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A PEST-SWOT ANALYSIS OF THE IMPACT OF CHINA'S REGULATORY FRAMEWORK ON CLINICAL RESEARCH AND THE TRANSLATION OF NOVEL BIOMEDICAL TECHNOLOGIES INTO HEALTHCARE APPLICATIONS

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ABSTRACT

China enacted the *Regulation on Clinical Research and Translation and Application of Novel Biomedical Technologies*, promulgated by the State Council on May 1, 2026. This study employed an integrated PEST–SWOT framework to systematically evaluate the impact of this regulation on China's healthcare sector. The PEST analysis indicated that: the restriction of clinical research to tertiary grade-A hospitals intensifies the concentration of medical resources at top-tier institutions; the breakthrough in fee-charging mechanisms creates new revenue streams for hospitals; the aging population generates rigid demand; and there is a widespread lack of GMP-compliant cell-manufacturing facilities and interdisciplinary clinical talent in Chinese hospitals. The SWOT analysis demonstrated that the sector's strengths include a massive patient volume and strategic government investment; weaknesses encompass uneven ethical-review capacity and unbalanced regional development; opportunities arise from aging-related demand, unmet rare-disease treatment needs, and the maturing medical-consortia network; while principal threats stem from compliance risks associated with cell and gene therapy (CGT) applications and uncertainty in reimbursement policies. Based on a PEST–SWOT cross-matrix, this paper proposes the following strategies: the construction of a three-tier clinical-research network comprising core hospitals, regional centres, and primary-level institutions; the establishment of dedicated cell-therapy operational units and outcome-based pricing models; the implementation of a talent-echelon programme specific to novel biomedical technologies and ethical-review accreditation; and the advancement of an integrated whole-cycle patient-management and real-world data platform.

KEYWORDS: novel biomedical technologies; clinical translation; administrative regulation; PEST–SWOT analysis; strategy.

1. INTRODUCTION

China enacted the *Regulation on Clinical Research and Translation and Application of Novel Biomedical Technologies* (State Council Decree No. 818), promulgated by the State Council on May 1, 2026. The healthcare sector is the ultimate bearer of clinical translation of novel biomedical technologies. By the end of 2025, China had 1.107 million healthcare institutions, including 38,000 hospitals, which together delivered 10.58 billion patient visits annually.[1] This vast healthcare system serves as both the terminal application scenario for CGT and the principal site for clinical research. In recent years, clinical translation of CGT in China has advanced rapidly[2], and multiple Chinese

research institutions rank among the global leaders in initiating CGT clinical trials.[2]

However, the 2018 "gene-edited babies" incident exposed systemic weaknesses in regulatory lag and ethical governance, and revealed the institutional fragility of the healthcare sector when absorbing frontier technologies.[3] Internationally, the US FDA has accelerated approvals through the Regenerative Medicine Advanced Therapy (RMAT) designation, approving products such as Aucatzyl (relapsed/refractory B-ALL), TECELRA (synovial sarcoma), BEQVEZ (haemophilia B), LENMELDY (metachromatic leukodystrophy) and AMTAGVI (melanoma) in 2024, and ZEVASKYN (recessive dystrophic epidermolysis bullosa) in April 2025.[4] The European Medicines Agency (EMA) approved four advanced therapy medicinal products in 2025, including Aucatzyl and Zemcelpro.[5] Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has authorised 21 regenerative-medicine products under its conditional/time-limited early-approval system since 2014.[6] South Korea established a dual-track system for advanced regenerative medicine and advanced biologics in 2019, and since February 2025 has permitted fee-charging during clinical studies, providing investigators with revenue sources and channels for real-world evidence collection.[7]

Compared with these international developments, China's healthcare sector still lags in CGT clinical translation: ethical-review capacity is uneven, GMP-compliant in-hospital cell-manufacturing facilities are severely inadequate, interdisciplinary clinical talent is scarce, and long-term follow-up systems remain underdeveloped. The State Council's *Regulation* is the first administrative regulation to govern the full life-cycle management of novel biomedical technologies from clinical research through clinical translation, establishing a dual-track system of "clinical-research filing" and "clinical-translation approval". For the healthcare sector, this institutional transformation represents both a historic opportunity to embrace frontier technologies and a severe test of existing infrastructure, talent reserves and governance capacity. This paper evaluates the regulation's impact on the healthcare sector using an integrated PEST–SWOT analytical framework and proposes principal strategies.

