

Regulatory Reform and Development of the Pharmaceutical Industry in China

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ABSTRACT

Over the past decade, China's pharmaceutical industry has transformed from a generics-focused manufacturing base into a global center of innovative drug development. This chapter examines the institutional mechanisms underpinning this transition, tracing the evolution of China's drug regulatory reform from 2015 to 2026 across three sequential stages. It analyzes how successive reforms dismantled structural barriers that had long suppressed domestic innovation, reoriented the regulatory system toward clinical value, and integrated China into global pharmaceutical development networks. The chapter also identifies persistent challenges—including limited original discovery capacity, regulatory capacity constraints, and commercialization bottlenecks—and outlines priorities for the next phase of reform.

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I. INTRODUCTION

Over the past decade, China's pharmaceutical industry has undergone a remarkable transformation. Once known primarily as a generics powerhouse, it has emerged as one of the world's most dynamic centers of pharmaceutical innovation. The scale and pace of this shift are demonstrated by the rapid expansion of China's innovative drug pipeline. Currently, China accounts for approximately 29% of the world's innovative drug candidates in the development pipeline,² as shown in Figure 1. In 2024, Chinese organizations accounted for 39% of innovative drugs receiving first global approval (Figure 2). Among these newly approved drugs, nearly half were developed by domestic firms.³ Beyond pipeline expansion, China has established itself as a key player in cutting-edge therapeutic domains such as antibody therapeutics and cell therapy, while the number and value of international licensing transactions involving Chinese companies have increased rapidly.⁴

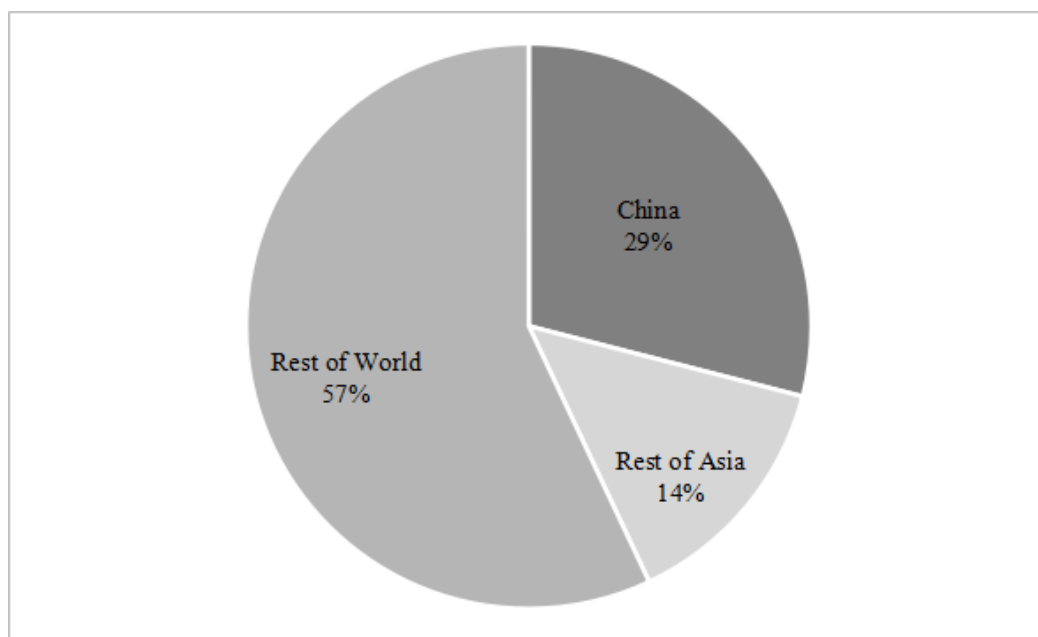


Figure 1 Regional Distribution of Global Innovative Drug Pipelines

Source: McKinsey & Company, The Emerging Epicenter: Asia's Role in Biopharma's

² McKinsey & Company, "The Emerging Epicenter: Asia's Role in Biopharma's Future," McKinsey & Company, January 7, 2026, <https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future> (last visited Aug. 23, 2026).

³ Sen Liu et al., "The Rise of China's Pharmaceutical Industry from 2015–2024: A Decade of Innovation," *Nature Reviews Drug Discovery* 24 (2025): 738–39.

⁴ Id.; Boston Consulting Group (BCG), *Emerging New Drug Modalities: Pipeline Growth, Deal Activity, and China's Rising Role*, BCG (Oct. 2025)

Future (January 7, 2026).

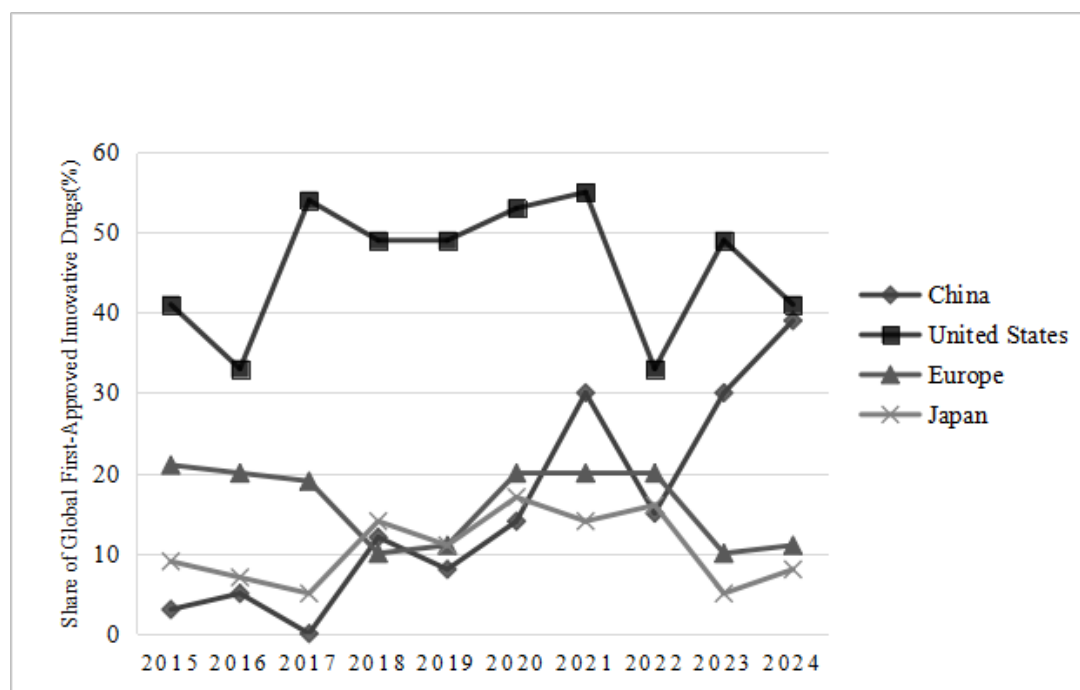


Figure 2 Regional Distribution of First Global Approvals of Innovative Drugs (2015-2024)

Source: Sen Liu et al., The Rise of China's Pharmaceutical Industry from 2015-2024: A Decade of Innovation (July 21, 2025).

Despite robust empirical evidence documenting China's rapid innovative ascent, the institutional mechanisms underpinning this industry-wide transformation remain underexplored in existing scholarship.⁵ To fully grasp the magnitude of this transition, it is critical to examine the structural barriers that stifled domestic pharmaceutical innovation for decades prior to reform. Prior to 2015, securing sufficient medicine supply and nurturing a domestic pharmaceutical manufacturing base constituted the overriding policy objectives in China's pharmaceutical regulatory framework.⁶ Consequently, the regulatory system was fundamentally oriented toward the assessment of generic drugs, prioritizing manufacturing "consistency" over clinical "scientific validity." While well-suited to these earlier objectives, this regulatory framework

⁵ Wei Guo & Lan Xue, "The Historical Evolution and Future Trend of the Regulation System of Drug Evaluation in China," *Journal of Public Management* 14 (2017): 26–38.

⁶ Ruixue Jia et al., "Improving Regulation for Innovation: Evidence from China's Pharmaceutical Industry," NBER Working Paper No. 31976, National Bureau of Economic Research, December 2023, <https://www.nber.org/papers/w31976>; Ministry of Industry and Information Technology, "2015 Pharmaceutical Industry Main Economic Indicators Completion," July 12, 2016, https://wap.miit.gov.cn/gyhxxhb/jgsj/xfpgys/gzdt/art/2020/art_2fc2815f80dc43c68009eac97337f7aa.html.

imposed growing constraints on innovation as the industry's technological frontier expanded. Severe misallocation of regulatory resources gave rise to substantial administrative review backlogs and extended drug-approval lags. In this framework, generic replication became far more commercially appealing than original drug discovery, with low-level imitation and “pseudo-innovation” crowding out genuine pharmaceutical innovation.⁷ In addition, clinical trial standards were inconsistent with international benchmarks. These barriers altogether trapped the sector in a self-reinforcing cycle of incremental, low-innovation production.⁸

However, beginning in 2015, a wave of regulatory reforms started to dismantle the entrenched barriers and propel China's transition from a generics powerhouse to a major source of pharmaceutical innovation. The reform unlocked China's latent strengths, including a large domestic market, extensive manufacturing capabilities, cost advantages, a growing professional talent pool, and abundant clinical research resources.⁹ Its agenda unfolded across three sequential stages, each targeting a distinct institutional constraint that had long suppressed pharmaceutical innovation.

The first stage in 2015 established the regulatory foundations necessary for pharmaceutical innovation by rebuilding the credibility, efficiency, and predictability of the regulatory system.¹⁰ Reforms such as redefining “new drugs” around global originality, eradicating systemic clinical data fraud, and laying the groundwork for automatic approval of clinical trial applications absent regulatory objection within a specified period—collectively transformed a previously innovation-impeding regulatory regime into an innovation-enabling governance framework.¹¹

Subsequently, the second stage from 2016 to 2019 tackled frictions embedded in the innovation system itself by reconfiguring the institutional relationships linking research, manufacturing, and regulation. The rollout of the Marketing Authorization

⁷ Jinxi Ding et al., “Research on Priority Review of New Drugs in China,” *Chinese Journal of New Drugs* 26 (2017): 872–77; Yaqin Liu et al., “Optimizing Innovation Policy Environment to Promote High-Quality Development of Pharmaceutical Industry—Analysis and Reflection on Drug R&D Innovation Trends in China,” *Price Theory & Practice*, no. 5 (2024): 82–86.

⁸ Na Ni et al., “Promoting Effect of Review and Approval System Reform on Clinical Trials,” *Chinese Journal of New Drugs* 30 (2021): 1825–29; Swagat Tripathy et al., “Challenges and Prospects in Chinese Pharmaceutical Regulatory Environment,” *Journal of Generic Medicines* 17 (2020): 106–14.

⁹ Tripathy et al., *supra* note 7; World Health Organization (WHO), *China Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health*, WHO (2017), <https://www.who.int/publications/i/item/9789241512176>.

¹⁰ Jia et al., *supra* note 5.

¹¹ Che Li et al., “Pilot Practice and Multi-party Enlightenment of Optimizing Innovative Drug Clinical Trial Review and Approval—Taking a Clinical Trial Institution in Shanghai as an Example,” *China Food & Drug Administration Magazine*, no. 4 (2026): 74–81.

