REVIEW ARTICLE

China's cell therapy landscape: Regulatory advances and emerging challenges

Peipei Zhao[1], Zhenbin Mao[2], Yuping Che[2], Zhe Huang[1, *]

[1]School of Business Administration, Shenyang Pharmaceutical University, Shenyang, Liaoning, China. [2]China Food and Drug Corporation Quality and Safety Promotion Association, Beijing, China.

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Since 2017, Chinese regulatory authorities have implemented a series of targeted reforms to expedite clinical translation, which includes classifying cell therapy, shortening investigational new drug (IND) review timelines, and introducing accelerated approval pathways. Although these measures have driven a remarkable increase in clinical trials and market approvals, they also present challenges in unifying dual-track oversight, sustaining long-term safety surveillance, and harmonizing manufacturing processes and quality control standards. This review evaluated the regulatory advances and ongoing challenges in China's cell therapy sector since 2017, assessing how these reforms had influenced approval pathways, industry growth, and technological innovation of cell therapy products. A comprehensive review of China's cell therapy regulatory framework was conducted with an emphasis on key reform initiatives. Clinical trial application records, product approval data, and market growth forecasts were analyzed to characterize industry development. The results showed that, since 2017, the National Medical Products Administration (NMPA) has progressively enacted regulatory reforms to accelerate approval processes for innovative drugs including cell therapy products. The Center for Drug Evaluation (CDE) has released a suite of more targeted guidelines to support research and development. There has been a significant increase in clinical trial applications in China from 2017 to 2024 with a total of 257 IND applications submitted for cell therapy projects. Market forecasts indicate robust expansion in the cell therapy sector, projecting the chimeric antigen receptor T cell therapy (CAR-T) market to reach $28.9 billion by 2030. China's regulatory framework for cell therapy has advanced markedly, driving innovation and industrial growth. Nevertheless, the increasing diversity and complexity of cell therapy products continue to challenge regulatory capacities. Ongoing refinement of regulations and strengthened collaboration across industry stakeholders will be pivotal to support sustainable development of the cell therapy sector.

Keywords: China; cell therapy products; regulatory progress; industry development; challenges.

[*]**Corresponding author:** Zhe Huang, School of Business Administration, Shenyang Pharmaceutical University, Shenyang, Liaoning 110016, China. Email: tougaoyong2025@163.com.

Introduction

The National Medical Products Administration (NMPA) and the National Health Commission (NHC) of the People's Republic of China regulate cell therapy products in China under the terms of "drug" and "technology." The Center for Drug Evaluation (CDE) of NMPA functions as its dedicated review division, responsible for evaluating clinical trial submissions and conducting technical assessments of marketing authorization applications [1]. At present, China

lacks dedicated legislation for cell therapy, and such products are evaluated and approved under the biological products framework. The CDE has not established a specialized review division for cell therapy products. Instead, the Chemistry, Manufacturing, and Controls (CMC) Department of Biological Products, the Clinical Department of Biological Products, the Department of Statistical and Clinical Pharmacology, and the Department of Pharmacology and Toxicology jointly oversee their assessment. For decades, China's cell therapy sector has operated under a dual-track system with the NHC regulating clinical research as "technology" and the NMPA governing marketing approval and post-market supervision as "drug." Since 2017, the registration pathway for cell therapy products has become progressively clarified, driving a surge in clinical trial submissions. According to the insight database, from 2017 to 2024, a total of 257 cell therapy programs in China submitted Investigational New Drug (IND) applications including 156 immunotherapies, 84 stem cell therapies, and 17 other programs. The first-time clinical trial registrations rose from 46 in 2022 to 81 in 2023 and remained high as 75 in 2024 [2], reflecting rapid growth and sustained research activity. This fast-growing trend is expected to continue in the coming years. The market size of chimeric antigen receptor T-cell immunotherapy (CAR-T) in China was approximately $200 million in 2021 and is forecast to reach $28.9 billion by 2030, growing at a compound annual growth rate (CAGR) of 45.0% from 2022 to 2030 [3]. This study reviewed China's regulatory advances and current oversight of cell therapy products since 2017, focused on application and approval processes, summarized the industry's status and influencing factors, examined existing challenges, and assessed future regulatory trends.

