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ORIGINAL RESEARCH

New Drug Approvals in China: An International Comparative Analysis, 2019-2023

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Purpose: Over the past five years, China's pharmaceutical industry has rapidly developed but still lags behind global leaders. This study aims to analyze and compare the trends in new drug approvals in China, the United States (US), the European Union (EU), and Japan from 2019 to 2023.

Methods: Data on new drug approvals were collected from the National Medical Products Administration (NMPA), Food and Drug Administration (FDA), European Medicines Agency (EMA), and Pharmaceuticals and Medical Devices Agency (PMDA), including information on the generic name, trade name, applicants, target, approval date, drug type, approved indications, therapeutic area, the highest R&D status in China, and special approval status. The approval time gaps between China and other regions were calculated.

Results: From 2019 to 2023, China led with 256 new drug approvals, followed by the US (243 approvals), the EU (191 approvals), and Japan (187 approvals). Oncology, hematology, and infectiology were identified as the leading therapeutic areas globally and in China. Notably, PD-1 and EGFR inhibitors saw substantial approval, with 8 drugs each approved by the NMPA. China significantly reduced the approval timeline gap with the US and the EU since 2021, approving 15 first-in-class drugs during the study period.

Conclusion: Despite COVID-19 challenges, China has improved in both the quantity and speed of new drug approvals, narrowing timeline gaps with major markets and enhancing its global pharmaceutical presence.

Keywords: new drug, special approval, therapeutic areas, targets, first-in-class

Introduction

From an international innovation perspective, China still lags behind developed pharmaceutical powerhouses like the United States (US), the European Union (EU), and Japan. Patients may miss out on timely access to innovative therapies due to delays in both pharmaceutical development and regulatory approval processes.[1] Previous study indicated that among the 291 new molecular entities (NMEs) approved in the United States during the period 2004–2014, only 79 were also approved in China, with a delay of an average of three years.[2] Several systemic factors have been identified as primary contributors to medication authorization bottlenecks in China, including extensive evaluation periods, an accumulation of pending pharmaceutical submissions, and insufficient regulatory personnel.[2–4] In 2021, the US dominated the global market with over half of the sales of innovative drugs, showcasing its leadership position. Meanwhile, the collective sales of innovative drugs in five European countries – Germany, France, Italy, Spain, and the United Kingdom – accounted for 16% of the global market, highlighting their significant influence in Europe. A comprehensive analysis examining the market authorization timelines of novel oncology therapies between 2010 and 2019 revealed significant disparities between the US and EU regulatory systems. The study demonstrated that American regulatory pathways consistently outperformed the EU, achieving accelerated approval through a combination of earlier application

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submissions and more streamlined review mechanisms at the US regulatory body.[5] Japan and South Korea each contributed 8% to global sales, demonstrating their substantial presence in the developed Asian market. However, Japan's drug approval process remains significantly slower than those in the US and the EU, primarily due to delays in regulatory reviews after New Drug Application (NDA) submissions to the PMDA and extended clinical development timelines. To address this issue, the Japanese government has implemented measures such as developing centralized clinical trial centers, increasing PMDA reviewers, and creating regulatory guidelines to enhance Japan's role in global drug development.[6] In contrast, China's share of global sales of innovative drugs was only 3% in 2021, considerably lower than other developed nations. In view of the above, the US, the EU, and Japan play vital roles in shaping the global pharmaceutical landscape. They drive innovation and advancements in the pharmaceutical industry, contributing to improved healthcare outcomes worldwide. Despite this, China's pharmaceutical sector has experienced remarkable growth in the past five years, especially in approving new drugs and focusing on indigenous research and development (R&D) initiatives. This study aims to compare China's new drug development trends with those of the US, the EU, and Japan, exploring the disparities between China and pharmaceutical powerhouse nations in terms of new drug approval at various levels.

Methods

Study Design

This study involved a comprehensive retrieval and comparison of data on new drug approvals from 2019 to 2023 across four regulatory bodies: the National Medical Products Administration (NMPA), the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Pharmaceuticals and Medical Devices Agency (PMDA). The data collected for each drug included the generic name, trade name, applicants, target, approval date, drug type, approved indications, therapeutic area, the highest R&D status in China, and special approval status. To assess approval timelines, we calculated the interval (in days) between the approval date by the NMPA and those of the FDA, EMA, and PMDA. These intervals were then analyzed to identify variations in approval times across the different regulatory bodies.

Statistical Analysis

We performed a comprehensive analysis of the time lag in market approvals for drugs available between China and the other three markets. The interval days between the approval date by the NMPA and the other institutions were assessed. Numerical data were displayed as medians and interquartile ranges. A nonparametric Mann–Whitney Wilcoxon (MWW) test was conducted to assess variations in the time lag for drug approvals between the NMPA and FDA, EMA, or PMDA. We used GraphPad Prism version 10.1.2 for statistical analysis. A two-tailed p-value of <0.05 was deemed to be statistically significant. The drugs therapeutic areas were organized based on the 10th Edition of the International Classification of Diseases (ICD-10).