Holder (MAH) system separated R&D from physical manufacturing requirements, ensuring that innovation activities were no longer constrained by manufacturing qualifications. Meanwhile, China's membership in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) integrated domestic regulatory standards with global operational norms.¹² Together, these reforms substantially lowered commercialization barriers and enabled innovative firms to better integrate into global pharmaceutical development systems.¹³

The final reform phase in the period of 2020 to 2026 introduced a value-centered shift in innovation incentive rules. Having opened up general channels for new drug development in prior rounds, regulators began to prioritize high-quality innovation with genuine clinical value instead of giving equal support to all new chemical modifications. Policymakers deployed a suite of value-based regulatory tools, including breakthrough therapy designations, conditional marketing authorization for unmet medical needs, and regulatory evaluation assisted by artificial intelligence (AI). These instruments tied official review support directly to substantive therapeutic gain rather than minor structural chemical modifications.¹⁴

While institutional reform can unlock existing potential, it cannot on its own generate the scientific capabilities underpinning next-generation pharmaceutical innovation. Challenges such as innovation gap in original discovery and clinical value, regulatory capacity constraints amid growing innovation capabilities, and commercialization bottleneck for innovative drugs will increasingly shape China's future innovative competitiveness. Accordingly, the central challenge faced by China's pharmaceutical industry is no longer unlocking existing potential but cultivating the scientific, technological, and institutional capabilities required for sustained frontier innovation.¹⁵

The remainder of this chapter is organized as follows. Section II reviews the development achievements of China's pharmaceutical industry in the period of 2015-

¹² Changjiao Gan et al., "Analysis of Implementation Status and Countermeasures of Drug Marketing Authorization Holder System in China," *Pharmaceutical Research* 43 (2024): 449–54; Jing Xue et al., "Reflections on the Related Work of Drug Registration Inspection under the New Situation," *Journal of Pharmaceutical Research* 60 (2025): 2645–49.

¹³ Liu et al., *supra* note 2.

¹⁴ Lijia Yuan et al., "Role and Prospect of Breakthrough Therapy Designation in Drug Registration System," *Chinese Pharmaceutical Affairs* 36 (2022): 973–83.

¹⁵ Chaoxian Guo & Ting Li, "Assessment of Pharmaceutical Industry Development During the '14th Five-Year Plan' and Key Directions for High-Quality Development During the '15th Five-Year Plan,'" *Guangxi Social Sciences*, no. 6 (2025): 177–83.

2026. Section III examines the institutional barriers that once constrained pharmaceutical innovation in China and elucidates the mechanisms through which they shaped industrial development. Section IV traces the evolution of pharmaceutical regulatory reform from 2015 to 2026, demonstrating how successive reforms systematically dismantled these barriers and facilitated the industry's transition from a generics-dominated to an innovation-driven model. Section V discusses the institutional weaknesses that continue to limit China's pharmaceutical innovation system and identifies key priorities for future reform. Section VI concludes.

II. DEVELOPMENT OF CHINA'S PHARMACEUTICAL INDUSTRY

After 2015, China's pharmaceutical industry achieved steady growth and continuously strengthened its innovation capacity. The sustained growth of R&D investment, research personnel, patenting activity, and drug registration applications reflects its gradual transition from production-led expansion towards innovation-driven development.

Figure 3 documents considerable volatility in the financial performance of Chinese pharmaceutical manufacturers above the designated size in the period of 2015-2024.¹⁶ Revenue and profit followed similar trajectories, peaking in 2021 at USD 453.98 billion and USD 97.21 billion, respectively, before stabilizing at USD 355.23 billion and USD 48.03 billion in 2024.¹⁷ However, Figure 4 shows a clear increase in the number of pharmaceutical manufacturers above designated size. The number rose from 7,392 in 2015 to 9,796 in 2024.¹⁸

¹⁶ Manufacturers above the designated size are industrial legal entities with annual revenue from principal business of at least RMB 20 million, as defined by China's National Bureau of Statistics. National Bureau of Statistics of China (NBS), *China Statistical Yearbook*, 2016–2025 (Beijing: China Statistics Press, 2016–2025), <https://www.stats.gov.cn/sj/ndsj/>

¹⁷ National Bureau of Statistics of China (NBS), *China Statistical Yearbook*, 2016-2025 (Beijing: China Statistics Press, 2016-2025), <https://www.stats.gov.cn/sj/ndsj/>

¹⁸ *Id.*

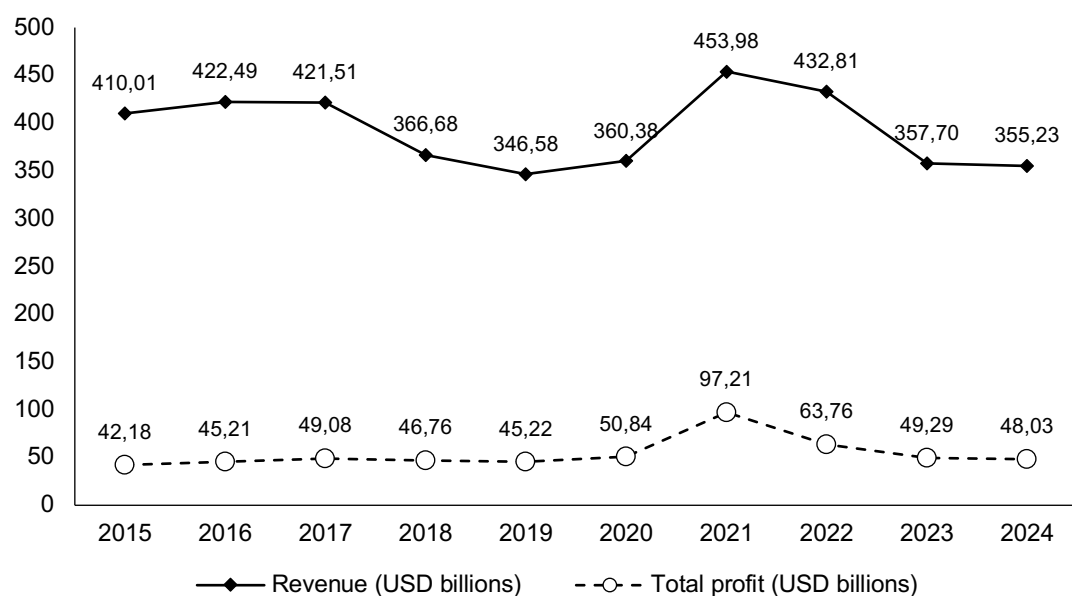


Figure 3 Operating Revenue and Total Profit of China's Pharmaceutical Manufacturing Industry (2015-2024)

Source: National Bureau of Statistics of China (NBS). China Statistical Yearbook, 2016-2025, <https://www.stats.gov.cn/sj/ndsj/>

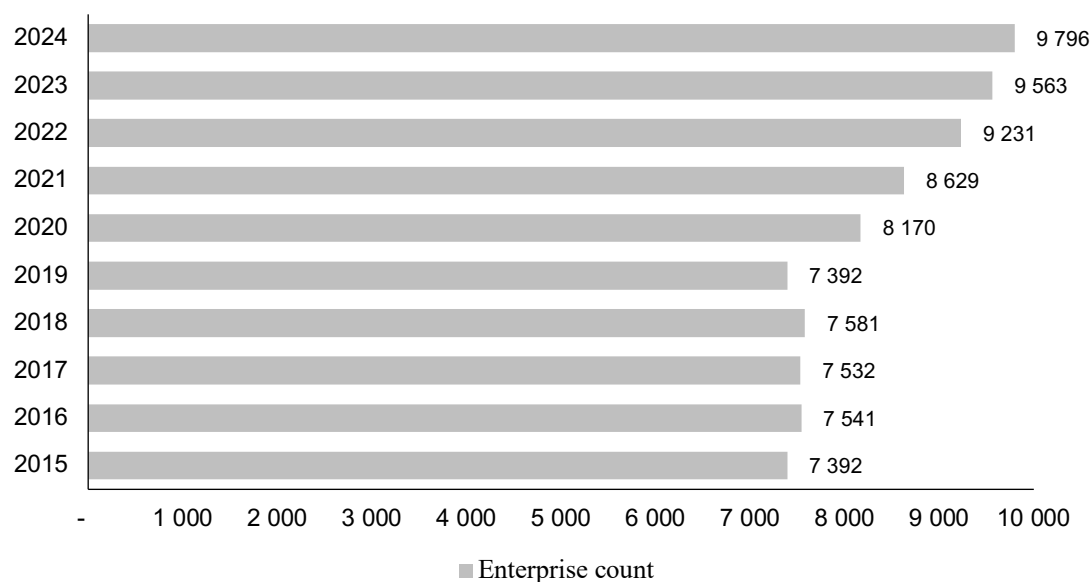


Figure 4 Number of Pharmaceutical Manufacturers Above Designated Size in China (2015-2024)

Source: NBS. China Statistical Yearbook, 2016-2025, <https://www.stats.gov.cn/sj/ndsj/>

The R&D indicators presented in Figures 5 and 6 reveal a steady strengthening of the industry’s innovation capacity. R&D expenditure increased from USD 7.09 billion in 2015 to USD 16.09 billion in 2024, representing an average annual growth rate of approximately 9.5%.¹⁹ Over the same period, the full-time equivalent of R&D personnel increased from 128,589 to 202,008 , representing an average annual growth rate of approximately 5.1%.²⁰

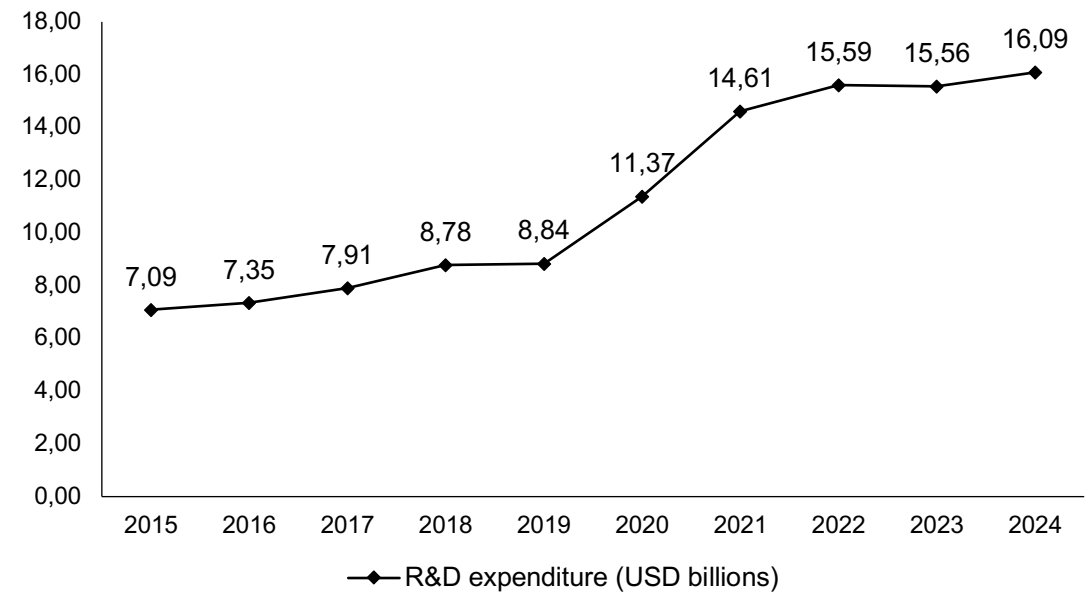


Figure 5 R&D Expenditure of China’s Pharmaceutical Manufacturing Industry (2015-2024)

Source: NBS. China Statistical Yearbook, 2016-2025, <https://www.stats.gov.cn/sj/ndsj/>

¹⁹ NBS, *supra* note 16.

