical Technology Regulations (Order No. 818) Enter into Force – Dual-Track System for Product Registration / Clinical Translation and Application Finally Takes Effect

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### Legislative Background of Order No. 818

In recent years, with the rapid development of cutting-edge biomedical technologies such as cell therapy, assisted reproductive technology, and brain-computer interfaces technology, a large number of enterprises have invested in R&D activities in related fields. Regulatory authorities have also been continuously exploring a dual-track regulatory framework for “drugs/medical devices” and “technologies”. On November 29, 2024, the Standing Committee of the Seventh People’s Congress of Hainan Province reviewed and adopted the *Regulations on the Promotion of New Biomedical Technologies in the Boao Lecheng International Medical Tourism Pilot Zone of the Hainan Free Trade Port*. On January 24, 2025, the Health Commission of Hainan Province issued the *Implementation Measures for the Translation and Application of New Biomedical Technologies in the Boao Lecheng International Medical Tourism Pilot Zone of the Hainan Free Trade Port (Provisional)* (the aforementioned documents are collectively referred to as the “**Hainan Boao Regulations**”), under which a pilot program was launched in the pilot zone for the clinical study, translation and application of new biomedical technologies<sup>2</sup>. On October 10, 2025, the State Council of the People’s Republic of China officially issued the *Regulations on the Administration of Clinical Study and Clinical Translation and Application of New Biomedical Technologies* (“**Order No. 818**”), establishing a regulatory framework for clinical study and clinical translation and application of new biomedical technologies (“**New Biomedical Technologies**”) at the level of administrative regulations, which officially came into force on May 1, 2026 (For a detailed analysis of *Order No. 818*, please refer to: [Key Takeaways on China’s Regulations on the Clinical Study and Clinical Translation and Application of New Biomedical Technologies – A New Era for IITs and Commercialization in Cell and Gene Therapy](#)).

Following the issuance of *Order No. 818*, the industry responded enthusiastically. Local authorities have

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<sup>2</sup> As of April 9, 2026, the pilot zone has approved 29 cutting-edge new biomedical technology projects, covering various refractory diseases including tumors, lung function impairment, neurodegenerative diseases, blood disorders, liver function impairment, and joint degenerative lesions. See *Hainan Daily*, “29 Cutting-Edge New Biomedical Technology Projects Land in Boao Lecheng”, April 9, 2026, <https://www.zmgrp.gov.cn/show-32177.html>.

also issued relevant documents aimed at implementing *Order No. 818*. For example, the Guangdong Quality Control Center for Stem/Somatic Cell Clinical Study, established by the Guangdong Health Commission, issued the *Guidelines for the Filing of Clinical Studies on New Biomedical Technologies (Stem/Somatic Cell) in Guangdong Province (Trial)* on February 11, 2026, to implement the filing of stem/somatic cell clinical study under *Order No. 818* in Guangdong. We have also received inquiries from domestic and foreign enterprises regarding *Order No. 818*, such as the application scope of *Order No. 818*, the harmonization between the New Biomedical Technologies translation and application pathway and the drug/medical device registration pathway, whether foreign-invested enterprises may serve as clinical study initiators, and the requirements for medical institutions translating and applying New Biomedical Technologies.

Prior to the effective date of *Order No. 818*, the National Health Commission (the “NHC”) released the *Work Standards for the Approval of Clinical Translation and Application of New Biomedical Technologies (Draft for Comments)* (the “**Work Standards (Draft for Comments)**”) on April 19, while on April 30, the NHC released *Work Standards for the Approval of Clinical Translation and Application of New Biomedical Technologies (Trial)* (the “**Work Standards (Trial)**”), the *Guiding Principles for the Classification of New Biomedical Technologies and Drugs/Medical Devices (Provisional)* (the “**Classification Guiding Principles**”), and the *Filing Guidance List for Clinical Study on New Biomedical Technologies* (the “**Filing Guidance List**”), and the China National Center for Biotechnology Development (the “CNCBD”) issued the *Guidelines for Filing of Clinical Studies on Fourteen New Biomedical Technologies (Version 1)*, which set forth institutional and personnel requirements, preparation and quality control of investigational products, and other technical requirements for new technologies such as brain-computer interfaces, xenotransplantation, and somatic cell/stem cell technologies (collectively, the “**Detailed Rules**”). The Detailed Rules provide guidance for industry in identifying New Biomedical Technologies, clarifying the relationship between the regulatory pathways for New Biomedical Technologies and those for drugs and medical devices, and implementing subsequent clinical translation and application.