Definition of New Drug

① NMPA: Defines new drugs as those approved for the first time, including NMEs (and combination formulations containing NMEs) and biologics. NMEs primarily fall under Category 1 (innovative drugs not marketed domestically or internationally) and Category 5.1 (applications for domestically marketing patented drugs that are already marketed internationally) of chemical drug registration. Biologics mainly include domestically produced and imported biologics approved by the NMPA for the first time.

② FDA: Defines new drugs as NMEs under NDAs, or as new therapeutic biological products under Biologics License Applications (BLAs). The active ingredient(s) in a novel drug has never been approved in the US.

③ EMA: Defines new drugs as those with new active ingredients approved for the first time.

④ PMDA: Defines new drugs as those with new active ingredients approved for the first time.

Exclusions across all institutions: chemical generics, traditional Chinese medicine, vaccines, blood products, cellular and gene therapy products, biosimilars, new indications, new formulations, new routes of administration, and changes in patient populations.

Results

Overall Trends and Special Approvals for New Drugs From 2019 to 2023

1. Over the past five years, a total of 877 new drugs were approved in China, the US, the EU, and Japan, yet the trends in drug approvals varied across these markets (Figure 1a). China has approved the highest number of new drugs, with 256 in total, followed by the US with 243, the EU with 191, and Japan with 187 (Supplementary Table 1). 2021 marked the year with the highest average number of new drug approvals, standing at 51.25. Both the US and China have witnessed an overall increasing trend in the number of new drug approvals. However, in 2022, there was a notable decrease in the number of new drug approvals in both markets, followed by a significant increase from 2022 to 2023. On the other hand, the EU and Japan saw a steady increase in the number of approvals in the first four years, followed by a sharp decline in 2023. Meanwhile, the number of Class 1 innovative drug approvals in China reached 101 from 2019 to 2023 (Supplementary Table 2). In 2023, the tally of innovative drugs reached 33, marking a notable 136% surge from the preceding year.

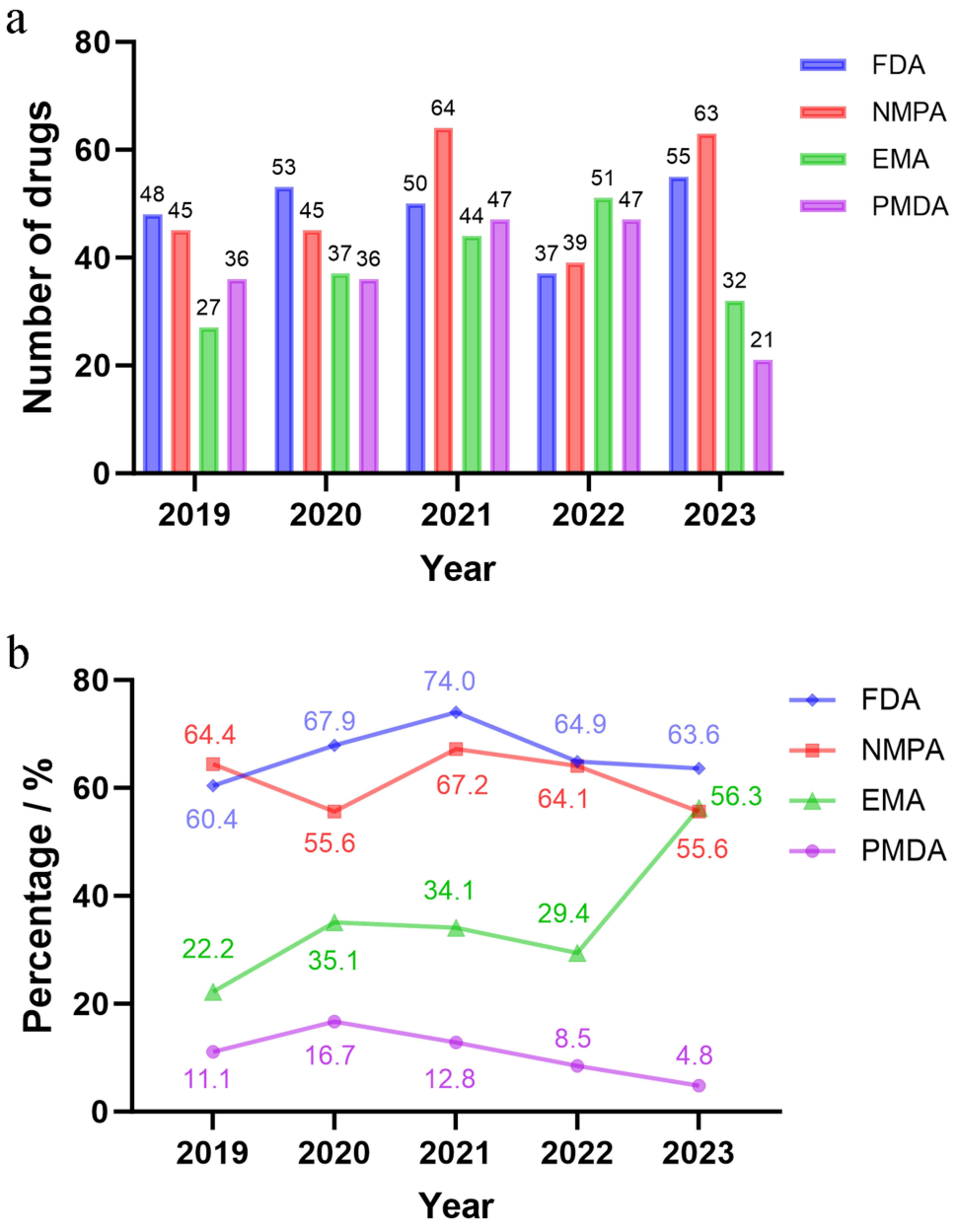

Figure 1 The number of new drugs from 2019 to 2023. (**a**) Overall trends of new drugs. (**b**) Proportion of special approval of new drugs.