²⁰ *Id.*

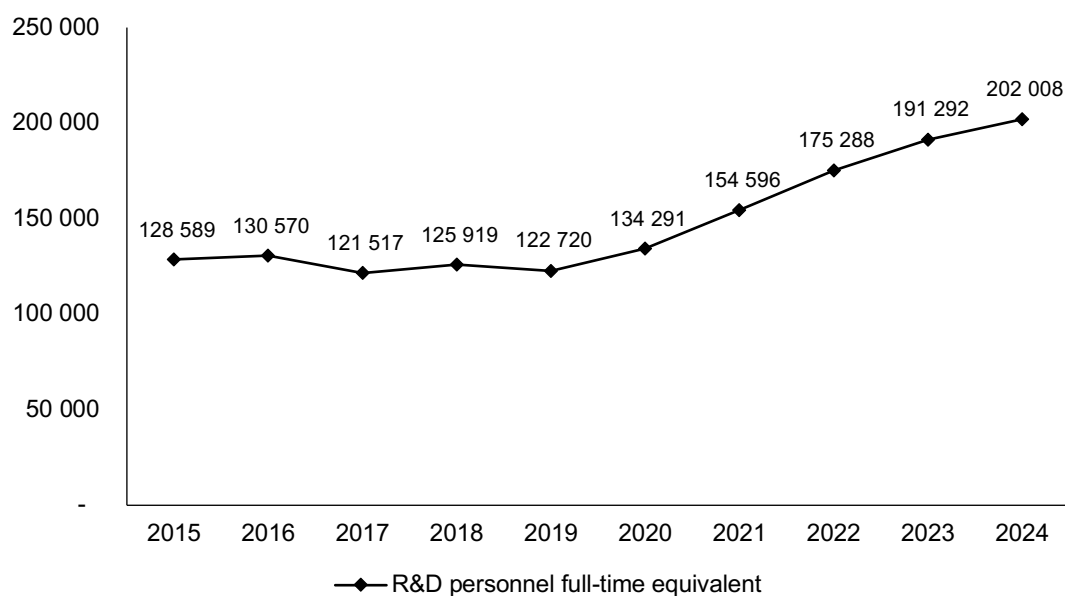


Figure 6 R&D Personnel in China's Pharmaceutical Manufacturing Industry (2015-2024)

Source: NBS. China Statistical Yearbook, 2016-2025, <https://www.stats.gov.cn/sj/ndsj/>

The total patent applications which include invention, utility model and design patent applications filed by Chinese pharmaceutical manufacturing companies in China increased steadily from 16,020 in 2015 to 34,973 in 2024 (Figure 7).²¹ This trend suggests that these firms are placing greater emphasis on technological advances and increasingly seeking patent protection.

²¹ NBS, *supra* note 16.

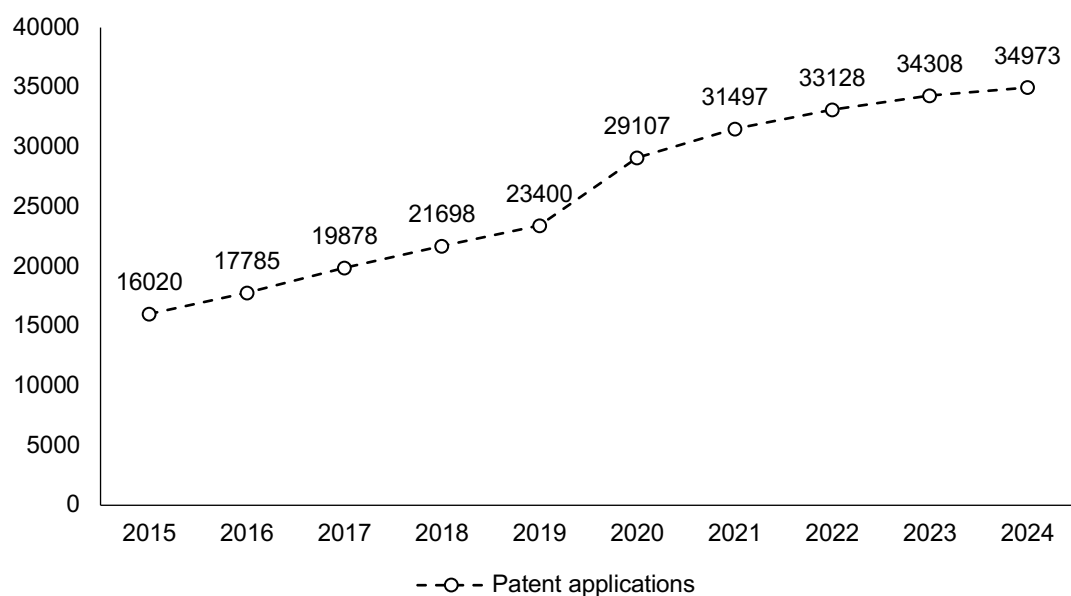


Figure 7 Patent Applications and Invention Patents Applications in China's Pharmaceutical Manufacturing Industry (2015-2024)

Source: NBS. China Statistical Yearbook, 2016-2025, <https://www.stats.gov.cn/sj/ndsj/>

The strengthening of the industry's innovation capacity is also reflected in the growing number of drug registration applications. As shown in Figure 8, the number of drug registration applications for which technical review was completed increased significantly over the period. It rose from 9,601 in 2015 to 15,318 in 2024.²² Figure 9 illustrates that among the three types of drug registration applications, chemical drugs accounted for the majority throughout the period.²³ Figure 10 shows that New Drug Application (NDA) recovered to 549 in 2024, while Abbreviated New Drug Applications (ANDA) reached 4,770, reflecting robust activity in both generic and innovative drug registration pathways.²⁴

²² Center for Drug Evaluation, National Medical Products Administration, *Annual Reports on Drug Evaluation, 2015–2024* (Beijing: Center for Drug Evaluation, 2015-2024), <https://www.cde.org.cn/>

²³ Id.

²⁴ These terms describe regulatory application pathways rather than a strict distinction between innovative and generic drugs: NDAs require a full marketing review, whereas ANDAs generally rely on comparison with an approved reference product and are primarily used for generic drugs.

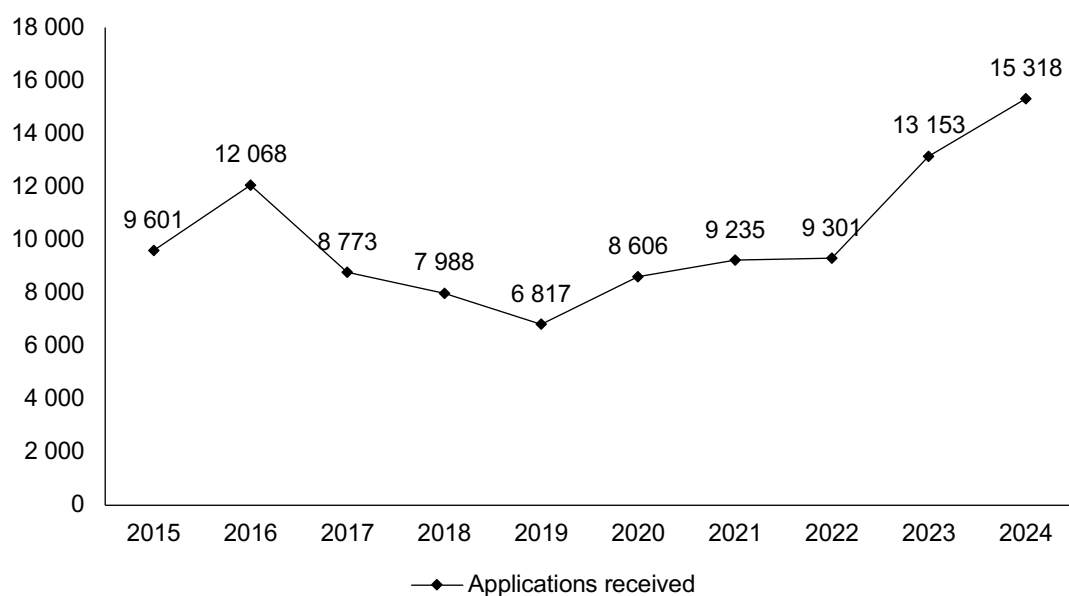


Figure 8 Drug registration applications with completed technical reviews (2015-2024)
Source: Center for Drug Evaluation (CDE), *Annual Reports on Drug Evaluation*, 2015-2024, <https://www.cde.org.cn/>

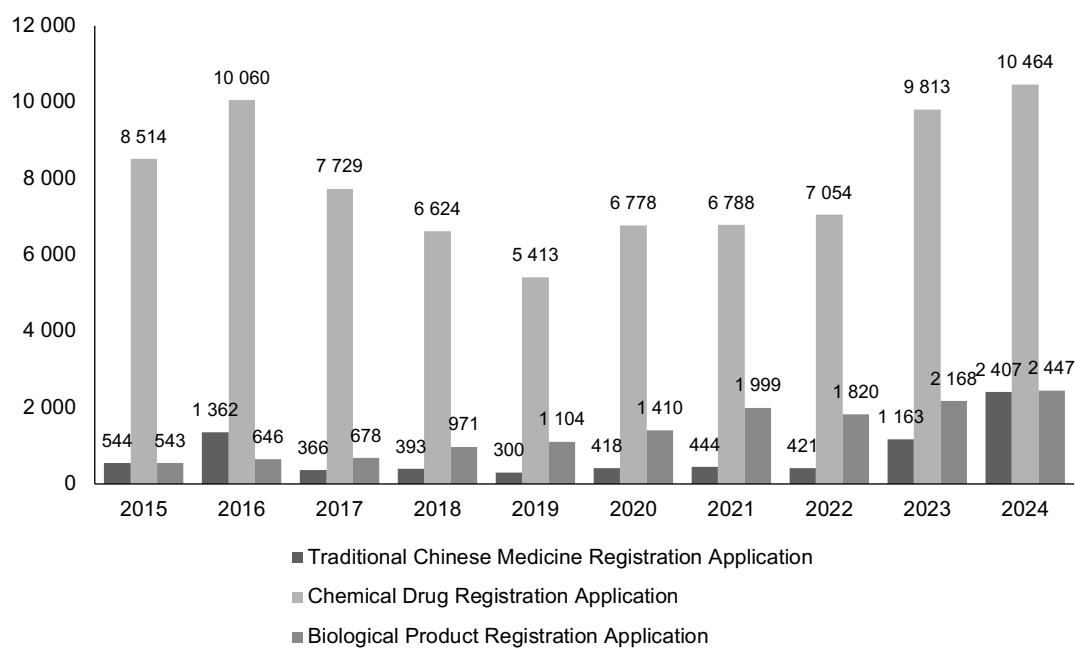


Figure 9 Drug registration applications with completed technical reviews by drug type (2015-2024)