Drawing on the perspectives of various stakeholders in practice, and building upon existing analyses of *Order No. 818*, this article further analyzes several key points reflected in the *Detailed Rules*, aims to provide reference for enterprises in assessing future product/technology pathways, conducting clinical study and clinical translation and application of New Biomedical Technologies.

## Key Analysis of the Detailed Rules

### I. Scope of New Biomedical Technologies

Pursuant to the *Classification Guiding Principles*, New Biomedical Technologies primarily encompass (i) new biomedical technologies that are difficult to develop into medical devices, and (ii) new biomedical technologies that are highly innovative, highly personalized, and have not yet been – or are difficult to – developed into drugs. From a practical standpoint, defining the specific scope of New Biomedical Technologies is particularly important.

Regarding the scope of New Biomedical Technologies, compared with the *Hainan Boao Regulations* established during the pilot period, which enumerated several New Biomedical Technologies such as

“cell therapy, gene therapy, tissue engineering, etc.”, *Order No. 818* defines the connotation of New Biomedical Technologies. Article 3 of *Order No. 818* defines “New Biomedical Technologies” as medical techniques and measures that are intended to assess health status, prevent or treat diseases, or promote health, which apply biological principles, act at the cellular or molecular level of the human body, and have not yet been clinically applied within China.

Building on *Order No. 818*, the NHC has established the *Filing Guidance List* to clearly define the scope of New Biomedical Technologies at early stages, including preclinical study and clinical study. Pursuant to the *Classification Guiding Principles*, this list is subject to inclusion and removal mechanisms. Accordingly, if a New Biomedical Technology with a similar mechanism has already completed clinical translation and application, there will be uncertainty as to whether subsequent New Biomedical Technologies can proceed with translation, pending the NHC and the National Medical Products Administration (the “NMPA”)’s organization of an expert review on whether such technologies should be removed from the *Filing Guidance List*.

Accordingly, we understand that *Order No. 818* imposes stringent requirements on the innovativeness of New Biomedical Technologies. New Biomedical Technologies at the same stage (e.g., clinical study stage) with the substantially same mechanisms and indications should closely monitor the translational progress of other similar technologies. Those applying for translation at a later stage may be removed from the *Filing Guidance List* due to the prior successful clinical translation of similar technologies, thereby losing the opportunity to achieve application through the New Biomedical Technology pathway.

Additionally, we note that the final version of the *Filing Guidance List* removed “new technologies for immune cell therapy” compared to the draft for comment released in March 2026. In this regard, we understand that such new technologies fall within the scope of “new technologies for somatic cell therapy” under the *Filing Guidance List*. Biologically, “somatic cells” is a broader concept that encompasses stem cells, immune cells, tissue cells, and other cell types. However, in defining new technologies for somatic cell therapy, the final version narrows the scope to “mature/functionally differentiated cells”, thereby excluding stem cells – as undifferentiated cells – from this subcategory (which are addressed under separate subcategories), while immune cells, being mature/functionally differentiated cells, are fully covered by this subcategory.

## II. The impact of the Classification Guiding Principles on the IIT Regulation

The *Classification Guiding Principles* clarifies that if a drug or medical device with substantially the same indication and mechanism has been approved for marketing in China, or if a biomedical technology has already been approved for clinical translation and application, the NHC shall, in consultation with NMPA, promptly organize an expert review and make adjustments based on the review outcome. If a technology is removed from the list following such review, any new related clinical study initiated by an investigator thereafter shall be conducted in compliance with the relevant provisions of the *Measures for the Administration of Investigator-Initiated Clinical Study Conducted by Medical and Health Institutions (2024)* (the “**IIT Regulation**”).