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As shown in Figure 1b, the proportion of special approval of new drugs in China and the US from 2019 to 2023 was all above 50%, reaching the peak level in 2021 respectively. The EU only exceeded 50% in 2023, while Japan's special approval ratio was significantly lower than other markets, less than 20% every year. Overall, the proportion of special approval in the EU and Japan was significantly lower than that in the US and China. The overall trends of special approvals in China and the US align closely with the trend in the number of approved drugs, highlighting the critical significance of special approvals for drug market entry.

Trends in New Drug Therapeutic Areas and Targets in China and Globally

The overall trends in the therapeutic areas for newly approved drugs by NMPA, FDA, EMA, and PMDA (Figure 2a) are consistent with the trend in China (Figure 2b). The top three areas are oncology, hematology, and infectiology, reflecting the medical field's focus and strong demand for addressing these diseases. In the past five years, non-small cell lung cancer (25.8%) and breast cancer (14.8%) have been the most actively researched types of tumors in terms of drug

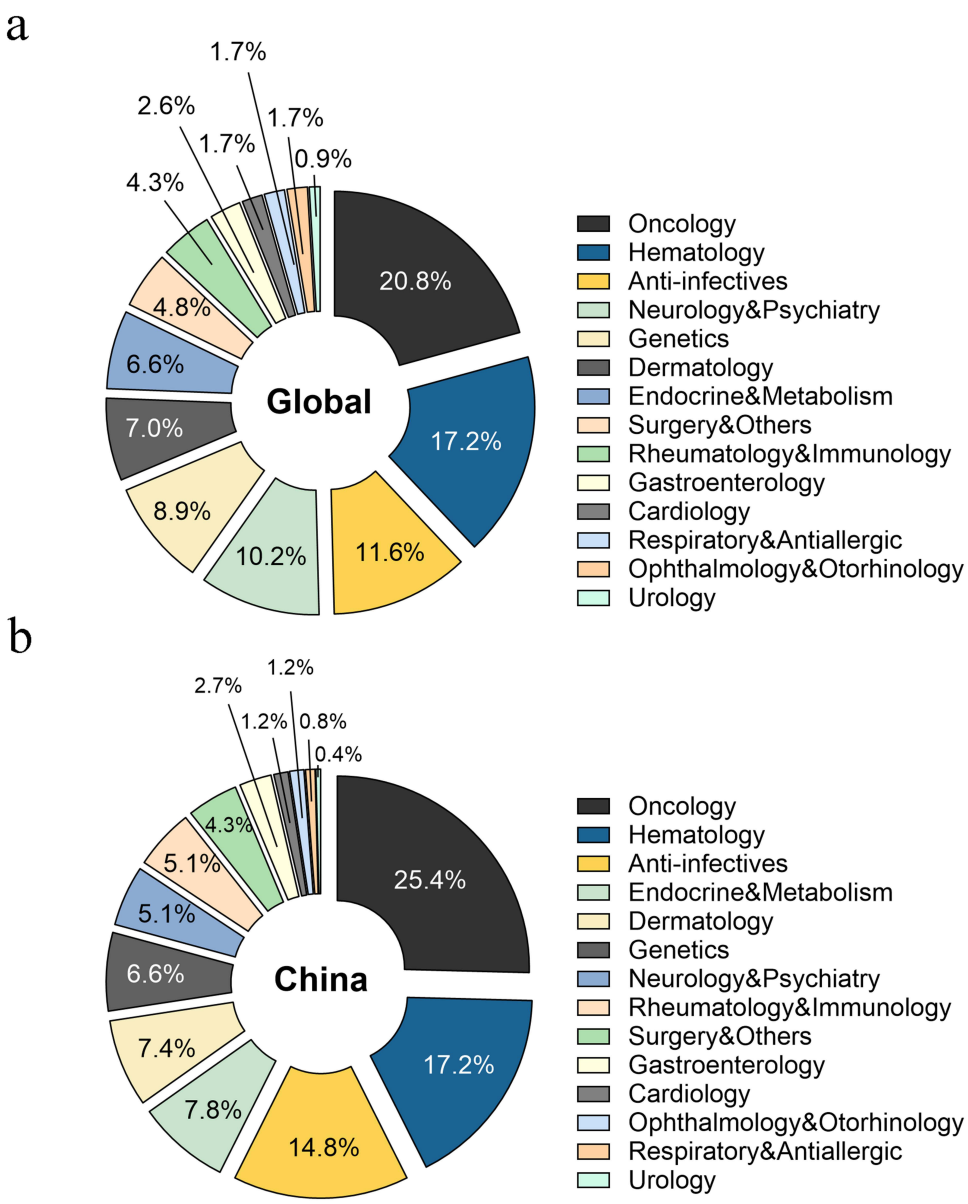

Figure 2 Therapeutic areas of approved drugs. (**a**) Drugs approved by NMPA, FDA, EMA, and PMDA. (**b**) Drugs approved by NMPA. Global refers to the overall landscape of drug development in China, the US, the EU, and Japan in this study.