Source: Center for Drug Evaluation (CDE), *Annual Reports on Drug Evaluation*, 2015-2024, <https://www.cde.org.cn/>

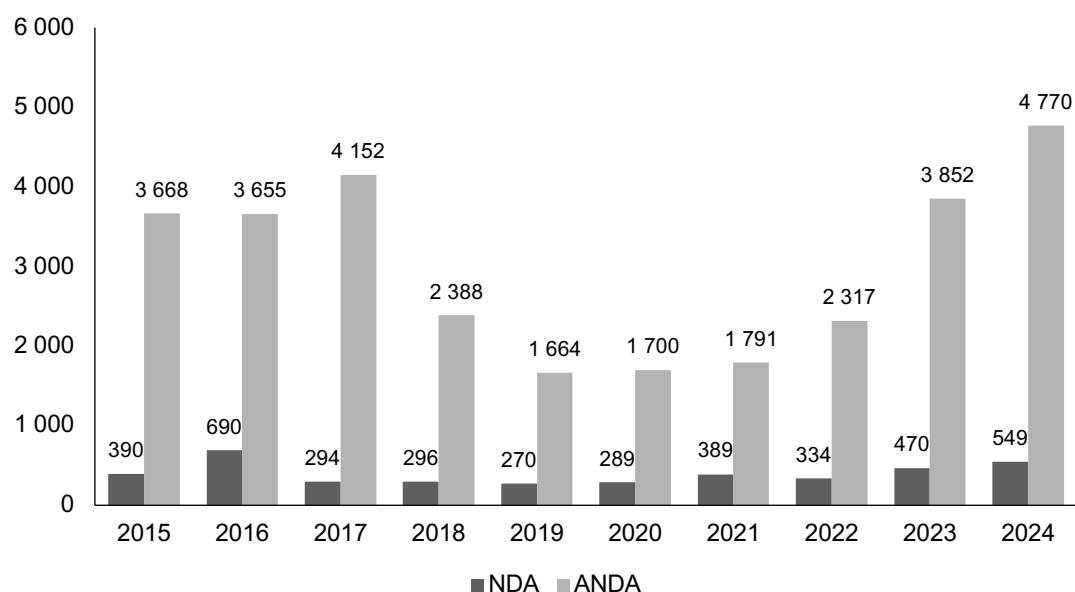


Figure 10 NDA and ANDA applications with completed technical reviews (2015-2024)

Source: Center for Drug Evaluation (CDE), *Annual Reports on Drug Evaluation*, 2015-2024, <https://www.cde.org.cn/>

Figure 11 illustrates the growing scale of international trade of China's pharmaceutical products. Exports increased from USD 6.94 billion in 2015 to USD 12.20 billion in 2024, while imports rose from USD 19.23 billion to USD 42.35 billion. Overall, total international trade of pharmaceutical products increased from USD 26.17 billion in 2015 to USD 54.56 billion in 2024,²⁵ demonstrating the continued integration of Chinese pharmaceutical companies into the international pharmaceutical market.

²⁵ United Nations Statistics Division, *UN Comtrade Database: Trade Data, 2015-2024* (New York: United Nations, 2015–2024), <https://comtradeplus.un.org/TradeFlow/>

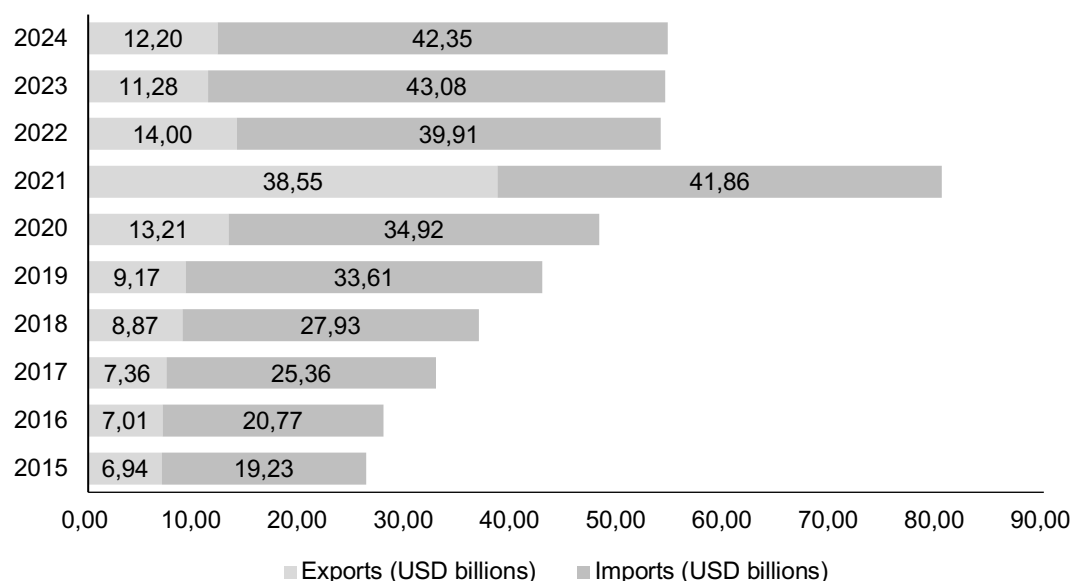


Figure 11 China's Pharmaceutical Exports, Imports, and Total Trade (2015-2024)
Source: United Nations Statistics Division (UNSD). *UN Comtrade Database: Trade Data*, 2015-2024, <https://comtradeplus.un.org/TradeFlow/>

III. INSTITUTIONAL CONSTRAINTS BEFORE REGULATORY REFORM

A. Origins of the Generics-Focused Regulatory System

Before the 2015 regulatory overhaul, China's pharmaceutical innovation faced structural constraints rooted in a long-standing policy bias toward generic drugs. When China launched its reform and opening-up in 1978, the domestic pharmaceutical industry had a fragile industrial foundation and suffered from severe medicine shortages. The central government prioritized expanding access to essential medicines and securing stable supply, making scaled-up generic drug production a pragmatic policy response.²⁶ This policy orientation gradually shaped China's drug review and approval system into a framework built for generics, not innovative drugs.²⁷ By 2015, generics made up roughly 97% of drugs manufactured by domestic firms, and accounted for approximately 80% of total pharmaceutical sales in the domestic market.²⁸

²⁶ National Medical Products Administration & National Health Commission, *Announcement on Matters Concerning the Review and Approval of Overseas New Drugs for Clinical Urgent Needs*, 2018 No. 79 (June 20, 2018), <http://www.cjpi.org.cn/zryyxxw/yaop/cfdatz/webinfo/2018/10/1523844775205032.htm>.

²⁷ Center for Drug Evaluation, State Food and Drug Administration, *2012 Annual Report of China Drug Review* (February 28, 2013), <https://www.cde.org.cn/main/news/viewInfoCommon/a28681d04382f4546668447fdaba90dd>.

²⁸ WHO, *supra* note 8.

Under this institutional setup, pharmaceutical review focused on verifying consistency with the reference listed drug, rather than assessing scientific novelty.²⁹ At the operational level, this “consistency” is defined as a static comparison of chemical equivalence—that is, verifying that the generic product shares the same active ingredients, dosage form, and strength as the reference products.³⁰ This is validated through in vitro dissolution profile comparisons, which assess whether the drug releases an equivalent amount of the active ingredient under laboratory conditions.³¹ Regulatory agencies, represented by China's Center for Drug Evaluation (CDE), built core expertise in quality testing and manufacturing compliance—the key capabilities for generic evaluation—but lacked sufficient proficiency in specialized domains for innovative drug R&D, including preclinical evaluation, clinical trial design, and pharmacological mechanism research.³²

This generics-focused review system in turn reshaped corporate incentives. Firms rationally prioritized generic applications with mature technical pathways and predictable risk-reward profiles, channeling more R&D and regulatory submission resources into established, low-risk projects. These collective market choices further reinforced the system's generics focus, creating a self-reinforcing path dependence.

B. Institutional Barriers to Pharmaceutical Innovation

The generics-focused regulatory system has created three barriers to pharmaceutical innovation in China. First, overwhelmed by high volumes of low-value, repetitive applications, regulators in China had limited capacity to evaluate truly innovative drug candidates, resulting in lengthy and unpredictable approval delays. The mismatch between regulatory staffing and review volume was a direct driver of the backlog. As documented in the *2014 Annual Report on Drug Evaluation*, by the end of 2014, the CDE had only 115 staff on its payroll, of whom a mere 89 served as full-time technical reviewers. In comparison, the U.S. Food and Drug Administration (FDA)'s Center for

²⁹ Menghan Shen, Xiaoxia Liang, & Han Wu, "The Impact of Bioequivalence Regulation on Pharmaceutical Firm Outcomes: Evidence from China," *Social Science & Medicine* 380 (2025): 118242.

³⁰ General Office of the State Council (GOSC), *Opinions on Carrying Out the Evaluation of the Quality and Efficacy Consistency of Generic Drugs*, Guo Ban Fa [2016] No. 8 (March 5, 2016), https://www.gov.cn/zhengce/content/2016-03/05/content_5049364.htm.

³¹ China Food and Drug Administration, *Guiding Principles for the Determination and Comparison of Dissolution Curves of Conventional Oral Solid Preparations* (March 18, 2016), <https://www.nmpa.gov.cn/directory/web/nmpa/zhuanli/lshzht/fzhypj/fzhycbzhj/20160318210001725.html>.

³² WHO, *supra* note 8.

Drug Evaluation and Research (CDER) employed nearly 4,000 review professionals.³³ Consequently, the CDE's per capita annual review workload was substantially higher than that of its international counterparts. In 2014, the China Food and Drug Administration (CFDA) received 8,868 new applications but completed only 5,261 reviews, leaving a cumulative backlog of 18,597 pending submissions.³⁴ This was not a temporary administrative bottleneck, but a structurally accumulated problem. Three major waves of review backlogs occurred since 2000, with the backlog peaking at more than 22,000 applications in 2015.³⁵

Between 2001 and 2016, developed economies approved 433 innovative drugs, yet barely 100 reached the Chinese market. On average, new drugs became available to Chinese patients five to seven years later than to patients in the U.S. and Europe.³⁶ Such prolonged, uncertain approval timelines amplified return uncertainty, discouraging firms from investing in costly, high-risk R&D projects.³⁷

Second, the generics-focused review regime distorted innovation incentives, driving misallocation of R&D resources and weak innovative output. For pharmaceutical firms, generic drug development remained a rational strategic choice: it carried lower risk, shorter development timelines, and smaller upfront investment.³⁸ Over time, R&D resources became heavily concentrated in low-value, duplicative projects. This pattern is visible in both existing approvals and new filings. For marketed products, many firms held approvals for the same drug varieties: over 100 manufacturers commonly held approvals for the same drug, and 0.3% of all drug varieties were authorized for 500 to 900 separate firms.³⁹ These figures show that firms were devoting substantial resources to developing the same established generic drugs, leading to widespread duplication of R&D efforts rather than investment in original drug innovation. For new applications, in 2012, 60.7% of new drug applications involved molecules for which 20 or more

³³ National Committee of the Chinese People's Political Consultative Conference, "When Will Generic Drug Approval No Longer Move at a 'Snail's Pace'?", CPPCC, August 14, 2015, <http://www.cppcc.gov.cn/zxww/2015/08/14/ARTI1439484945962138.shtml> (last visited Aug. 23, 2026).