2. Direct Impact Pathways of the Regulation's Core Provisions on the Healthcare Sector

The core provisions of the *Regulation* will affect the healthcare sector through four pathways.[8,9] First, institutional access thresholds: clinical research must be conducted in tertiary grade-A hospitals equipped with an independent scientific-review committee and an ethics committee, and clinical translation is limited to institutions that have participated in the clinical research of that specific technology, meaning only a minority of hospitals nationwide possess initial eligibility. Second, revenue-structure reshaping: once clinical translation is approved, hospitals may charge patients according to regulations. Against the backdrop of DRG payment reform, which has compressed the drug-income share of tertiary public hospitals to 24.3%, biomedical novel-technology fee items provide hospitals with a high-value-added revenue source independent of fixed medical-insurance quotas. Third, competency-certification requirements: hospitals must establish cell manufacturing, quality control, cold-chain transport and adverse-event surveillance systems that meet regulatory standards. This imposes rigid pressure for infrastructure upgrading on the majority of hospitals still oriented toward traditional drug therapy. Fourth, strengthened legal liability: when a serious adverse event occurs, the research institution must immediately suspend the study and report it; the National Health Commission may order adjustment or termination of the study. This provision directly converts technological risk into institutional reputational risk and administrative liability risk.

3. PEST Analysis: Macro-Environmental Impacts on Healthcare Sector Actors

3.1 Political environment

The *Regulation* establishes, for the first time, a unified national-level regulatory system, with the National Health Commission as the sole approval and supervisory department.[8,9] For tertiary grade-A hospitals, this means a direct and predictable communication channel with the regulator. Yet centralised approval also creates a professional bottleneck: the National Centre for Biotechnology Development and the Hospital Management Institute perform assessment functions, and the scale and disciplinary coverage of their expert pools show a marked gap relative to the innovation demands of tertiary hospitals nationwide. In particular, for technology platforms as divergent as gene editing and cell therapy, a generalist review model cannot guarantee assessment depth. Compared with the US FDA, which maintains a dedicated Office of Therapeutic Products within the Centre for Biologics Evaluation and Research for cell and gene therapy[4], China's review architecture awaits further professional subdivision. Risk-tiered management classifies technologies as high, medium or low risk, imposing restriction periods of five, three and one year respectively.[9] For medical institutions, this means high-risk technologies will remain locked within a limited number of institutions over longer cycles; hospitals that secure approval first may gain exclusive patient volume and revenue streams, while latecomers face formidable access barriers.

3.2 Economic environment

The breakthrough in fee-charging mechanisms exerts the most direct impact on hospital revenue structures. Under DRG payment reform, the drug-income share of tertiary public hospitals has fallen from approximately 36% before reform to 24.3%, while medical-service income has risen to 48.9%.[10] Fee items for clinical translation of novel biomedical technologies provide hospitals with a high-value-added revenue source independent of

medical-insurance quotas and unconstrained by DRG grouping. For departments such as haematology and oncology, this signals a transition from the traditional chemotherapy-plus-surgery model to a new model of cell therapy plus comprehensive management. Yet several problems remain: patient out-of-pocket ratios will stay extremely high[11]; China has not yet issued a specific medical-service price catalogue or mark-up standard[8], leaving hospitals unable to perform accurate cost–benefit analyses in the absence of pricing benchmarks.