development, while multiple myeloma (13.9%) and diffuse large B-cell lymphoma (10.6%) have also garnered significant attention in the area of hematology (Supplementary Table 1). In the category of infectiology, COVID-19 therapeutic drugs account for 21.6% of the total in the global trend, while in China, they only represent 18.4% (Supplementary Table 1). In addition to the top three therapeutic areas with the largest share, the global trend is more focused on the progress of new drugs in the neurology and psychiatry (10.2%) and genetics (8.9%), while China is more focused on endocrinology (7.8%) and dermatology (7.4%).

Figure 3a lists the top 10 target points for the most approved new drugs by NMPA, FDA, EMA, and PMDA, while Figure 3b displays the targets in China that are associated with five or more drug approvals. The JAK1/JAK2/JAK3/TYK2 targets stand out as the most approved across the four markets, with a combined total of 25 approvals (Supplementary Table 1). Notably, PD-1 and EGFR stand as the most approved targets in China, with 8 drugs approved. Only in China, Tubulin, ALK, and RT are the targets of much concern. It is evident that China's prevalent targets continue to vary from global trends, underscoring a distinct R&D focus.

NMPA Narrows Time Lag With FDA and EMA for Drug Approvals

Overall, the approval timelines for new drugs in the US, the EU, and Japan have been earlier than those in China. However, compared to pre-2021, China has significantly narrowed the gap in new drug approval dates with the US and the EU from 2021 onwards (Figure 4). Post-2021, the approval date gap between China and the US shortened by 351 days (735 versus 384 days), with a statistically significant difference ($P = 0.0065$). Similarly, the gap decreased by 663 days (795 versus 132 days) with the EU ($P < 0.0001$), while post-2021 the approval time gap between China and the EU was smaller than in other markets. Post-2021, the disparity in approval timelines between China and Japan has widened by 34 days compared to pre-2021 (169 versus 203 days), though lacking statistical significance ($P = 0.6022$).

Breakthrough Progress and Challenges of Innovative Drugs in China

There are 11 drugs approved earlier in China than in other markets (Figure 5). Seven drugs are approved in the US, six in Japan, and four in the EU. China exported more innovative drugs to the US than to the EU and Japan. It is worth noting that in 2024 new approvals of our innovative drugs were granted in the US, the EU, and Japan. Benvitimod and

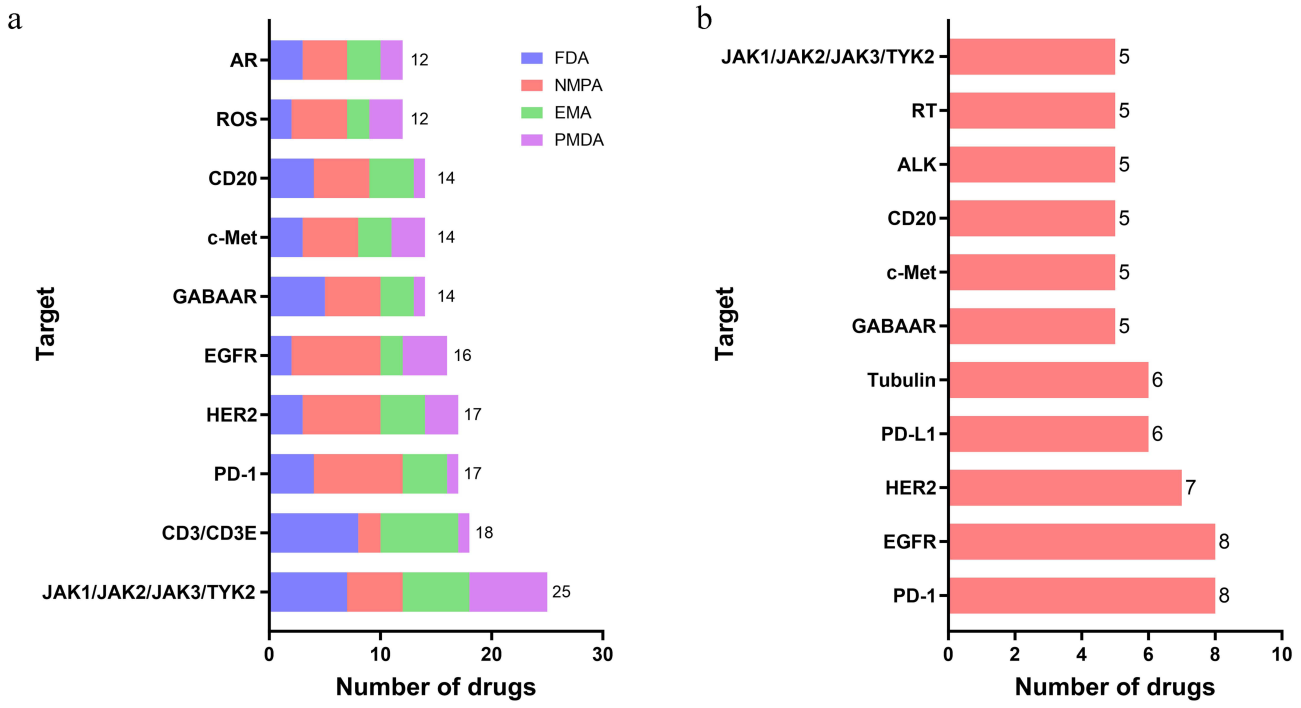

Figure 3 The targets of approved drugs. (**a**) Drugs approved by NMPA, FDA, EMA, and PMDA. (**b**) Drugs approved by NMPA.