However, Article 12 of the *IIT Regulation* provides that clinical study using surgical procedures,

operations, physical therapy, psychotherapy, behavioral interventions, clinical treatment protocols, population-based health measures, or biomedical technologies as interventions shall use drugs, medical devices, or other products that have already been approved for marketing. We understand that the *IIT Regulation* may be amended in due course to add, alongside drugs and medical devices already approved for marketing, New Biomedical Technologies that have already been approved for clinical translation and application. This would also address the practical need to ensure that, if a New Biomedical Technology has been removed from the *Filing Guidance List* following review and approved for clinical translation and application as a medical technology, it may subsequently participate in general IITs in compliance with the requirements of the *IIT Regulation*.

### **III. Who Determines Whether a Technology Intended for Clinical Study Qualifies as a New Biomedical Technology?**

Pursuant to Article 2 of the *Classification Guiding Principles*, clinical study initiators shall, with reference to the *Filing Guidance List*, independently determine the classification of the technology intended for New Biomedical Technology clinical study. Meanwhile, the NHC entrusts a professional institution to provide consultation and guidance services related to such classification. At present, such a professional institution has yet to be identified, and this matter remains to be further observed in practice.

However, Article 14 of *Order No. 818* stipulates that clinical study may only proceed after passing both academic and ethics reviews by the clinical sites. Therefore, in practice, clinical sites (such as hospitals) have significant discretion in deciding whether to allow clinical study initiators to pursue clinical study under the New Biomedical Technology pathway. Accordingly, companies should engage proactively with hospitals to reach consensus on classification and the applicable regulatory pathway, so as to facilitate the advancement of clinical studies.

For technologies determined not to fall within New Biomedical Technologies, if commercialization is intended, clinical trials for registration purposes should be conducted in accordance with the *Good Clinical Practice for Drugs* and the *Good Clinical Practice for Medical Devices*, and be subject to the corresponding regulatory oversight.

### **IV. Scope, Conditions, Procedures, and Outstanding Issues for the Clinical Translation and Application of New Biomedical Technologies**

Articles 3 and 6 of the *Work Standards (Trial)* provide detailed clarification on the scope of New Biomedical Technologies eligible for clinical translation and application. First, such technologies must be included in the *Filing Guidance List*, and must have completed clinical study. The technologies must have been proven safe and effective through such study, compliant with ethical principles. In addition, during the clinical study stage, the technology must have been independently implemented by multiple centers in accordance with clinical application operation standards, with consistent conclusions reached on safety and efficacy. Second, the technology must meet one of the following conditions:

1. It is highly personalized, and no drug based on the similar mechanism has obtained marketing

authorization or initiated confirmatory clinical trials in China; or

2. It is intended for the treatment of rare diseases and no drug with the similar mechanism and indication has obtained marketing authorization or initiated confirmatory clinical trials in China.

The *Work Standards (Trial)* does not provide explicit definitions for “highly personalized” or “similar mechanism”. However, in the official interpretation of the *Work Standards (Trial)* released concurrently by the NHC, it is stated that the criteria for determining “similar mechanism” will vary depending on the characteristics of different technologies, and separate rules will be developed. Furthermore, the *Work Standards (Trial)* does not extend the requirement of “no similar mechanism” to foreign jurisdictions, but merely requires that no drug with the similar mechanism has obtained marketing authorization or initiated confirmatory clinical trials in China. This means that even if a foreign drug with the similar mechanism has been approved for marketing or entered confirmatory clinical trials abroad, a domestic enterprise may still apply for clinical translation and application of such technology in China (for example, by introducing foreign technology through a license-in arrangement and achieving clinical translation and application of the New Biomedical Technology domestically).

Additionally, the requirements regarding “obtaining marketing authorization” and “initiating confirmatory clinical trials” are relatively clear. We understand that, since the aforementioned conditions require that there are no drugs with similar mechanism already marketed or in confirmatory clinical trials in China, technologies similar to drugs already on the market will lack the possibility of applying for clinical translation and application. Examples include cell and gene therapy (“CGT”) technologies similar to marketed CGT products, or to CGT drugs that have already initiated confirmatory clinical trials (such as Phase III clinical trials). On the other hand, if multiple technologies or drugs with similar mechanisms and the same indications are all still in the IIT stage, similar New Biomedical Technologies would still retain the possibility of applying for clinical translation and application.