3.3 Social environment

In recent years, the proportion of elderly people in China has risen year by year[13], creating long-term rigid demand for regenerative medicine and cell therapy. It is predictable that demand from patients with degenerative diseases such as Alzheimer's disease, Parkinson's disease and osteoarthritis will increase markedly; traditional drug efficacy is limited, and novel biomedical technologies are expected to become a new service-growth point. Nevertheless, public awareness of and support for the clinical use of novel biomedical technologies vary.[14,15] A nationwide survey covering more than ten thousand participants found that 72.0% of respondents worried about side effects of gene therapy and 61.9% about high costs.[16] Approximately two-thirds of respondents answered two or fewer gene-editing knowledge questions correctly, and the majority believed that the government-rather than physicians or patients themselves—should decide the scope of technology application.[15] This indicates that the informed-consent process must move beyond legal compliance to genuine patient education, yet physicians' time costs and knowledge reserves are often insufficient to support in-depth communication. Any treatment failure or adverse event may be rapidly amplified through social media into a public trust crisis, causing irreparable damage to hospital brand equity.[3,16]

3.4 Technological environment

The explosive growth of clinical trials of novel biomedical technologies in China poses a severe test to the technological infrastructure of medical institutions. Clinical trials of novel biomedical technologies require hospitals to possess the full capability chain of cell collection, cold-chain transport, preconditioning chemotherapy, cell infusion, cytokine release syndrome (CRS) monitoring and ICU rescue. At present, the number of haematology and oncology centres with this integrated capability is highly concentrated in top-tier tertiary hospitals in Beijing, Shanghai, Guangzhou and Hangzhou. Moreover, unlike pharmaceutical companies that can manufacture cells in standalone facilities, hospital-based cell therapy usually needs to be completed in in-hospital or hospital-adjacent laboratories, imposing extremely high demands on GMP-standard cleanrooms, quality-control testing platforms, batch-traceability systems and staff training.[12] Regarding digital regulatory infrastructure, the *Working Specifications* require hospitals to report clinical-application cases individually through an information system[9], necessitating interfacing of electronic medical record systems, adverse-event reporting systems and follow-up management systems with the national platform. Currently, hospital informatisation levels vary markedly: leading hospitals have largely achieved interoperability, yet numerous tertiary hospitals in central and western China still operate isolated legacy systems. Clinical implementation of novel biomedical technologies demands interdisciplinary talent combining clinical medicine, cell biology, molecular biology, genetic informatics and ethical-review literacy. At present, very few practising physicians have received systematic training in novel biomedical technologies. Nursing teams' knowledge and skills in CRS recognition and management, long-term follow-up execution and patient psychological support await improvement.

4. SWOT Analysis: Competitive Position of the Healthcare Sector

4.1 Strengths

The core strengths of the healthcare sector arise from the triple overlay of massive patient volume, government strategic investment and concentrated clinical resources. China's huge patient population provides an excellent scenario and cohort for clinical trials of novel biomedical technologies. Meanwhile, the "Healthy China 2030" initiative and the 14th Five-Year Plan have listed stem-cell and gene therapy as priority fields, and government investment at all levels has provided policy and financial support for healthcare-system upgrading.[17] This combination of "patient volume + policy support + specialist reputation" constitutes a barrier that is difficult to replicate.

4.2 Weaknesses

Regarding ethical-review capacity, ethics committees of tertiary hospitals nationwide vary widely in quality; review at some institutions is perfunctory, and protection mechanisms for vulnerable populations are weak.[16] Regionally, restricting clinical research to tertiary hospitals objectively concentrates resources in eastern coastal cities while leaving an extremely unbalanced regional distribution.[1] On pricing, the *Regulation* only permits fee-charging in principle, lacking a concrete price-formation mechanism, so hospitals face a policy vacuum in actual operations.[8,11] In talent structure, interdisciplinary personnel combining clinical, cellular and ethical knowledge are severely inadequate, and the specialised capacity of nursing teams in novel biomedical technologies is largely non-existent.