³⁴ Jia et al., *supra* note 5.

³⁵ Zhonghong Wu & Dong Li, "Analysis of the Current Situation of Drug Priority Review System in China," *Journal of China Prescription Drug* 20 (2022): 29; CDE, *2015 Annual Report on Drug Review* (2016), <https://www.cde.org.cn/main/news/viewInfoCommon/962da6d54695d4f2f91faef72d1b6776>

³⁶ Linghui Kong et al., "Innovation in the Chinese Pharmaceutical Industry," *Nature Reviews Drug Discovery* 22, no. 1 (2023): 12–13.

³⁷ Yuan Zhang, "A Preliminary Study on the Impact of Drug Regulation on the Performance of Chinese Pharmaceutical Enterprises and Its Mechanism," *Chinese Pharmaceutical Journal* 54, no. 6 (2019): 506–10.

³⁸ Kong et al., *supra* note 37.

³⁹ Gan et al., *supra* note 11.

products had already been approved, showing that duplicative R&D was widespread.⁴⁰

The historically broad definition of a “new drug” also spawned extensive pseudo-innovation: products with minor chemical modifications that delivered no meaningful clinical advantages over existing therapies.⁴¹ Innovation pipelines also suffered from severe homogenization: in the PD-1/PD-L1 cancer immunotherapy category alone, 16 products had reached the market and nearly 100 more were in development. While this crowded landscape reduced drug costs for patients, it also wasted substantial R&D resources on redundant projects.⁴²

Third, weak regulatory capacity and substandard clinical research practices barred Chinese firms from full participation in global pharmaceutical innovation networks.⁴³ Before 2015, clinical trial records in China were mostly paper-based, which undermined traceability, verification and standardization, and increased the risk of incomplete or unreliable data.⁴⁴ In July, 2015, the CFDA issued *Announcement on Carrying out Self-inspection and Verification of Drug Clinical Trial Data*, requiring self-inspection of 1,622 clinical trial projects; approximately 80% of the corresponding drug registration applications were later voluntarily withdrawn by applicants.⁴⁵ Follow-up on-site inspections uncovered systematic data falsification, including unauthorized modification of trial data, concealment of data, and non-traceable data records.⁴⁶ Although China introduced Good Clinical Practice (GCP) regulations in 2003, clinical research quality still lagged behind international standards, due to insufficient oversight from research institutions and a shortage of qualified, high-capacity contract research organizations.⁴⁷ Poor trial quality also eroded the international credibility of Chinese-developed medicines. U.S. regulators and investors have long questioned the reliability of clinical evidence generated in China, and the FDA has rejected several China-developed drugs over flaws in clinical trial design.⁴⁸

⁴⁰ CDE, State Food and Drug Administration, *supra* note 28; Guo & Xue, *supra* note 4.

⁴¹ Ding et al., *supra* note 6.

⁴² Liu et al., *supra* note 2.

⁴³ Ni et al., *supra* note 7.

⁴⁴ Swagat Tripathy et al., *supra* note 7.

⁴⁵ China Pharmaceutical Innovation and Research Development Association (PhIRDA), “A Decade of Clinical Trial Quality Reform in China: Reflections on the ‘July 22’ Initiative,” PhIRDA, July 23, 2025, https://www.phirda.com/artilce_39652.html (last visited August 23, 2026).

⁴⁶ CFDA, *Announcement on Disapproval of 11 Drug Registration Applications from 8 Enterprises*, Announcement No. 229 (November 11, 2015), <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/ypggtg/ypqtggtg/20151111213701531.html>

⁴⁷ Ni et al., *supra* note 7.

⁴⁸ Wayne Chang et al., “A Little-Known Chinese Company Made a Drug That Beat the World’s Biggest-Selling Medicine,” CNN, February 25, 2025, <https://www.cnn.com/2025/02/25/business/china-biotech-global-disruption->

In sum, China's pharmaceutical innovation challenges before 2015 did not stem primarily from insufficient scientific or technological capability. Instead, they reflected a regulatory system built for an earlier development priority—expanding medicine access and enforcing compliance with established standards—that had become increasingly misaligned with the needs of an innovation-driven industry. As these institutional barriers blocked further innovation, regulatory reform became a necessary step.

IV. THE THREE-STAGE EVOLUTION OF PHARMACEUTICAL REGULATION

Prior to regulatory reform, China accounted for only 4% of innovative drug development projects in the global pharmaceutical R&D pipeline in 2015, marking a substantial gap relative to the leading innovative economies in Europe and North America.⁴⁹ Chinese pharmaceutical enterprises remained overwhelmingly focused on generic drug production, lagging behind the global R&D frontier.⁵⁰ Regulatory review backlogs and substandard clinical trial quality created systemic frictions that prevented Chinese pharmaceutical companies from generating innovative outputs. To address these weaknesses and challenges, Chinese policymakers launched drug regulatory reform in three sequential stages.

A. Stage 1: Reform of the Foundational Regulatory Framework (2015)

The 2015 reform opened with a redefinition of two core regulatory categories: new drugs and generic drugs. Previously, “new drug” was broadly defined as any pharmaceutical product not previously marketed in China. This broad definition created regulatory loopholes. It triggered a flood of low-quality, repetitive applications that made only superficial changes to dosage forms or specifications, erasing the dividing line between genuine innovation and generic modification.

Under the *Drug Registration Regulation*, issued by the State Food and Drug Administration (SFDA, renamed as China Food and Drug Administration in 2013 and further changed to National Medical Products Administration in 2018) in July 2007, chemical drugs were classified into six categories. One of the categories (Category 5)

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⁴⁹ McKinsey & Company, "Building the Bridge to Global Innovation," BioCentury, 2025, <https://www.biocentury.com/whitepaper/cmioz2bgv386q07o2it47zwot/building-the-bridge-to-global-innovation>.

⁵⁰ National Business Daily, "From 27% to 53%! Innovative Drugs Now Account for 'Half the Sky' in the Antitumor Drug Market," *National Business Daily*, August 14, 2026, <http://www.nbd.com.cn/rss/zaker/articles/4539642.html> (last visited Aug. 23, 2026).

encompassed “preparations that alter the dosage form of a drug already marketed in China, without modifying the route of administration.” Applicants could secure a new drug monitoring period of up to five years for such products, during which no other firm could get approval for the same product, yet they were not required to discover a new molecular entity.⁵¹ Under this rule, a manufacturer could reformulate a tablet as a capsule, an immediate-release tablet as a sustained-release tablet, or an injection as a lyophilized powder, and then register the product as a new drug. In this period, while annual new drug application volumes were high, 75% were full copies or dosage form modifications.⁵² Developing a new dosage form took only a few months, whereas discovering an original new drug took years. Therefore, firms faced strong commercial incentives to tweak existing medicines rather than invest in novel targets or new molecular entities.

In August 2015, the State Council (SC) issued the *Opinions of the State Council on the Reform of Review and Approval System for Drugs and Medical Devices*. The document narrowed the definition of a new drug to “a drug not previously marketed either inside or outside China,” and further subdivided new drugs into innovative drugs and improved new drugs based on the originality and novelty of their active pharmaceutical ingredients. Innovative drugs are with novel chemical structures, while improved new drugs are optimized versions of existing drugs that must show superior efficacy or safety relative to the originator. For generic drugs, the definition shifted from “drugs produced in line with existing national standards” to “drugs matching the quality and therapeutic efficacy of the reference listed drug.”⁵³ This revision raised the threshold for new drug designation, stripped policy advantages from products without global novelty.

Efficiency gains were another target of the policy document. The pre-reform “two applications, two approvals” system—requiring separate approvals for clinical trial initiation and marketing authorization—ran counter to the logic of pharmaceutical R&D and unnecessarily extended innovation cycles.⁵⁴ The policy reform introduced the

⁵¹ SFDA, *Measures for the Administration of Drug Registration*, Order No. 28 (July 10, 2007), https://www.gov.cn/gongbao/content/2008/content_934084.htm.

⁵² Lin Zhang, “Most New Traditional Chinese Medicines Are Imitations or Modifications, and Low-Level Repetition Is Highly Harmful,” *China Hi-Tech Industry Herald*, July 28, 2008, <https://wap.cnki.net/touch/web/Newspaper/Article/GJCD20080728D051.html> (last visited Aug. 17, 2026).

⁵³ SC, *Opinions on Reforming the Review and Approval System for Drugs and Medical Devices*, Guo Fa [2015] No. 44 (August 9, 2015), https://www.gov.cn/zhengce/content/2015-08/18/content_10101.htm.

⁵⁴ Guo & Xue, *supra* note 4.

concept of “deemed approval,” that is, a drug application would be automatically approved unless the regulator objects within a specified time. This was intended to replace unpredictable delays with clear timelines, giving sponsors more confidence in planning their product pipelines.⁵⁵

Meanwhile, to resolve the core constraint of severe understaffing in review functions, the policy document introduced concrete workforce measures: open-market recruitment of technical reviewers, establishment of senior technical reviewer positions, and development of a professional inspector corps.⁵⁶ The size of the drug review workforce grew from approximately 115 at the reform’s launch to roughly 800 by 2018,⁵⁷ enabling the agency to reduce accumulated backlogs and process the rapidly growing volume of innovative drug applications. These reform measures produced immediate positive impact. In 2015, the CDE completed 9,601 review assignments, representing an increase of nearly 90% over 2014. The backlog of pending review applications fell from a peak of more than 22,000 to fewer than 17,000 by the end of 2015.⁵⁸ In the same year, the agency approved 342 applications for drug manufacturing (marketing) registration and 1,673 applications for clinical trial registration,⁵⁹ marking an initial reversal of the long-standing regulatory backlog.

In addition, in July 2015, the CFDA ordered comprehensive self-inspection of clinical trial data for all 1,622 pending drug applications.⁶⁰ At the same time, applicants were permitted to withdraw their submissions to avoid possible penalties,⁶¹ a move that encouraged many low-quality applications to drop out of the review pipeline voluntarily. These measures substantially raised the cost of regulatory non-compliance, driving low-quality and weak applications out of the pipeline either through voluntary withdrawal or formal rejection. Consequently, the review system could redirect its limited resources toward projects with genuine innovation, offering them more thorough evaluation and predictable timelines.

⁵⁵ Li et al., *supra* note 10.

⁵⁶ SC, *supra* note 54.

⁵⁷ Jia et al., *supra* note 5.

⁵⁸ CDE, 2015 Annual Report on Drug Review (2016), <https://www.cde.org.cn/main/news/viewInfoCommon/962da6d54695d4f2f91faef72d1b6776>.

⁵⁹ Xinhua News Agency, “CFDA Releases 2015 Annual Report on Drug Review,” Xinhua News Agency, March 4, 2016, http://www.xinhuanet.com/politics/2016-03/04/c_128774479.htm (last visited Aug. 23, 2026).

⁶⁰ CFDA, *Announcement on Issuing the Key Points for On-Site Inspection of Drug Clinical Trial Data*, No. 228 (Nov. 10, 2015), <https://www.nmpa.gov.cn/xxgk/ggtg/ypggtg/ypqtggtg/20151110203701981.html>.

⁶¹ Jia et al., *supra* note 5.