Notably, for New Biomedical Technologies eligible for translation and application in the treatment of rare diseases, the *Working Standards (Draft for Comments)* explicitly required that such rare diseases be included in the Rare Disease Directory published by the NHC. However, the reference to the “Rare Disease Directory” was removed in the *Working Standards (Trial)*. We understand that this may signal greater flexibility in the clinical translation and application of New Biomedical Technologies for rare disease treatment, though it cannot be ruled out that regulators may in the future continue to manage such technologies through a directory-based approach.

Overall, we understand that *Order No. 818* and its *Detailed Rules* clarify the boundaries for clinical translation and application through New Biomedical Technologies. For technologies that are truly innovative and highly personalized but have not yet been – or are difficult to – developed into drugs or medical devices (such as brain-computer interface technology), a pathway is provided for clinical translation and application. Conversely, for drugs and medical devices that already possess a clear product profile and are capable of standardized, large-scale production, the route of registration as drugs and medical devices should continue to apply. For example, regarding in vivo CAR-T technology – a topic of significant industry interest – it may be possible to conduct clinical trials as a

New Biomedical Technology. However, whether clinical translation and application will be permitted in the future will depend on the regulatory stance at that time and the development of the technology itself. If standardized, large-scale production of in vivo CAR-T products emerges, such products may fail to satisfy the high degree of personalization requirement and thus be ineligible for clinical translation and application.

## V. Are Fees Permissible for the Clinical Translation and Application of New Biomedical Technologies?

According to Article 34 of *Order No. 818*, medical institutions may charge fees for the authorized clinical translation and application of New Biomedical Technologies in accordance with relevant regulations. This implies that such technologies can now enter a commercial revenue-generating stage. This has been a primary focus of industry attention, as it provides a commercialization pathway through clinical translation and application under *Order No. 818*, alongside the traditional market authorization channels for drugs and medical devices.

We note that the *Application Form for Clinical Translation and Application of New Biomedical Technologies*, which is an appendix to the *Work Standards (Trial)*, stipulates that the applicant shall submit a cost statement for the clinical application of the technology. At present, the *Work Standards (Trial)* does not clarify the price management procedures following the clinical application, such as whether a price filing is required. This remains an area to be observed in future practice.

However, it is important to note that Article 20 of *Order No. 818* remains explicit that no fees may be charged to participants during the clinical study stage of New Biomedical Technologies. Regulators have not relaxed their stance on this patient-centric principle. The prohibition against charging fees for clinical studies continues to be a non-negotiable “red line”.

## VI. Whether Enterprises May Freely Choose Between Technology Translation and Product Registration Pathways, and The Submission and Use of Clinical Data

Pursuant to Article 55 of *Order No. 818*, we understand that clinical trials conducted for the purpose of product registration remain subject to the *Drug Administration Law* and the *Regulations on the Supervision and Administration of Medical Devices*, rather than *Order No. 818*. However, we have observed the parallel operation of these two pathways in practice. For instance, data generated from clinical study and translation and application of New Biomedical Technologies within the pilot zone can still be referenced as real-world data during the drug marketing authorization process<sup>3</sup>.

We understand that clinical study on New Biomedical Technologies is subject to different regulatory rules from drug clinical trials conducted for registration purposes. Clinical data generated in New Biomedical Technology clinical study, unlike clinical data from IND trials, may not be directly used to

<sup>3</sup> The *Interpretation of the Regulations on the Promotion of New Biomedical Technologies in the Boao Lecheng International Medical Tourism Pilot Zone of the Hainan Free Trade Port*: Strengthen the application of real-world data; support medical institutions in the pilot zone in the effective accumulation of real-world data during the process of translation and application of New Biomedical Technologies; enhance the applicability of real-world data; and provide data references for products already marketed overseas when applying for marketing authorization in China. Please refer to: <https://v4.hainanpc.gov.cn/eportal/ui?pagelId=000127408b2d40c8ba893bd463d02c9c&articleKey=c2b5c3af547b4b5eaf0175d184cd0ca5&columnId=7760d1655bc4469391f12e9b269c788c>.