4.3 Opportunities

Accelerated population aging in China is driving a sustained increase in patients with degenerative diseases, providing a broad patient base for novel biomedical technology applications.[13] The *Regulation* includes rare-disease technologies within its approval scope; China's two batches of the *Rare Disease Catalogue* cover 207 diseases[9], most of which lack effective treatments. For

tertiary hospitals with the relevant specialist capacity, establishing rare-disease CGT diagnosis and treatment centers will bring high-value-added patient cohorts and enhanced academic reputation. Regarding medical-consortia collaboration, the construction of national regional medical centres and county-level medical communities provides an organisational framework for a tiered collaboration model in which core hospitals export technology and primary-level institutions assume follow-up responsibilities.[17]

4.4 Threats

At present, any serious adverse event or treatment failure related to novel biomedical technologies may be rapidly amplified through social media, causing irreparable damage to hospital brand equity.[3,16] Regulatory arbitrage risk arises from the filing system during the clinical-research phase. Some institutions may exploit grey zones to conduct de facto unapproved fee-charging projects; once detected, the entire institution's research credentials may be implicated.[8,9] Uncertainty in reimbursement policy means that even after clinical-translation approval, if basic medical insurance, catastrophic illness insurance and commercial health insurance fail to form effective linkage, hospitals will face dual pressure from insufficient patient payment capacity and accounts-receivable backlog.[11]

5. PEST–SWOT Cross-Matrix and Healthcare-Sector Response Strategies

Based on the above PEST and SWOT analyses, we constructed a PEST-SWOT cross-matrix and propose corresponding healthcare-sector response strategies (Table 1).

Table 1: PEST–SWOT cross-matrix analysis of novel biomedical technologies and healthcare-sector response strategies.

Cross dimension	Environmental–competitive tension	Core contradiction	Healthcare-sector response strategy direction
P × S	Unified regulation vs. uneven ethical review	The state demands high-level ethical governance, yet hospital ethics-committee capacity is severely inadequate	Construct a three-tier clinical-research network of core hospitals, regional centres and primary-level institutions to achieve mutual recognition of ethical-review results
P × T	Tertiary-hospital access threshold vs. regional resource imbalance	Only a minority of tertiary hospitals nationwide possess novel-biomedical-technology capability; institutions in central and western China are easily marginalised	Establish a national network of clinical research centres for novel biomedical technologies, achieving regional balance through remote review and technology export
E × S	Fee-charging breakthrough vs. DRG cost-control pressure	High-value-added fee items for novel biomedical technologies conflict with the direction of medical-insurance cost containment	Establish dedicated cell-therapy operational units and pilot outcome-based pricing models
E × T	Revenue opportunity vs. infrastructure investment cost	Hospitals must invest tens of millions of yuan to build GMP laboratories, yet patient volume is uncertain	Promote hospital–enterprise collaboration to co-build cell-manufacturing centres, adopting a mixed-ownership "hospital + enterprise" model to share risk
S × O	Aging-related rigid demand vs. inadequate patient education	The aging population accelerates demand for novel biomedical technologies, yet informed-consent quality is difficult to guarantee	Establish a whole-cycle patient-management platform, converting informed consent into a continuous patient-education process
T × W	Talent-loss threat vs. interdisciplinary talent shortage	International competition intensifies poaching risk, yet a domestic training system for novel biomedical technologies has not been established	Implement a dedicated talent-echelon programme for novel biomedical technologies, establishing a three-dimensional physician–technician–nurse competency-certification system

5.1 Construct a three-tier clinical-research network of "core hospitals–regional centres–primary-level institutions"

Addressing the problem that clinical research is restricted to tertiary hospitals, yet fewer than one hundred tertiary hospitals nationwide possess integrated novel-biomedical-technology capability, ethical-review quality is uneven, and central and western institutions are effectively excluded from the innovation ecosystem[16], we propose constructing a three-tier clinical-research network of core hospitals, regional centres and primary-level institutions. Measures include: (1) Designate 50–

100 tertiary grade-A hospitals possessing state-key disciplines in haematology or oncology as national clinical research centres for novel biomedical technologies. These centes shall be granted preliminary review authority for clinical research filings and final ethical-review authority. They will undertake high-complexity clinical research and assume talent-training responsibilities.