*B. Stage 2: Reform of Regulatory Approach and Strengthening Pharmaceutical R&D
(2016–2019)*

After the reform narrowed the scope for low-quality, repetitive filings in the first stage, the focus of reform shifted to address four persistent bottlenecks: quality and efficacy inconsistency of generic drugs, bundling of marketing authorization and manufacturing licensing, overemphasis of regulation on extensive ex ante control, and misalignment of regulatory rules with international standards.

1. Improving Quality and Efficacy Consistency of Generic Drugs

On the generics front, the General Office of the State Council (GOSC) issued the *Opinions on Carrying out Quality and Efficacy Consistency Evaluation for Generic Drugs* in February 2016, launching an effort to establish a quality and efficacy consistency evaluation system for marketed generic drugs, requiring generics to match the quality and therapeutic effect of reference listed drugs.⁶² By the end of 2018, the CDE had received 440 applications for the consistency evaluation of oral solid dosage forms, covering 155 drug varieties, of which 111 applications spanned 57 varieties-received approval.⁶³ By November 2019, the cumulative number of drug varieties that had passed consistency evaluation nationwide reached 123, corresponding to 323 product specifications, marking the transition of consistency evaluation from a targeted campaign to a routine regulatory process.⁶⁴

A March 2018 follow-up policy document, the *Opinions of the General Office of the State Council on Reforming and Improving Policies on the Guaranteed Supply and Use of Generic Drugs*, added systemic supporting measures in public procurement and health reimbursement. Generics that passed consistency evaluation were added to a catalog of therapeutically interchangeable alternatives to reference listed drugs, creating institutional incentives for clinical substitution.⁶⁵

The reform also differentiated the regulatory treatment of generic and innovative drugs. While consistency evaluation strengthened quality and efficacy requirements for

⁶² GOSC, *supra* note 31.

⁶³ National Medical Products Administration, *2018 Annual Report on Drug Review* (July 1, 2019), <https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/fgwj/gzwj/gzwjyp/20190701175801236.html>.

⁶⁴ People's Daily Online, "Generic Drug Consistency Evaluation Enters Normal Phase, 123 Varieties Approved," People's Daily Online, November 28, 2019, <http://health.people.com.cn/n1/2019/1128/c14739-31478411.html> (last visited Aug. 23, 2026).

⁶⁵ GOSC, *Opinions on Reforming and Improving the Supply Security and Use Policy of Generic Drugs*, Guo Ban Fa [2018] No. 20 (March 21, 2018), https://www.gov.cn/gongbao/content/2018/content_5283184.htm.

generics, the priority review and approval system evolved from an emergency backlog-clearing tool into a permanent mechanism for accelerating the review of qualifying innovative drugs. In February 2016, the CFDA issued the *Opinions on the Implementation of Priority Review and Approval to Resolve Backlogged Drug Registration Applications*, which adopted the priority review and approval system as a solution to reduce application queues.⁶⁶ The CFDA's December 2017 revision, *Opinions on Encouraging the Prioritized Review and Approval for Drug Innovations*, further refined eligibility criteria, procedural rules, and communication mechanisms of the system to enhance its function of accelerating innovative drug review.⁶⁷ Throughout 2018, a total of 313 registration applications were placed under the priority review procedure, and 83 drug varieties received expedited marketing authorization through this pathway.⁶⁸

2. Unbundling of Marketing Authorization and Manufacturing Licensing

The MAH system initiated in May 2016 eliminated the long-standing link between R&D and manufacturing. This reform promoted the development of R&D-specialized firms and strengthens R&D activities in the sector. Previously, marketing authorization and manufacturing licensing were tightly bundled: R&D institutions had to either build their own production facilities or sell their technology outright to bring a product to market. Physical production capacity became a prerequisite for market entry, forcing innovative firms to tie up capital in fixed assets instead of investing in R&D. This created a structural paradox: widespread manufacturing overcapacity coexisted with redundant facility buildup by new drug developers.⁶⁹

In May 2016, the GOSC launched the *Pilot Program for the Drug Marketing Authorization Holder System*, allowing R&D institutions and individual researchers in pilot regions to file marketing authorization applications and become holders upon approval. Holders without manufacturing qualifications could contract production to qualified manufacturers.⁷⁰ The reform allowed R&D-focused companies to hold

⁶⁶ CFDA, *supra* note 47.

⁶⁷ *Id.*

⁶⁸ China News Service, 2019: <https://www.chinanews.com/m/gn/2019/07-02/8881131.shtml>.

⁶⁹ Zhengyu Wu et al., "Experiences in Europe, U.S., and Japan for the Key Issues on Certificate Holding and Product Manufacturing During the Implementation of China's Marketing Authorization Holder (MAH) System," *China Food & Drug Administration Magazine*, no. 4 (2024): 20–31.

⁷⁰ GOSC, *supra* note 67.

marketing rights and outsource production,⁷¹ eliminating the need for transferring early-stage drug candidates to other companies due to lack of manufacturing qualifications.

For small and medium-sized innovative firms, the MAH model reduced heavy manufacturing asset investment, freeing resources for drug discovery and clinical research, and lowering financial entry barriers to boost sector-wide R&D intensity.⁷² By the end of July 2019, a total of 3,239 drug varieties had been covered under the MAH framework nationwide, corresponding to 156 distinct authorization holders.⁷³ After a four-year pilot, the system was codified in the revised *Drug Administration Law*, adopted by the Standing Committee of the National People's Congress in August 2019, fully removing the R&D-manufacturing linkage and fostering entrepreneurial activity among innovative firms.

The MAH pilot's practical value is exemplified by Hua Medicine, one of the first firms to join the program. As an R&D-focused firm with no in-house manufacturing qualifications, Hua Medicine acted as the MAH and entrusted production to contract manufacturing organizations (CMOs). For its diabetes therapy Huatangning (dorzagliatin), this approach cut approximately two years of facility construction and certification timelines and saved around RMB 100 million in production line investment.⁷⁴ Approved for marketing in 2022, dorzagliatin became the world's first authorized glucokinase activator,⁷⁵ and was cited by the Shanghai Municipal Medical Products Administration as a flagship case of the MAH system.⁷⁶

3. Change to a Process-oriented Regulatory Approach

The reform reconfigured regulator-developer relationship toward a more flexible one. The reform in stage one had established a new regulatory order, but regulator-developer

⁷¹ Gan et al., *supra* note 11.

⁷² Feng He et al., "Research on the Impact of Drug Marketing Authorization Holder System on Pharmaceutical Industry Innovation," *Chinese Journal of New Drugs* 33 (2024): 1990–97.

⁷³ NMPA, *supra* note 65.

⁷⁴ Zou Juan, "Ten Years of the Free Trade Zone: This System Originated in the FTZ and Is Shaping the Biomedical Industry Landscape," *The Paper*, September 26, 2023, https://www.thepaper.cn/newsDetail_forward_24753626 (last visited Aug. 14, 2026).

⁷⁵ Information Center of the National Medical Products Administration, "Jiangsu Province's AI-Based Intelligent Drug Approval System," May 13, 2024, https://www.nmpaic.org.cn/zhuanli/ypzhjgdxdxal/zjhd/dxal/zjgal_958/202405/t20240513_424335.html (last visited Aug. 14, 2026).

⁷⁶ Shanghai Municipal Medical Products Administration, "A 'Global New' Innovative Drug Developed and Produced in Shanghai Approved for Marketing, Providing a New Treatment Option for Diabetic Patients," October 9, 2022, <https://yj.sh.gov.cn/sjdt/20221009/4024db3e352142a0a4007577cf626183.html> (last visited Aug. 14, 2026).

interaction still followed a traditional “approval-compliance” logic: regulators intervened ex ante at every R&D stage, with no mechanism to align review capacity with industry needs.

In October 2017, the General Office of the Communist Party of China Central Committee and the GOSC issued the *Opinions on Encouraging Innovation of Drugs and Medical Devices by Deepening the Reform of the Review and Approval System*, introducing systemic adjustments. Clinical trial accreditation shifted from an approval system to a notification system, with regulators monitoring compliance during and after trials rather than controlling market entry. Ethics approval for multicenter trials issued by the lead institution became valid across all participating sites, eliminating redundant reviews and replacing parallel approvals with cross-institutional mutual recognition. For clinical trial applications, the *Opinions* codified deemed approval, transforming the regulator-developer relationship from direct administrative intervention to a predictable, rule-based one.⁷⁷ In its initial rollout, more than 300 clinical trial applications received deemed approval within 60 working days—a timeline on par with the European Union national regulatory agencies.⁷⁸ These changes shifted regulators away from extensive ex ante control toward a process-oriented approach, combining guidance, supervision, and collaboration with developers and giving firms greater operational flexibility while maintaining quality and safety oversight.

4. Alignment of Regulatory Rules with International Standards

Beyond these domestic reforms, China also sought to reshape the relationship between the domestic pharmaceutical industry and the global innovation network by aligning domestic regulatory standards with international practices. In 2017, China formally joined ICH, beginning a systematic process of adopting and implementing international technical norms for pharmaceutical R&D and registration. This move facilitated the conduct of global multi-regional clinical trials and opened the door to full alignment of drug registration technical requirements with international practice.⁷⁹

This alignment allowed Chinese firms to design clinical trials according to

⁷⁷ General Office of the Central Committee of the Communist Party of China & GOSC, *Opinions on Deepening the Reform of the Review and Approval System and Encouraging Innovation in Drugs and Medical Devices*, Ting Zi [2017] No. 42 (October 8, 2017), Ting Zi (2017) No. 42, https://www.gov.cn/zhengce/2017-10/08/content_5230105.htm.

⁷⁸ Ni et al., supra note 7.

⁷⁹ Liu et al., supra note 2; Jing Xue et al., supra note 11.

internationally accepted standards and participate easily in global drug development programs. Accordingly Chinese companies could participate in global multi-regional trials at an earlier phase. By 2021, China had implemented more than 70% of ICH guidelines.⁸⁰

The tangible impact of this regulatory harmonization is best illustrated by a landmark milestone in Chinese pharmaceutical globalization. In November 2019, zanubrutinib, an anticancer therapy developed by Chinese biopharmaceutical firm BeiGene, received accelerated approval from the FDA. Critically, the approval was granted primarily on the basis of clinical trial data collected from Chinese patients. As the National Health Commission (NHC) noted in November 2019, this marked “the first time the FDA has approved a new drug primarily relying on Chinese clinical trial data.”⁸¹ This FDA approval represented formal recognition of Chinese clinical trial data by a leading global regulator, and marked a concrete outcome of China's regulatory alignment with international pharmaceutical standards.

Taken together, the 2016–2019 reforms restructured China’s pharmaceutical innovation system on both domestic and international fronts. They improved quality and efficacy consistence of generic drugs, unbundled the relationship between R&D and manufacturing, changed the regulation from extensive ex ante control to a process-oriented approach, and opened a regulatory gateway to international standards through ICH accession. Together, these reforms lowered entry barriers for innovative firms, allowing them to allocate more resources to drug discovery and clinical development rather than manufacturing capacity and regulatory compliance.

C. Stage 3: Reform to Encourage High-Quality Pharmaceutical Innovation (2020–2026)

The reform in the first two stages drove a surge in new drug applications, but the share of products with genuine clinical advantages remained low.⁸² In response, the focus of regulatory reform in stage three shifted from simply enabling innovation to identifying

⁸⁰ McKinsey & Company, "China Biopharma: Stepping on the Global Stage," McKinsey & Company, 2021, <https://chinahealthcaresummit2021.meeting-mojo.com/uploads/2992/documents/2021-mckinsey-biocentury-biopharma-report.pdf> (last visited Aug. 23, 2026).