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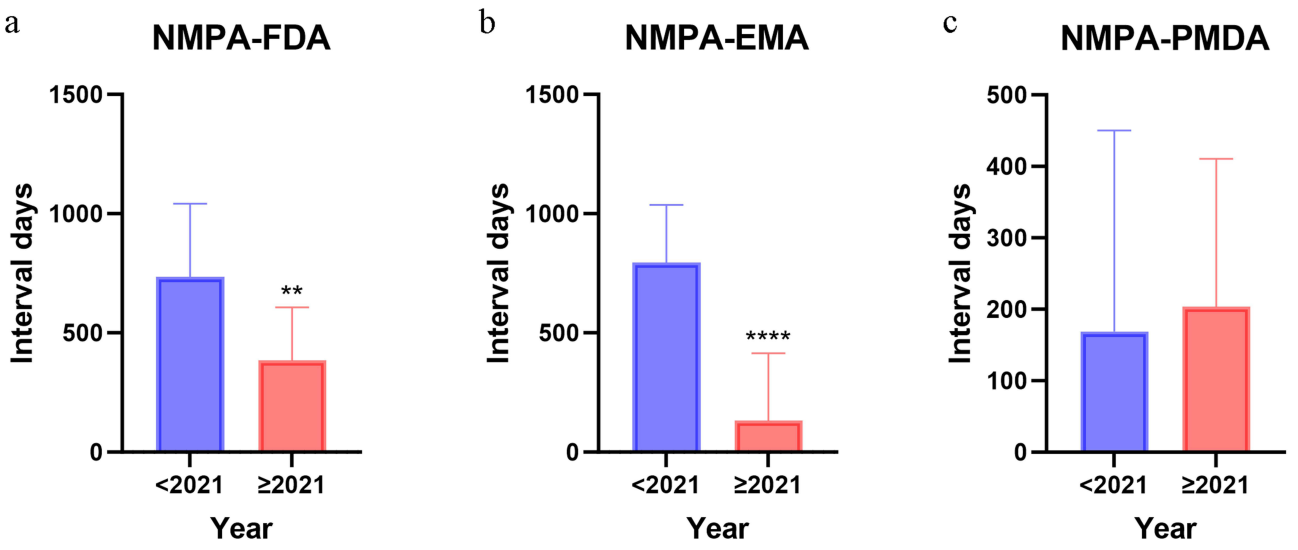

Figure 4 Time lags for drug approvals. Numerical data were displayed as medians and interquartile ranges. A nonparametric Mann–Whitney Wilcoxon (MWW) test was conducted to assess variations in the time lag for drug approvals between the NMPA and the FDA, the EMA, or the PMDA. Based on the approval dates of the US, the EU, and Japan, drugs are categorized into those approved before 2021 and those approved in or after 2021. The terms of NMPA-FDA, NMPA-EMA, and NMPA-PMDA refer to the approval date in NMPA minus the approval date in FDA, EMA, and PMDA. $^{**}P < 0.01$. $^{****}P < 0.0001$. (**a**) Time lags for drug approvals between the NMPA and the FDA. (**b**) Time lags for drug approvals between the NMPA and the EMA. (**c**) Time lags for drug approvals between the NMPA and the PMDA.