Regulatory framework for cell therapy products in China

(1) Establishing definitions and classifications

Internationally, cellular products are commonly classified as Advanced Therapy Medicinal Products (ATMPs), encompassing genetically modified and/or *in vitro* manipulated cells or tissues, such as gene-edited cells, nucleic acids, viral vectors, and engineered tissues. Classification criteria vary among jurisdictions due to the intrinsic complexity and heterogeneity of these products and differing regulatory frameworks. ATMPs have been explicitly defined in the United States of America, the European Union, and Japan. In contrast, China lacked a formal regulatory definition for cell therapy products until 2017 when the former State Food and Drug Administration (SFDA) issued the Technical Guidelines for the Research and Evaluation of Cell Therapy Products (Trial Implementation) [4]. Under the 2020 Provisions for Drug Registration by the State Administration for Market Regulation and the NMPA's Classification and Filing Requirements for Registered Biological Products, cell therapy products have been designated as therapeutic biological products [5, 6]. Recent data show a steady rise in cell therapy applications in China with ATMP INDs being comprised 13% of all biologic's INDs in 2023 and 12% in 2024, respectively [7]. To address emerging regulatory challenges, the CDE convened domestic experts in early 2024 to clarify China's ATMP definition. ATMPs are now categorized into three groups including gene therapy products, cell therapy products, and other products including tumor neoantigen products and cell derivatives with genetically modified cells expressly placed under cell therapy products [7].

(2) Optimizing the review process

China has conducted clinical research on cell therapy since the 1990s, but it was not that pharmaceutical companies and research organizations began to prioritize this field until after 2010. The "Wei Zexi incident" in 2016, in which a 21-year-old student died after receiving an unproven immune cell therapy at a hospital where he located *via* paid online "Baidu search" ads, provoked widespread public outrage over misleading medical advertising and regulatory shortcomings, which led regulators to strengthen oversight of cell therapies and other emerging

Table 1. Cell therapy product launches in China since 2017.

Name	Availability	Enterprise	Target
Zevorcabtagene autoleucel	2024	CARsgen Therapeutics	BCMA
Ciltacabtagene autoleucel	2024	Nanjing Legend Biotechnology	BCMA
Inaticabtagene autoleucel	2023	Juventas Cell Therapy	CD19
Equecabtagene autoleucel	2023	Innovent (Suzhou); Nanjing IASO Biotherapeutics	BCMA
Relmacabtagene autoleucel	2021	JW Therapeutics (Shanghai)	CD19
Axicabtagene ciloleuce	2021	Kite Pharma	CD19

medical technologies with a heightened focus on patient protection. Since 2017, the NMPA's CDE and the NHC have issued a series of guidelines that establish a technical framework for regulating cell therapy products. As of that year, six such products have received market approval (Table 1). A notable trend in China's drug regulation has been the progressive optimization of the review process. In 2018, the NMPA introduced implicit approval for clinical trials, reducing the review period for new drug applications from 90 days to 60 days. The 2020 Provisions for Drug Registration further accelerated these timelines, in which the New Drug Applications (NDAs) must be reviewed within 200 days of receipt, whereas advanced therapy medicinal products (ATMPs) receive priority review in 130 days [8]. Additionally, the adoption of a parallel inspection and registration review mechanism has substantially improved approval efficiency [9].

(3) Accelerate approval speed

To accelerate approval of clinically necessary therapies including cell therapy products, foster innovation, and expedite market access, China has implemented a suite of incentives to stimulate research and development and shorten time-to-market. These measures aim to improve treatment availability for patients with life-threatening conditions or severely compromised quality of life, while bolstering the global competitiveness of Chinese innovative drug developers. Specifically, cell therapy products could incorporated into China's accelerated approval pathways, comprising breakthrough therapy designation, priority review, and conditional approval to facilitate rapid market entry for products demonstrating clear advantages over existing treatments. In addition, the CDE provides regulatory support and consultation services such as early scientific advice, guidance on critical technologies, rolling submission of dossiers, and enhanced communication channels to help sponsors navigate uncertainties and overcome technical or regulatory hurdles during development. Nevertheless, an independent accelerated pathway exclusively for ATMPs including cell therapies has not yet been established, which may constrain further rapid industry growth. In 2024, fifteen cell therapy products entered the priority review pathway, and three were granted breakthrough therapy status.