apply for drug marketing authorization. However, companies still have the opportunity to engage in close communication with regulators prior to applying for marketing authorization of drugs and may have the chance to submit clinical data generated from New Biomedical Technology clinical study as real-world data for regulatory reference. It is worth noting that, unlike drugs, most clinical trials for medical devices conducted for registration purposes do not require an IND approval (except for those falling within the catalog of Class III medical devices subject to clinical trial examination and approval). Therefore, if a technology developed through New Biomedical Technology clinical study is classified as a medical device at the clinical translation and application stage, such clinical study data will have a greater chance of being accepted by the regulatory authorities when applying for marketing registration. We will continue to monitor how this unfolds in practice.

Additionally, as to whether enterprises may freely choose between the two pathways of product registration and clinical translation and application, we understand under the *Classification Guiding Principles* that during the clinical study stage, an enterprise may independently assess based on the *Filing Guidance List* whether the technology falls within the scope of New Biomedical Technologies or constitutes a drug or medical device. At the subsequent translation stage, however, Article 3 of the *Working Standards (Trial)* stipulates that technologies meeting the definition of a medical device do not fall within the scope of examination and approval for clinical translation and application, and shall instead undergo relevant registration procedures pursuant to medical device regulations. This indicates that medical devices cannot be translated as New Biomedical Technologies. Nevertheless, with respect to drugs and drug-led combination products, the *Working Standards (Trial)* does not preclude enterprises from choosing either the technology translation pathway or the product registration pathway. Of course, from an efficiency perspective, if a technology can be directly translated as a New Biomedical Technology, a lot of enterprises would prefer to avoid registering it as a drug, thereby eliminating the need to file a new IND and NDA.

## VII. Implications of Order No. 818 for IITs on Stem Cells and Somatic Cells

We understand that with the official entry into force of *Order No. 818*, the regulatory environment for IITs involving stem and somatic cell therapies is expected to tighten. Historically, cell therapy companies operated within a distinct regulatory lane. When conducting IITs, they typically followed specialized measures and guidelines, such as the *Administrative Measures on Stem Cell Clinical Study (Trial)* and the *Work Guidelines for Somatic Cell Clinical Study (Trial)*. This specific pathway sets them apart from other IITs governed by the general *IIT Regulation*.

Since *Order No. 818* came into effect on May 1, it is our understanding that stem cell and somatic cell therapies will be categorized as New Biomedical Technologies. Although *Order No. 818* has not yet explicitly superseded the aforementioned specific regulations, we believe it may materially reshape the regulatory landscape for IITs on cell therapy. For instance, regulatory authorities may subsequently require all cell therapy IITs to be filed strictly via the New Biomedical Technology pathway, thereby precluding relevant enterprises from invoking the previous specialized regulations to conduct IIT studies. The precise regulatory stance remains to be further clarified by forthcoming implementing rules and administrative practices.

## VIII. Hospitals Implementing Approved Translation and Applications for New Biomedical Technologies

During the pilot phase, the *Hainan Boao Regulations* established various specific conditions for hospitals implementing approved translation and application for New Biomedical Technologies<sup>4</sup>. Although Article 11 of *Order No. 818* sets forth the requirements for institutions conducting clinical studies of New Biomedical Technologies (such as Grade 3A hospital status), it does not explicitly define the qualifications for hospitals to translate and apply such technologies in clinical practice. However, Article 33 of *Order No. 818* mentions that when the NHC approves the clinical translation and application of a New Biomedical Technology, it shall publish the name of the technology, the qualifications required for the medical institutions and health professionals utilizing said technology, and the operational specifications for its clinical application.