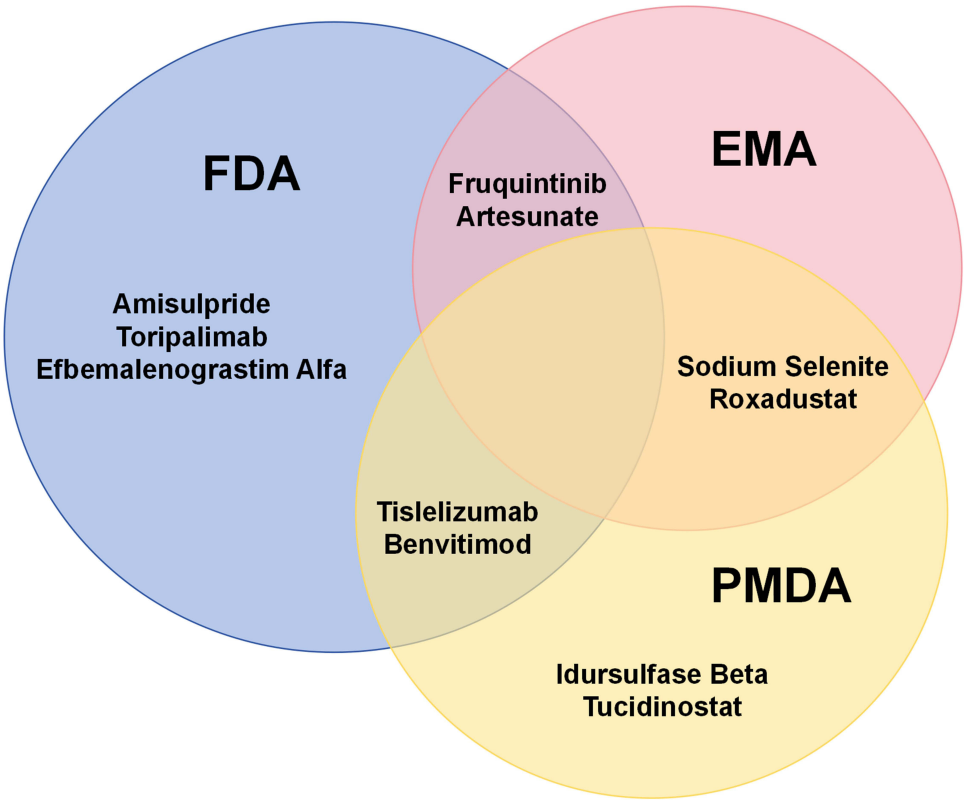

Figure 5 Situation of China's earliest approved drugs being launched overseas. The size of the circle represents the number of new drugs approved by FDA, PMDA, and EMA.

fruquintinib were approved by PMDA and EMA respectively in June 2024, while tislelizumab was approved by FDA in March 2024 (Supplementary Table 1). China has made remarkable breakthroughs in first-in-class drugs over the past five years, with a total of 15 drugs approved from 2019 to 2023 (Table 1). The trend in the number of first-in-class drugs

Table 1 First-in-Class Drugs in China From 2019 to 2023

Drug Name	Approval Date	Indication	Drug Type	Approved Markets
Sodium Oligomannate	2019/11/2	Alzheimer's disease	NME	NA
Benvitimod	2019/5/29	Plaque psoriasis	NME	FDA
Amubarvimab/Romlusevimab	2021/12/8	COVID-19	Biologics	NA
Chiglitazar Sodium	2021/10/19	Type 2 diabetes mellitus	NME	NA
Azvudine	2021/7/20	HIV infection	NME	NA
Telitacicept	2021/3/9	Systemic lupus erythematosus	Biologics	NA
Spesolimab	2022/12/14	Plaque psoriasis	Biologics	FDA, EMA, PMDA
Dorzagliatin	2022/10/8	Type 2 diabetes mellitus	NME	NA
Ormutivimab	2022/1/25	Rabies	Biologics	NA
Pegmolesatide	2023/6/30	Renal anemia	NME	NA
Anaprazole Sodium	2023/6/25	Duodenal ulcer	NME	NA
Zuberitamab	2023/5/12	Diffuse large B-cell lymphoma	Biologics	NA
Leritrelvir	2023/3/23	COVID-19	NME	NA
Glumetinib	2023/3/7	Non-small cell lung cancer	NME	NA

Note: NA: The drug has not been approved in other markets as of December 31, 2023.

aligns closely with the overall trend in new drug approvals in China, peaking in 2021 and 2023. However, no first-in-class drugs were approved in 2020.

Discussion

Despite challenges posed by the COVID-19 pandemic, China has made considerable advancements in both the quantity and speed of new drug approvals from 2019 to 2023. Oncology drugs have consistently dominated as the most active area of R&D in both China and globally. Notably, targets like PD-1 and EGFR in anti-tumor drugs have played pivotal roles in advancing new drug development in China. Moreover, a growing array of Chinese domestic medications are penetrating global markets. These improvements not only signify the country's growing capacity for innovation but also enhance its position in the global pharmaceutical market. As China continues to refine its regulatory processes and increase the international presence of innovative drugs, it is well-positioned to become a formidable player on the world stage.

By comparing with leading pharmaceutical nations, it is evident that China has been consistently producing new drug R&D achievements, with the overall number of approved new drugs showing a growth trend. The high number of new drug approvals in China in the past five years is mainly attributed to two factors: the increase in approvals of overseas drugs and the rise in domestically developed innovative drugs. China currently stands as the world's second-largest pharmaceutical market, with evolving healthcare demands, swift market expansion, and regulatory reforms compelling China to focus not only on importing foreign medications but also on fostering innovation in domestic drugs.[7] The significant increase in the number of innovative drugs reflects positive changes in drug R&D, regulation, and market dynamics, demonstrating the continuous development momentum in the pharmaceutical field of China. However, factors such as intensified industry competition and the prevalence of COVID-19 may have affected drug development and approval,[8] leading to a slight decrease in approvals after 2021. However, the emphasis on quantity over quality raises important questions about the sustainability of this growth. To truly establish itself as a leader in the global pharmaceutical landscape, China should shift its focus from merely increasing the number of drug approvals to enhancing the quality and innovation of its offerings.