(4) Initiate regulatory science action

In 2019, China launched the Regulatory Science Action Plan to strengthen research, development, and regulation of emerging technologies, spanning pharmaceuticals and medical devices, through in-depth studies in regulatory science [10]. Its primary aim was to align scientific discoveries with regulatory policies and establish an evidence-based oversight framework [11]. To achieve this, the plan prioritized interdisciplinary collaboration and the integration of diverse scientific resources to tackle regulatory challenges inherent to novel and complex technologies. By conducting systematic research and data analysis, the initiative supported government decision-making on efficient regulatory strategies that ensured the safe, effective, and standardized deployment of innovative technologies, thus

fostering synchronized advancement of science and public health. In the domain of cell therapy, the Regulatory Science Action Plan has been pivotal to progress. It has been carried out for three periods, each addressing key research areas such as cell preparation, quality control, and clinical trial design to establish comprehensive standards for products including CAR-T and stem cell therapies. The plan's science-based approval process and risk-based assessment methodologies have markedly accelerated the transition of cell therapy products from research and development to market, improving overall review efficiency. Moreover, by issuing clear, evidence-driven guidelines [11], the initiative has bolstered China's competitiveness in the global regenerative medicine field and incentivized innovation among companies and research institutions. It has strengthened safety monitoring and risk management systems for cell therapy products, ensuring prompt identification and mitigation of potential hazards during clinical use. Collectively, these measures advance standardization and underpin the sustainable, healthy development of regenerative medicine in China.

Emerging trends in China's cell therapy products industry development

(1) Current status of the industry

The development of China's cell therapy industry began in the late 20th century and remained nascent until 2017. Following the 2017 reform of the drug review and approval system, domestic technological innovation and multi-level policy support have accelerated industry growth. By 2025, the market size of China's stem cell therapy sector was estimated at approximately ¥140 billion (CNY) [12]. The Insight database indicates that, from 2017 to 2024, China conducted 257 clinical trials of cell therapy products, comprising 143 phase I, 45 phase I/II, 42 phase II, 10 phase III, and 17 other studies. Early phase trials including phases I, I/II, and II represented 89.5% of the total. In 2024, China registered 75 inaugural cell therapy clinical trials across 62 product variants including 29 stem cell–based (25.2%), 27 CAR-T–based (23.5%), 8 oncolytic virus–based (7.0%), and 6 tumor-infiltrating lymphocyte (TIL)–based (5.2%) with phase I studies predominating 49 trials (65.3%) followed by 8 trials of phase II (10.6%), 3 trails of phase III (4.0%), and 15 trials of other protocols (20.0%). When indications were categorized, anti-tumor trials led with 38 studies (50.7%) followed by hematological disease trials with 9 studies (12.0%), and digestive disease trials with 7 studies (9.3%). As of May 2024, a total of 273 cell therapy products have received global approval with six approved in China, representing 12% of the worldwide cohort and predominantly targeting the CD19 and BCMA therapeutic antigens. In terms of market scale, China's cell and gene therapy (CGT) market expanded to grow rapidly under favorable polices and increased research and development investment. The compound annual growth rate is likely to be higher than the global average [13]. Projections indicate continued rapid expansion with a forecasted CAGR of 127% between 2022 and 2025, driving market size to approximately ¥16.8 billion by 2025 [14]. From an industry development standpoint, leading Chinese cell therapy firms have begun formulating global commercialization strategies. For example, Legend Biotech's Carvykti obtained U.S. marketing authorization in 2022 [15]. Moreover, there is a clear regional concentration of research and development activity with 70% of the 187 facilities conducting clinical trials between 2017 and 2023 based in Shanghai, Beijing, and Guangzhou, China, suggesting that supportive local policies and infrastructure are catalyzing robust sector growth.

(2) Analyzing promoting factors

The convergence of technological innovation, regulatory enhancements, commercial insurance coverage, and capital investment has catalyzed the rapid expansion of China's cell therapy market, meeting growing clinical needs, and laying a solid foundation for future therapeutic breakthroughs. The rising cancer burden has

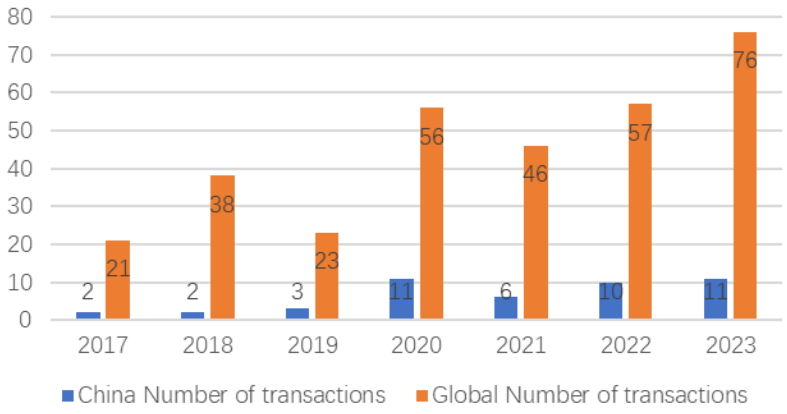

Figure 1. Global and Chinese drug companies deal with trends in cell therapy research and development (Source: Insight database).