⁸¹ NHC, Major New Drug Creation Major Special Achievement: Zanubrutinib Approved for Marketing in the United States (Nov. 15, 2019), <https://www.nhc.gov.cn/qijys/c100015/201911/76881350a56b496690b31bf189883116.shtml> (last visited Aug. 14, 2026).

⁸² Liu et al., *supra* note 2.

and supporting innovations with substantial clinical value.

The revised *Measures for the Administration of Drug Registration*, issued in March 2020 by the State Administration for Market Regulation, and supporting *Requirements for the Registration Classification and Application Dossiers of Chemical Drugs*, released in June 2020 by the NMPA, reclassified chemical drugs into innovative drugs, improved new drugs, and generics, granting new-drug status only to products not yet marketed worldwide.⁸³ Clinical value became the central criterion for regulatory resource allocation, with innovation evaluated by patient benefit rather than formal novelty alone. Improved new drugs qualify for policy support only if modifications deliver demonstrable clinical benefits, closing the loophole that allowed minor formal changes to secure new drug designation.

Policymakers also put in place incentives spanning drug development and post-marketing authorization. On the development side, the 2020 revised *Measures for the Administration of Drug Registration*, established four accelerated approval pathways: breakthrough therapy designation, conditional approval, priority review and approval, and special approval, forming a tiered system to accelerate high-value innovation. Breakthrough therapy designation flags high-potential candidates at an early stage and enables early regulatory guidance. Conditional approval allows therapies for life-threatening conditions to reach the market based on early data such as surrogate endpoints, reducing clinical wait times via a risk-proportionate approach. Priority review redirects review capacity to products with clear clinical value.⁸⁴

In 2024, of 48 approved Class 1 innovative drugs, 17 went through priority review, 11 received conditional approval, and 13 were granted breakthrough therapy designation.⁸⁵ On the post-marketing side, the *revised Regulations for the Implementation of the Drug Administration Law*, promulgated by the SC in January 2026, formalized incentives as market exclusivity of up to two years for pediatric medicines, up to seven years for rare disease treatments, and up to six years of clinical trial data protection for drugs with new chemical entities.⁸⁶ Market exclusivity is the

⁸³ Ni et al., *supra* note 7.

⁸⁴ Ping Wang et al., "Design and Construction of Drug Registration Management System in the New Era—New Concepts, New Contents, New Requirements and Implementation Progress of the 2020 Edition of Provisions for Drug Registration," *China Food & Drug Administration Magazine*, no. 6 (2021): 8–17.

⁸⁵ CDE, NMPA, *2024 Annual Drug Evaluation Report* (March 18, 2025), <https://www.cde.org.cn/main/news/viewInfoCommon/54538c67b7e764fc51666567fc620241>.

⁸⁶ SC, *Implementing Regulations of the Drug Administration Law of the People's Republic of China*, State Council Order No. 828 (January 16, 2026), effective May 15, 2026, State Council Gazette, 2026, No. 4, https://www.gov.cn/zhengce/zhengceku/202601/content_7056256.htm.

right to exclusively market the product, during which no competitor can obtain approval for the same drug. These exclusivity provisions improve the expected return on high-risk R&D, creating a more predictable commercial framework for innovative drug development.

Value assessment on drugs depends on regulatory capacity, but the Chinese assessment agency has relatively small capacity. In 2021, the CDE employed 350 staff, compared with 6,058 employees at the FDA's CDER.⁸⁷ To address this bottleneck, the NMPA issued the *Opinions on the Implementation of "Artificial Intelligence + Drug Regulation"* in April 2026, integrating AI as a core enabling tool to handle initial screening and dossier processing for standardized review tasks, freeing review staff to focus on substantive innovation value judgments.⁸⁸

This approach has already proven effective in provincial regulatory practice. The Jiangsu Provincial Medical Products Administration, for example, has launched an AI-powered intelligent drug review and approval system, which has delivered operational gains: the first-time acceptance rate for enterprise submissions now exceeds 90%, overall review efficiency has risen by over 30%, and approval lead times have been cut by half. The system has a built-in intelligent assistant who can guide applicants to submit standardized, compliant materials while performing automated preprocessing and preliminary checks. By taking over rule-based, highly repetitive review work, the system relieves reviewers of administrative burdens and redirects their focus to the tasks that require professional judgments.⁸⁹

We summarize the important policy documents issued during the reform period in the following Table 1.

⁸⁷ Xingyue Zhu & Dongmei Xiao, "Innovative Drugs Approved in China After Registration Classification Reform: Current Status, Disparities, and Challenges," *Clinical Pharmacology & Therapeutics* 119, no. 2 (2025): 470–79.

⁸⁸ NMPA, *Implementing Opinions on "Artificial Intelligence + Drug Regulation"*, Guo Yao Jian Zong [2026] No. 6 (March 11, 2026), https://www.gov.cn/zhengce/zhengceku/202604/content_7064591.htm.

⁸⁹ Information Center of the National Medical Products Administration, *supra* note 77.

Table 1 Overview of Major Pharmaceutical Reform Policies

Policy	Issuing Authority	Promulgation date	Main provisions
Opinions of the State Council on the Reform of Review and Approval System for Drugs and Medical Devices	State Council (SC)	August 9, 2015	Reforms the drug and medical device review and approval system; raises registration standards, verifies clinical data authenticity, clears application backlog, expands review workforce, and defines regulatory boundaries between innovative and generic drugs.
Opinions on Carrying out Quality and Efficacy Consistency Evaluation for Generic Drugs	General Office of the State Council (GOSC)	February 6, 2016	Establishes a quality and efficacy consistency evaluation system for marketed generic drugs, requiring generics to match the quality and therapeutic effect of reference listed drugs.
Opinions of the General Office of the State Council on Reforming and Improving Policies on the Guaranteed Supply and Use of Generic Drugs	General Office of the State Council (GOSC)	March 21, 2018	Improves policies for generic drug R&D, centralized procurement, medical insurance coverage and clinical use, to ensure drug supply and promote clinical use of qualified generics.
Opinions on the Implementation of Priority Review and Approval to Resolve Backlogged Drug Registration Applications	China Food and Drug Administration (CFDA)	February 26, 2016	Drug registration review management, covering priority review pathways and addressing registration backlog.
Opinions on Encouraging the Prioritized Review and Approval for Drug Innovations	China Food and Drug Administration (CFDA)	December 21, 2017	Establishes priority review and approval as a regular system for supporting drug innovation, with clear applicable scope and procedures.
Pilot Program for the Drug Marketing Authorization Holder System	General Office of the State Council (GOSC)	May 26, 2016	Separation of marketing authorization from manufacturing licensing, allowing R&D entities to hold drug approvals without owning production facilities.

Policy	Issuing Authority	Promulgation date	Main provisions
Drug Administration Law	Standing Committee of the National People's Congress	August 26, 2019	Revision of the core drug regulatory law, codifying the MAH system and full life-cycle regulatory framework.
Opinions on Encouraging Innovation of Drugs and Medical Devices by Deepening the Reform of the Review and Approval System	General Office of the Communist Party of China Central Committee & General Office of the State Council (GOSC)	October 8, 2017	Optimizes clinical trial management, improves ethics review mechanisms, establishes regulator-innovator communication channels, builds patent linkage and data protection systems, and implements full life-cycle drug regulation.
Measures for the Administration of Drug Registration	State Administration for Market Regulation	March 30, 2020	Restructures the drug registration system; sets up four-tiered expedited approval pathways (breakthrough therapy, conditional approval, priority review, special approval), and establishes a clinical-value-oriented review framework.
Requirements for the Registration Classification and Application Dossiers of Chemical Drugs	National Medical Products Administration (NMPA)	June 30, 2020	Redefines the registration classification system for chemical drugs, clarifying classification criteria and application dossier requirements for innovative drugs, improved new drugs and generic drugs.
Regulations for the Implementation of the Drug Administration Law	State Council (SC)	January 16, 2026	Revision of drug regulatory administrative regulations, adding market exclusivity and clinical data protection for innovative drugs.
Opinions on the Implementation of "Artificial Intelligence + Drug Regulation"	National Medical Products Administration (NMPA)	April 2, 2026	Upgrading of drug regulation, promoting AI application across the entire drug regulatory process.

V. CURRENT CHALLENGES AND FUTURE REGULATORY REFORM IN CHINA'S PHARMACEUTICAL INDUSTRY

Building on the three stages of regulatory transformation discussed above, China's reform in pharmaceutical industry has dismantled many institutional constraints inherited from the generics-focused regulatory regime.⁹⁰ Nevertheless, challenges still remain in the areas of innovative drugs and regulatory capacity.

A. Unresolved Deficiencies and Emerging Regulatory Issues

Three challenges faced by China's pharmaceutical industry are along the pharmaceutical innovation value chain: insufficiency in original discovery and clinical value; difficulty of generating adequate commercial returns from innovation; and growing gap between the expansion of innovative drug pipelines and regulatory review capacity.

1. Innovation Gap in Original Discovery and Clinical Value

China's capacity for original innovation needs to be strengthened. In 2025, China approved a record 76 Class 1 (the highest innovation tier in China's drug registration classification system) innovative drugs—new chemical entities that had not previously been marketed either domestically or globally. Yet only 11 of these 76 drugs involved new mechanisms or targets, a lower number than that reported for the U.S. and Europe,⁹¹ and only four were independently developed by domestic firms.⁹² Morgan Stanley (2025) argued that China's pharmaceutical industry has developed world-class capabilities to launch “from 1 to N” innovative drugs, but still needs sustained efforts to achieve “from 0 to 1” breakthroughs.⁹³

One important reason for the limited number of original drug discoveries is underinvestment in basic research. Xuetao Cao, an academician of the Chinese Academy of Engineering, contends insufficient investment in basic research as a major constraint on China's drug development. Basic research rarely yields immediate

⁹⁰ Xiaoyong Zhang et al., "Research on the Optimization Direction of Drug Review and Approval Based on Continuous Encouragement of Innovation," *Chinese Journal of New Drugs* 34, no. 3 (2025): 256--63.

⁹¹ Xuetao Cao, "Strategic Thinking and Implementation Path of the National Science and Technology Major Project for Innovative Drug R&D" (keynote address, 10th Pharmaceutical Innovation and Investment Conference, China, October 26, 2025), <https://cbiic.phirda.com/portal/article/index/id/954.html>.

⁹² CDE, NMPA, *2025 Annual Report on Drug Evaluation* (May 13, 2026).

⁹³ Morgan Stanley, *China Biotech: Innovation Dawn* (New York: Morgan Stanley Research, September 2025).

commercial returns, but it provides the scientific foundation for long-term drug discovery breakthroughs.⁹⁴ In 2025, basic research accounted for 7.08% of China's total R&D expenditure, exceeding 7% for the first time.⁹⁵ In biomedicine, however, basic research accounted for less than 5% of total research funding, compared with a long-standing share of 15-18% in the U.S..⁹⁶

2. Commercialization Bottleneck for Innovative Drugs

China's pharmaceutical industry continues to struggle to generate sufficient revenues from innovative drugs. Although the number of newly approved drugs continues to reach record levels, many firms struggle to generate enough revenue from these products to recover their R&D costs. In 2025, 29.1% of pharmaceutical firms operated at a loss, up 5.3% from the previous year.⁹⁷ One important source of this problem is the highly fragmented structure of the industry. By the end of 2024, China had 5,219 finished-drug manufacturers, 33% more than in 2020, with micro and small enterprises accounting for 76% of the total.⁹⁸ Such fragmentation not only encourages duplicated R&D spending but also leaves most firms without the scale or resources needed to build mature commercialization capabilities and achieve economies of scale.