On May 1, 2026, the CNCBD issued the *Guidelines for Risk Classification of New Biomedical Technologies*, which, taking into consideration dimensions such as the complexity of technical operations, reversibility of effects on the human body, and impacts on public health and social ethics, classifies the four major categories of New Biomedical Technologies (excluding brain-computer interface technology) in the *Filing Guidance List* into three risk levels: high-risk, medium-risk, and low-risk. According to the *Work Standards (Trial)*, high-risk technologies may only be clinically applied within medical institutions that participated in the clinical study and meet the conditions for five years following approval; medium-risk technologies for three years following approval; and low-risk technologies for one year following approval. Upon expiration of such periods, if no change has occurred in the understanding of their safety and efficacy, no serious adverse reactions or uncontrollable risks have emerged, no major social stability risks have been caused or major events affecting social stability have occurred, or if re-evaluation confirms that benefits far outweigh risks, other qualified medical institutions may then conduct clinical application. Furthermore, the *Work Standards (Trial)* explicitly requires that other qualified medical institutions, when conducting clinical application of the aforementioned New Biomedical Technologies, shall perform filing procedures with reference to Restricted Medical Technologies as in the *Administrative Measures for the Clinical Application of Medical Technologies*. We understand that, when carrying out clinical application of such technologies, other medical institutions shall also fulfill filing procedures with the health administrative department that issued their Medical Institution Practicing License, pursuant to the *Administrative Measures for the Clinical Application of Medical Technologies*.

We understand that the regulators have been considering the issue of applying such New Biomedical Technologies at institutions other than the original clinical sites. Article 6 of the *Work Standards (Trial)*, which sets out the conditions of clinical translation and application of New Biomedical Technologies, includes the technology must have been independently implemented by multiple centers during the clinical study stage, in accordance with clinical application operation standards, with consistent

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<sup>4</sup> The *Hainan Boao Regulations* stipulate specific requirements for hospitals utilizing approved translational technologies. These include: maintaining Grade 3A hospital status; maintaining both academic and ethics committees; possessing appropriate personnel, equipment, and facilities; establishing quality management systems and risk control frameworks for the translation and application of new technologies; and formulating emergency contingency plans for handling adverse events and medical incidents.

conclusions reached on safety and efficacy. This suggests that New Biomedical Technologies intended for clinical translation and application shall meet the standard of being reproducible across different institutions. However, before such technologies are applied at other institutions, different periods should be set based on different risk levels to collect adverse reaction data and monitor safety and efficacy. We understand that this is a “safety observation period” established by the regulatory authorities for such new technologies, reflecting a balance between patient accessibility and technological safety.

## IX. Coordination with Human Genetic Resources Regulation

The appendix to the *Work Standards (Trial)* expressly provides that a filing or approval document for human genetic resources should be submitted when applying for translation and application of New Biomedical Technologies. The *Guidelines for the Filing of Clinical Studies on New Biomedical Technologies (Stem/Somatic Cell) in Guangdong Province (Trial)* also state that a filing or approval document for human genetic resources is required for clinical study filing, and such filing or approval document falls under “other materials prescribed by the health department under the State Council” as set forth in Article 16 (9) of *Order No. 818*. However, whether the practices and positions that have developed in the filing or approval practice for human genetic resources will apply to the filing of clinical studies on New Biomedical Technologies remains to be seen.

Given that clinical study on New Biomedical Technologies under the *Order No. 818* is not conducted for the purpose of product registration, the relevant clinical study agreements entered into between enterprises and hospitals may in the future be subject to provisions under China’s human genetic resource administration stipulating that patent rights to resulting outcomes shall be jointly owned by both parties. Accordingly, enterprises intending to conduct clinical studies involving New Biomedical Technologies should carefully consider the relevant patent-sharing requirements and make advance plans regarding patent ownership.