driven demand for effective interventions, presenting substantial opportunities for cell therapy. In 2022, new cancer cases in China were estimated at approximately 4,824,700 with cancer-related mortality increasing by 21.6% from 2005 to 2020 [14, 16]. Technological advances such as refined manufacturing processes and advanced therapeutic protocols have improved the safety and efficacy of cell therapy products, while emerging tools like gene editing and precision medicine continue to expand treatment possibilities. Concurrently, regulatory authorities have issued a series of cell therapy guidelines to keep pace with these technological developments and to establish a robust oversight framework. The introduction of commercial insurance has significantly reduced financial barriers for patients, broadening treatment access, and encouraging uptake of novel therapies. Furthermore, the influx of investment has strengthened research and development capacities and enriched product pipelines (Figure 1). For example, funding rounds led by CRC Pharma, Cart-Med, and Neowisebio have accelerated development of CAR-T and TCR-T technologies [17-19].

Regulatory challenges and prospect

The development of cellular therapies in China has advanced considerably under successive regulatory reforms, yet several challenges remain. The current dual-track system, comprising Investigator-Initiated Trials (IIT) under "technology" oversight and Investigational New Drug (IND) registrations under "drug" regulation, provides flexibility for early-stage research and development, but seamless translation to market authorization remains problematic. The emergence of gene editing and cell reprogramming technologies has diversified the cell therapy pipeline, placing greater demands on regulatory capacity. Currently, most cell therapy approvals rely on short-term clinical data and are granted conditionally, expediting market entry but leaving gaps in long-term safety and efficacy evidence [20]. To address these issues, more adaptive, science-based standards are needed for CMC changes, animal model selection, and clinical endpoint determination. Moreover, regulatory complexity will increase further due to challenges in sourcing individual donor tissues, segmented manufacturing processes, and limited clinical subject availability. The continual introduction of novel products and methodologies has elevated the competency and expertise required of regulatory personnel. To meet these demands, authorities should implement targeted training and continuing education programs to strengthen professional skills and resilience. Concurrently, forming interdisciplinary regulatory teams will foster collaboration among specialists from diverse fields, enhancing overall review efficiency and quality. These measures will not only improve the

accuracy and timeliness of evaluations but also deepen regulators' understanding and oversight of emerging technologies and complex products, ensuring that regulatory practices remain proactive and adaptable. To address these challenges, regulators should implement adaptive, evidence-based standards. For example, expanding the pool of expert reviewers and allocating additional resources will enhance both the efficiency and rigor of the review process. Concurrently, China's cell therapy regulatory framework must be aligned with international norms by establishing a comprehensive product database and enabling real-time monitoring and analysis of clinical data and adverse events, thereby strengthening the scientific basis and timeliness of oversight. Promoting interdisciplinary collaboration, integrating expertise in biology, medicine, and data science through dedicated regulatory teams, will further improve staff proficiency and resilience, driving overall review quality. Finally, fostering continuous communication and partnership among industries, research institutes, and regulators will help address research and development and approval challenges while enhancing the sector's innovation capacity and competitiveness.

Conclusion

Since 2017, China's regulatory reforms in cell therapy have markedly influenced innovative drug research and development and industry expansion. Optimizing review procedures, accelerating approval timelines, and initiating the Regulatory Science Action Plan have collectively enhanced market access efficiency and competitive positioning for cell therapy products. Nevertheless, as technologies evolve and product portfolios diversify, the regulatory framework must adapt to address increasing complexity in market requirements and safety monitoring. Key measures such as adopting international standards, improving data sharing and transparency, fostering interdisciplinary collaboration, and refining oversight mechanisms will be critical to sustaining the healthy growth of China's cell therapy sector. These initiatives are expected to elevate China's role in the global cell therapy landscape, meeting rising domestic and international demand for advanced therapeutic options.

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