(2) Within each province, select 1–2 tertiary hospitals as regional clinical research centres for novel biomedical technologies. These regional centres will receive technology transfer and standardized training from core national centres and will be responsible for the clinical translation of medium- to low-risk technologies. Furthermore, they shall establish bidirectional referral and tele-consultation mechanisms with the core hospitals.

(3) Through medical consortium agreements, integrate community health service centres and secondary hospitals into the follow-up and rehabilitation management network for novel biomedical technologies. Primary-level institutions will not perform cell manufacturing or infusion functions but will be tasked with long-term follow-up data collection, quality-of-life assessments, and patient education. Data collected at this level will be incorporated into the core hospitals' real-world data (RWD) system.[17]

(4) Establish an ethical-review collaboration platform at the regional-centre level. Protocols approved by the ethics committees of core hospitals shall be mutually recognized within the region to avoid duplicate ethical review. Primary-level institutions may obtain ethical review services through this platform, thereby shortening the start-up time for multicentre trials.[16]

5.2 Establish dedicated cell-therapy operational units and outcome-based pricing models

Addressing the directional conflict between biomedical novel-technology fee items and China's DRG payment reform, as well as insufficient patient payment capacity, we propose establishing dedicated cell-therapy operational units and outcome-based pricing models. Specific measures are as follows.

(1) Within the hospital, or within haematology or oncology departments, establish independent gene and cell therapy centres equipped with dedicated cell-manufacturing laboratories (which may be co-built with enterprises), full-time CRS monitoring teams, independent fee-coding systems and dedicated cost-accounting systems.

(2) Explore a composite pricing structure of base fee plus efficacy performance, linking hospital revenue to treatment outcomes. The base fee covers cell manufacturing, quality control and infusion costs; the efficacy-performance component is paid in instalments according to patient treatment response or quality-of-life improvement.

(3) Hospitals should establish a patient-service department for novel biomedical technologies, specifically responsible for medical-insurance policy interpretation, commercial insurance interfacing, charity-assistance application and instalment-payment scheme design. Incorporate post-translation novel biomedical technologies into the negotiation scope of catastrophic illness insurance and inclusive supplementary insurance (Huiminbao), and encourage hospitals to co-develop dedicated insurance products for novel biomedical technologies with insurance companies.[11]

(4) Adopt a mixed-ownership model in which the hospital provides premises and clinical resources while the enterprise provides technology and capital, to co-build a GMP cell-manufacturing centre. This model converts tens of millions of yuan in fixed-asset investment into shared operating costs, reducing the hospital's financial risk.[12]

5.3 Implement a dedicated talent-echelon programme and ethical-review accreditation for novel biomedical technologies

To address the critical deficit of interdisciplinary professionals integrating clinical medicine, molecular biology, cell biology, genetic informatics, and ethical knowledge, alongside the superficial nature of ethical review[16], we propose the implementation of a dedicated talent-echelon program and an accreditation system for ethical review pertaining to novel biomedical technologies. The specific measures are delineated as follows.

(1) Establish a competency certification framework for novel biomedical technologies. Physician certification should encompass indication assessment, preconditioning regimen design, cytokine release syndrome (CRS) grading and management, and long-term follow-up management. Technician certification should include cell collection, cold-chain transportation, Good Manufacturing Practice (GMP) laboratory operations, and batch traceability. Nurse certification should cover patient education, symptom monitoring, psychological support, and data entry. The certification system will adopt a tiered structure (junior, intermediate, senior) linked to professional title promotion and post allowances.