## X. Competent Authorities and Procedures for Approval of Clinical Translation and Application of New Biomedical Technologies

During the pilot phase, the *Hainan Boao Regulations* set out detailed procedures for the clinical translation and application of New Biomedical Technologies<sup>5</sup>. *Order No. 818* only briefly addresses the process for translation and application of New Biomedical Technologies, simply providing that translation requires review and approval by the NHC. The *Work Standards (Trial)*, however, clarifies the approval authorities and procedures for the clinical translation and application of New Biomedical

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<sup>5</sup> The *Hainan Boao Regulations* set out relatively detailed procedures for the clinical translation and application of New Biomedical Technologies. For example, clinical studies must demonstrate that the New Biomedical Technology is safe, effective, and compliant with ethics principles, and the hospital applies to the medical products administration for translation and application. However, the hospital itself must first complete an access qualification assessment to ensure that it meets qualification requirements such as being a Grade 3A hospital and having a quality and risk control system. Once the application is accepted by the pilot zone’s medical products administration, it should be transferred to the pilot zone’s management agency for a technical evaluation, and the pilot zone’s medical products administration shall then make the decision on whether to approve the translation and application based on the evaluation results. Finally, once approved, the New Biomedical Technologies shall be submitted to the local healthcare security administration and the local health commission for price filing.

Technologies.

First, the approval process will involve multiple authorities and institutions, including the NHC, local health commissions, CNCBD, and the National Center for Medical Service Administration of the NHC (the “**NCMSA**”). The NHC holds the ultimate approval authority to determine whether a new technology may be translated and applied. However, the specific review work, including materials verification and technical and ethics evaluations, will be delegated to the CNCBD, and the NHC will make its decision based on the evaluation opinion of the CNCBD. The CNCBD is also the department responsible for the regulation of human genetic resources. The NCMSA is responsible for coordinating with the CNCBD to conduct re-evaluation of technologies already approved for clinical translation and application. If the understanding of the safety or efficacy of an approved technology changes, or serious adverse reactions, uncontrollable risks, or major risks to social stability arise during application, the NCMSA will organize a re-evaluation of its safety and efficacy. Application of the technology will be suspended during the re-evaluation period. If the re-evaluation determines that safety and efficacy cannot be ensured, the NHC will prohibit application of the technology and make a public announcement.

Additionally, for technologies used to treat diseases that are seriously life-threatening and for which no effective treatment is available, or technologies urgently needed for public health, the applicant may submit a priority review and approval application form when filing the application for clinical translation and application.

Under public health emergency circumstances, New Biomedical Technologies still in the clinical study stage may be applied on an exceptional basis. To address particularly serious public health emergencies or other emergencies that pose a serious threat to public health, if the NHC, after organizing an expert review, determines it to be necessary, it may approve the emergency application of new technologies currently undergoing clinical study within a certain scope and time limit; specific implementing rules shall be formulated separately.

## Conclusion

We understand that the clinical translation and application of New Biomedical Technologies opens up another pathway in addition to the marketing authorization of drugs and medical devices, which is of landmark significance in the history of drug and medical device regulation in China. However, this pathway differs from the drug and medical device registration regulatory pathway in terms of its purpose and requirements, and companies may make decisions based on their own business considerations and the development status of their technologies.

On the one hand, the drug/medical device registration pathway is relatively mature, stable, and highly predictable. Once a product is approved for marketing, it may be sold and used nationwide, without being limited to specific medical institutions, and may have the opportunity to be included in the *National Reimbursement Drug List*, thereby forming a stable payment mechanism. However, this pathway generally requires the completion of systematic clinical trials, involves a longer timeline and greater capital investment, and requires the marketing authorization holders (“**MAH**”) to continuously fulfill comprehensive

responsibilities, including GxP compliance. On the other hand, the regulatory system for the technology translation and application pathway is being rapidly improved. For cutting-edge innovative technologies, this pathway may enable faster translation by leveraging the policy window and may bring certain policy benefits. However, the relevant regulatory requirements are also stringent and should not be underestimated. The scope of medical institutions to which this pathway applies is relatively limited, which is also related to the complexity of New Biomedical Technologies themselves. In addition, arrangements regarding intellectual property ownership and allocation of benefits in collaboration with medical institutions should also be carefully designed. We look forward to the promulgation and implementation of more regulatory rules on New Biomedical Technologies in the future, so as to set a steady course for the new regulatory framework and stimulate its vitality, thereby enabling it to complement the established and continuously improving drug and medical device marketing authorization system, and jointly creating greater benefits for patients worldwide.

## ***Important Announcement***

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