In addition, fewer than 30% of drugs approved in the period of 2021-2023 had recorded sales,⁹⁹ suggesting a substantial gap between regulatory approval and commercial success. Many firms cluster around a small set of high-profile targets, resulting in marketed products with minimal competitive differentiation, which in turn squeezes profit margins across the industry. In China, the top 10 targets account for 38% of the oncology drug development pipeline and 26% of the non-oncology pipeline. Although these shares have declined substantially since 2015, they remain roughly 8% higher than the corresponding shares for foreign pharmaceutical companies.¹⁰⁰

On the demand side, patients' ability and willingness to pay also limit demand for

⁹⁴ Cao, *supra* note 93.

⁹⁵ NBS, *Statistical Communiqué of the People's Republic of China on the 2025 National Economic and Social Development* (Beijing: National Bureau of Statistics, February 28, 2026).

⁹⁶ Xin Zhi Guan Cha, "International Comparison of Basic Research Investment in Biomedicine," *Xin Zhi Guan Cha*, June 9, 2026, <https://m.thepaper.cn/detail/33337089>.

⁹⁷ Xuegong Wang, "Pharmaceutical Industry Development Situation and '15th Five-Year Plan' Outlook," industry report, China Pharmaceutical Enterprise Management Association, June 6, 2026, <https://www.cpema.org/>.

⁹⁸ *Id.*; Gan et al., *supra* note 11.

⁹⁹ *Id.* at 11.

¹⁰⁰ Tsinghua University Institute for Regulatory Science of Pharmaceutical Products & PHARMCUBE, "Insights into the 10-Year Trends of Global Clinical Trials," PHARMCUBE, 2025, <https://bydrug.pharmcube.com/report/detail/8c7d8b2debc64daf91c72997e345fde2>.

innovative drugs. China's innovative drug market relies heavily on basic medical insurance, which covers approximately 46.4% of spending on innovative drugs, while out-of-pocket payments account for 49%.¹⁰¹ Yet a basic insurance system designed primarily to ensure access to essential care cannot broadly cover innovative drugs. At the same time, innovative drugs tend to carry high prices because of the substantial upfront investment and risks involved in their development. This heavy out-of-pocket burden reduces both patients' ability and willingness to pay, dampening uptake of high-priced innovative drugs and limiting overall market size. As a result, per capita spending on innovative drugs in China remains far below expected levels,¹⁰² which constrains post-launch sales and ultimately erodes firms' commercial returns.

At a broader institutional level, the commercialization problem also reflects a misalignment between the policy objectives of the drug regulator, the NMPA, and the health insurance authority, the National Healthcare Security Administration (NHSA). The NMPA places substantial weight on the clinical value of new drugs and uses tools such as conditional approval and priority review to shorten the time from development to market entry, encouraging firms to undertake high-risk innovation. The NHSA, by contrast, must balance the financial sustainability of the health insurance funds with the need to control pharmaceutical spending. After new drugs enter the market, it can exert substantial downward pressure on prices through National Reimbursement Drug List (NRDL) negotiations and volume-based procurement (VBP)—a centralized bulk-purchasing scheme that guarantees large, predictable purchase volumes for manufacturers in exchange for steep negotiated price cuts. The result is a policy disconnect: regulatory policy encourages firms to undertake high-risk innovation upstream, while pricing and reimbursement policies can substantially compress the returns downstream.

3. Regulatory Capacity Constraints amid Growing Innovation Capabilities

The rapid expansion of innovative drug development has increased the workload and technical demands facing regulators. By 2024, the number of innovative drugs in Chinese firms' R&D pipelines had nearly doubled from the level recorded in July

¹⁰¹ China Life Reinsurance Company Ltd. & MediTrust Health Technology Group Co., Ltd., *White Paper on Diversified Payment for Innovative Drugs and Medical Devices in China (2026)* (May 21, 2026), <https://www.chinarelife.cn/chinarelife/zyyj/xybg/2026052619320653864/index.html>.

¹⁰² Id.

2021,¹⁰³ while the regulatory review workforce had grown much more slowly. As a result, more than 75% of drug applications take longer than the statutory review timelines. The problem is particularly pronounced for new oncology drugs: the median technical review time at the NMPA reached 409 days, compared with 200 days at the FDA.¹⁰⁴

AI can streamline routine review tasks, but it cannot replace the scientific judgment required to evaluate complex, cutting-edge therapies. By applying AI to drug regulation, regulators can speed up formal checks of submissions and streamline the review and compilation of dossiers. However, Chinese drug R&D is moving increasingly into frontier areas such as bispecific antibodies, small nucleic acid therapeutics, and radiopharmaceuticals.¹⁰⁵ In these fields, mature technical guidelines and evaluation standards are often lacking, making regulatory decisions highly dependent on experts' specialized judgment and their understanding of emerging science. As pharmaceutical innovation advances rapidly, shortages of regulatory personnel and limited expertise in emerging fields have become major bottlenecks to the industry's continued growth.¹⁰⁶

B. Future Regulatory Reform in Pharmaceutical Industry

In its March 2026 Government Work Report, delivered by the SC, China for the first time designated biopharmaceuticals as an “emerging pillar industry,” marking a new phase in the development of the country's pharmaceutical sector. Against this backdrop, the pharmaceutical regulatory reform in the next stage should be prioritized in the following three areas.

1. Enhancing Originality and Clinical Value of Innovative Drugs

China has built a large, fast-growing innovative drug R&D pipeline, yet its original drug discovery capacity remains limited. The next stage should prioritize long-term, open-ended basic biomedical research and targeted funding to translate new mechanisms and targets into drug candidates, bridging the funding gap between laboratory research and industrial R&D.

¹⁰³ Zhimin Chen et al., “Chinese innovative drug R&D trends in 2024,” *Nature Reviews Drug Discovery* 23 (2024): 810–11.

¹⁰⁴ Zhu & Xiao, *supra* note 89.

¹⁰⁵ Wang, *supra* note 99.

¹⁰⁶ Zhu & Xiao, *supra* note 89.

Expanded original research alone does not guarantee meaningful clinical benefits. Regulators should apply differentiated evaluation standards tailored to therapeutic context: stricter requirements for incremental clinical benefit in areas with mature treatments and intense competition, and more flexible criteria for areas with large unmet medical needs. This will reduce duplicative R&D on established targets and direct resources toward innovations that truly improve patient outcomes. Regulatory incentives should favor drugs combining novel mechanisms of action with clear clinical value. For such high-risk candidates, differentiated data protection and market exclusivity can deliver more predictable returns, encouraging investment in genuine innovation and steering R&D resources away from overcrowded, well-established targets.

2. Increasing Commercial Returns to Pharmaceutical Innovation

Sustained pharmaceutical innovation relies on commercial returns sufficient to cover high R&D costs and risks. Given the industry's fragmentation and widespread low-value manufacturing overcapacity, lifecycle quality oversight should continue to phase out manufacturers with inadequate quality management systems, curbing low-value duplicative production and creating market room for R&D-focused firms.

On the domestic market, basic medical insurance has limited scope to expand coverage of innovative drugs, so diversified payment channels including commercial health insurance are needed. More critically, policy coordination between the NMPA and the NHSA must be enhanced: drugs granted breakthrough therapy designation, conditional approval or other priority status should receive prioritized NRDL inclusion or flexible pricing and reimbursement terms, translating recognized clinical value into stronger market uptake and returns commensurate with R&D risks. As the domestic market alone cannot generate enough returns for high-risk original innovation, global market access is critical. Barriers should be lowered in three areas: greater overseas acceptance of Chinese clinical trial data, reduced institutional obstacles to cross-border licensing and registration, and targeted compliance support for small and medium-sized enterprises. These measures will help Chinese innovations reach global patients while making their commercial prospects more predictable for foreign firms and investors who evaluate investment, licensing, or cross-border partnership opportunities.

3. Strengthening Regulatory Capacity to Evaluate Emerging Technologies

The rapid expansion and evolution of innovative drug pipelines require regulatory capacity to keep pace. Regulators should expand their pool of specialized reviewers to match the growing scale and complexity of frontier R&D, and establish sustained support for regulatory science research to ensure review standards evolve alongside pharmaceutical advances. For technologies without established evaluation standards, regulators should engage developers early in the R&D process. Formal consultation and guidance channels can clarify nonclinical research and clinical trial design requirements upfront, reducing regulatory uncertainty and redundant research.

AI should play a larger role in drug review with clear boundaries between automated tasks and human judgment. AI can handle repetitive, rule-based work such as formal application checks, standardized data verification, and routine dossier processing to lighten reviewers' administrative load, freeing senior experts to focus on scientific and clinical assessment. In the era of AI-driven innovation, China's pharmaceutical sector can provide real-world data and diverse application scenarios for advancing such technologies across the industry. This fosters opportunities for international collaboration.

VI. CONCLUSION

China's pharmaceutical industry has undergone a fundamental institutional transformation since 2015. Before then, a regulatory system designed primarily to secure drug supply, expand manufacturing capacity, and ensure compliance with established standards had become increasingly misaligned with the demands of an industry moving toward the technological frontier. The resulting institutional constraints discouraged investment in higher-risk R&D and limited the translation of existing scientific and industrial capabilities into innovative drug development.

The reforms initiated in 2015 progressively removed these constraints, improving the efficiency and predictability of drug regulation, reconfiguring institutional relationships across R&D and commercialization, channeling support toward innovations with demonstrable clinical value, and eliminating institutional frictions that had previously trapped the sector in a generics-focused growth model. The broader expansion of R&D investment, research personnel, patenting, and the rapid growth of China's innovative drug pipeline reflects rising innovation inputs and outputs in the sector.

For all these gains, however, the core challenge facing the industry has

fundamentally shifted. It is no longer whether the regulatory system allows firms to innovate, but whether the broader innovation ecosystem can generate, evaluate, and sustain innovation with sufficient originality and clinical value. The remaining constraints extend across the innovation chain: limited translation of basic science into new targets and drug candidates, commercial and reimbursement arrangements that do not always provide returns commensurate with the risks of innovative drug development, and regulatory capacity that has not kept pace with the expansion and increasing complexity of frontier R&D.

The next phase of reform therefore requires a shift from removing institutional barriers to building the capabilities needed to sustain innovation at the technological frontier. Strengthening the connection between basic biomedical research and drug discovery, supporting high-risk and long-horizon research, and expanding regulatory expertise will become increasingly important. Institutional reform can unlock existing potential, but sustained progress will depend on whether China can build the scientific capabilities and institutional conditions needed to generate genuinely new therapeutic opportunities. As China's pharmaceutical innovation capabilities continue to grow, they will not only expand treatment options for patients worldwide, but also offer institutional experience from an emerging economy that may inform global pharmaceutical governance.