While traditional regulatory pathways have traditionally relied on large randomized superiority trials, the urgent clinical demand has prompted the emergence of alternative approval methods. New regulatory models facilitate expedited reviews and accelerated approvals for specific drugs, addressing the need for swift access to effective treatments.[9] The significant increase in special approvals in China in 2021 may primarily be attributed to updates in the Provisions for Drug Registration. In response to the growing demand for pharmaceuticals and to keep pace with the rapid development of the pharmaceutical industry in China, Provisions for Drug Registration (2020) was issued on January 22, 2020. Compared to the previous one, this new policy explicitly added a chapter on "Accelerated Drug Registration", which includes "Breakthrough Therapy Drug Procedure", "Conditional Approval Procedure", "Priority Review and Approval Procedure", and "Special Approval

Procedure". The establishment of these four "procedures" in China is equivalent to opening a "green channel" for new drug R&D, providing valuable support for the development of the pharmaceutical industry and the safe and effective use of medicines by the public. However, unlike the US, the EU, and Japan, China does not have a specific definition for orphan drugs in its special drug evaluation process. In contrast, the other markets may benefit from both an orphan drug designation and special approval processes, which have contributed to faster therapeutic approvals.[10]

Oncology and hematology are crucial medical domains due to the global challenges posed by cancer and blood disorders, which have high mortality rates. In 2022, approximately 20 million new cancer cases and 9.7 million cancer-related deaths occurred globally. Lung cancer remains the leading cause of cancer mortality to date.[11] The significance of the field of infectiology is evident in combating infections caused by bacteria, viruses, and other pathogens, particularly amidst global pandemics like COVID-19 and the rise of antibiotic-resistant bacteria. Although COVID-19 therapeutic drugs make up a significant portion, it is evident that China's capacity to respond to sudden public health emergencies falls short compared to global standards. Faced with such unforeseen circumstances, there is a relative lag in the country's ability to develop new drugs. In other therapeutic domains, China exhibits a distinct R&D focus compared to the global landscape. These discrepancies may arise from variations in market dynamics, disease prevalence, regulatory frameworks, investment levels, etc. The importance of these areas drives accelerated drug development and clinical trials to meet healthcare needs and enhance patient quality of life. For example, with the ongoing advancements in technologies like tRNA therapy, the treatment of genetic diseases such as Duchenne muscular dystrophy has become increasingly precise and effective, necessitating the development of more genetic drugs to meet clinical demands.[12] CD3 molecule, a universal marker on the surface of T cells, is the prime target for the development of bispecific antibody drugs worldwide. Bispecific antibodies are artificial antibodies capable of simultaneously binding to two different antigens or two distinct epitopes on the same antigen. Due to their specificity and dual functionality, they have become a hotspot in antibody engineering and hold great promise in cancer immunotherapy.[13] In this study, bispecific drugs targeting the CD3 receptor include epcoritamab (Epkinly®), mosunetuzumab (Lunsumio®), teclistamab (Tecvayli®), etc. However, blinatumomab and glofitamab are the only CD3-targeting bispecific antibodies approved in China in the study, both indicated for hematological system diseases.

Some popular targets in drug development, such as PD-1, EGFR, and HER2, are relatively concentrated, leading to intense competition. This concentration indicates not only a significant influx of funds and technology but also hints at potential market saturation and risks of homogeneous competition in the future. China has seen a proliferation of me-too approvals, with therapeutics being authorized for the same targets and exhibiting similar mechanisms of action.[14] According to statistics, the concentration of the top ten hot targets in global new drug research is 7.68%, while China has reached 19.38%. This reflects a trend towards homogenization in China's new drug development, to some extent revealing the weakness of China's basic research capabilities.[15] As a representative drug in tumor immunotherapy, PD-1 inhibitors have sparked a surge in R&D activity due to their innovative mechanisms and broad spectrum of effectiveness. At present, several PD-1 inhibitors have been approved for marketing domestically. The development of PD-1 inhibitors may be influenced by the disease spectrum in China, where the urgent therapeutic needs of prevalent diseases help drive both drug imports and innovation. For example, tislelizumab, a monoclonal IgG4 antibody, acts as an immunotherapeutic and anti-neoplastic agent by specifically inhibiting PD-1.[16] On September 15, 2023, the EU approved tislelizumab as a monotherapy for the treatment of adult patients with unresectable, locally advanced, or metastatic esophageal squamous cell carcinoma (ESCC) who have previously received platinum-containing chemotherapy. Tislelizumab has become the first successful homegrown PD-1 inhibitor to enter the international market.

R&D productivity remains a significant challenge for China. Studies indicated that the average R&D efficiency of large pharmaceutical companies was $6.16 billion per new drug developed.[17] In the United States, recognized as the most dynamic and pioneering nation in pharmaceutical innovation, 50% of all new drugs globally receive their first approval.[18] This achievement is closely tied to the country's well-structured medical intellectual property protection system, encompassing both patent and regulatory exclusivity, which collectively enhance the safeguarding of innovative drugs.[19] While China has significantly ramped up the approval of new drugs, the focus on increasing the quantity of approvals has sometimes overshadowed the need for robust innovation and high-quality research that can compete with Western standards.