(2) Implement compulsory training accreditation for members of tertiary hospital ethics committees, covering the principles of novel biomedical technologies, risk identification, special informed consent requirements, and protection of vulnerable populations. Additionally, establish an ethical review quality-rating system; the rating results should be tied to the hospital's clinical research credentials, and institutions failing to meet standards should have their qualification for new project filings suspended.[16]

(3) Core hospitals should establish specialized training centers for physicians in novel biomedical technologies, exploring innovative training models, and may establish exchange programs with overseas premier centers for novel biomedical technologies, dispatching key physicians abroad for advanced study annually.[12]

5.4 Advance an integrated whole-cycle patient-management and real-world data platform

Addressing the uncertainty of long-term risks of novel biomedical technologies, the difficulty of capturing delayed adverse events within traditional follow-up periods, and the silo effect of hospital information systems that obstructs data integration[15], we propose advancing an integrated whole-cycle patient-management and real-world data platform. Specific measures are as follows.

(1) A patient-management platform encompassing the entire continuum from screening, collection, manufacturing, infusion, monitoring, follow-up to relapse should be established. During the screening phase, AI-assisted indication assessment is employed; the collection phase ensures complete traceability of cell samples; the infusion phase incorporates a cytokine release syndrome (CRS) early-warning scoring system; and the follow-up phase mandates long-term tracking for 5-10 years, integrating measures of survival quality, functional status, health economics, and patient-reported outcomes (PROs). Data from the platform are automatically interfaced with the national information system dedicated to clinical research and the clinical translation of novel biomedical technologies.

(2) A staged informed-consent process should be implemented, comprising pre-treatment education delivered via video, graphics, and three rounds of face-to-face interviews; daily risk updates throughout the treatment period; and quarterly follow-up education after treatment. All educational sessions are documented and archived to provide evidence for ethical reviews and potential medical disputes.[16]

(3) Hospital Health Information System (HIS), Laboratory Information System (LIS), Picture Archiving and Communication System (PACS), and Electronic Medical Record (EMR) systems should be integrated with a dedicated database for novel biomedical technologies, thereby establishing standardized data-collection templates. These systems should interface with medical-insurance settlement data, mortality surveillance data, and patient-registry databases to enhance hospital-level capacity for generating real-world evidence. The aggregated data are utilized not only for safety surveillance but also to facilitate research outputs, reimbursement negotiations, and academic exchanges.

6. Outlook

The enactment of China's *Regulation on Clinical Research, Translation, and Application of Novel Biomedical Technologies* signifies a shift within the healthcare sector from spontaneous exploration toward institutional standardization in the application of frontier technologies. Looking ahead, the deployment of novel biomedical technologies in China will progressively evolve from discrete applications to comprehensive integration. It is anticipated that an increasing number of tertiary hospitals will establish routine clinical-translation capabilities for such technologies, thereby forming a nationwide clinical-research network. In terms of payment models, as outcome-based payment pilots expand, commercial health insurance products mature, and catastrophic illness insurance catalogs undergo dynamic adjustment, a multi-tiered payment system is expected to crystallize; dedicated commercial insurance products for novel biomedical technologies are likely to emerge in the coming years. Concurrently, with the development of real-world data (RWD) integrated platforms and enhanced analytical capacity, hospitals adopting novel biomedical technologies will be positioned to generate high-quality evidence from reported data, supporting research outcomes, reimbursement negotiations, and international regulatory harmonization. Ultimately, the successful integration of novel biomedical technologies into China's healthcare landscape will depend on several critical factors: whether their therapeutic efficacy demonstrably surpasses conventional medical approaches; whether their quality and end-to-end management withstand rigorous scrutiny; whether hospital administrators perceive these technologies as strategic opportunities for transformation rather than merely revenue-generating tools; and whether clinical teams genuinely embrace the value of personalized medicine.

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Conflict of Interest

The authors declare no conflict of interest.

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