Drug lag, characterized by delays in drug approval, has remained a persistent challenge in China's healthcare system, significantly impacting the nation's ability to deliver cutting-edge treatments to patients.[18] Our study shows that despite the shortening of the time lag in new drug approval times between China and the US and the EU, there is still

a substantial gap between China and the US. However, there was no significant difference in the approval time of new drugs between China and Japan before and after 2021. This trend may stem from Japan's relatively lower rate of new drug approvals in recent years, leading to a convergence in the overall market entry timelines between the two countries. This phenomenon highlights the global landscape of pharmaceutical innovation. The sustained dominance of the US underscores its absolute leadership in pharmaceutical innovation, showcasing its robust research infrastructure and regulatory environment. At the same time, China has shown rapid advancement in drug innovation over the past three years, progressively narrowing the gap with other leading nations.

In recent years, China has made significant strides in developing indigenous drugs that are gaining approval in foreign markets. One key factor could be the proposal of the Investigational New Drug (IND) Implicit License System in 2018, which represents a major innovative reform aimed at expediting the review and approval process for clinical trials of pharmaceuticals. By drastically reducing the review and approval time for clinical trials to achieve implicit licensing within 60 working days, this system enables the synchronization of global R&D of innovative drugs at the operational level. Additionally, the NMPA has made significant improvements in reducing the approval timeline for new drugs, narrowing the gap with the US and EU. Experts indicated that approval in China was often pursued first for less common or rare cancer types before being extended to more prevalent cancers. Expedited review processes can help facilitate quicker approvals to meet the unmet medical needs associated with these uncommon or rare cancers.[14] In recent years, the total amount of license-out for innovative achievements in biopharmaceutical R&D in China has been rapidly increasing, with the total contract value reaching over 40 billion US dollars in 2023.[15] 2023 stands out as a milestone year for the overseas market debut of domestically developed innovative drugs. It not only witnessed an unprecedented surge in the number of pharmaceutical exports but also marked significant breakthroughs across various fronts. For instance, toripalimab is the first domestically approved PD-1 monoclonal antibody drug in China. It fills a gap in domestically produced PD-1 inhibitors and breaks the monopoly of some high-priced imported drugs.[20] Toripalimab received FDA approval on October 27, 2023, becoming the first domestically developed and manufactured innovative biologic drug from China to be granted market approval in the US. However, the export of domestically produced drugs still faces significant obstacles and requires applicability to populations in other markets. Due to the higher incidence of nasopharyngeal cancer in China compared to the US, conducting large-scale multicenter trials may be challenging, making FDA approval potentially more suitable.[21] While many elements of trial design in China have significantly advanced in recent years and now align closely with those in the US, challenges persist regarding the implementation and operational aspects of these trials. Despite having a population more than four times that of the US, China initiated fewer than half as many interventional clinical trials between 2000 and 2021 (4910 vs 1726).[14] Recent efforts to enhance the clinical trials process in China have been substantial; however, concerns persist about the capacity to conduct high-quality trials, particularly regarding ethical review, registration, implementation, and reporting issues.[22]

The increasing number of first-in-class drugs in China signifies a shift towards more innovative and novel therapeutic approaches in the country's pharmaceutical industry. The absence of any first-in-class drug approvals in 2020 can be primarily attributed to the potential impact of the COVID-19 pandemic. The onset of the COVID-19 pandemic in 2019 prompted notable alterations in the execution of clinical trials. Although strategies like online meetings, remote follow-ups, and medication delivery aided in sustaining trial advancement to a degree, they fell short of upholding trial standards as robustly as previously. Consequently, these adjustments presented specific challenges to the execution of clinical trials.[23] This suggests that the pharmaceutical industry's focus on innovative and first-in-class treatments may have been momentarily disrupted by the global health crisis, leading to a temporary decline in such approvals. While the number of approved first-in-class drugs in China still lags behind that of developed countries like the US, the peaks in 2021 and 2023 have laid a foundation and instilled confidence in the future of new drug development in China. The unmet treatment needs of overseas patients are among the key factors contributing to the successful overseas expansion of Chinese pharmaceutical products. Benvitimod became the first Chinese first-in-class drug to be initially launched in China before entering the US market, receiving approval from the NMPA three years ahead of the FDA. Continued efforts to bridge the gap and enhance capabilities in drug discovery and development are pivotal to solidifying China's position as a key player in the global pharmaceutical landscape.

Compared to leading pharmaceutical nations, China's new drug R&D still faces some challenges. Firstly, there is a shortage of high-level talent for technology transfer. China lacks clear policy guidance in cultivating and deploying high-level innovative R&D talent, with only 9.3% of R&D personnel in the pharmaceutical industry, a significant gap compared to the US (24.5%) and the EU (15.1%).[24] However, it is important to note that true innovation often stems from the "freedom of research" in academic settings, which does not require immediate commercial outcomes. In fact, China's recent progress in pharmaceutical innovation may, in part, be attributed to this lack of rigid policy constraints, allowing a significant portion of R&D personnel to focus on exploratory and original discoveries in academic research. Secondly, although China's investment in pharmaceutical R&D has been steadily increasing as a percentage, the total amount still lags behind developed countries significantly. Additionally, medical insurance policies have insufficient coverage for innovative drugs. Developed countries like the US and Japan have medical insurance payment systems that cover innovative drugs, with reimbursement qualifications being obtained almost simultaneously with market approval. In China, only a few innovative drugs are on the national basic medical insurance drug list, and the waiting time for inclusion in reimbursement is relatively long. Furthermore, the synergy between research and industrial innovation has not yet been established. The separation of innovative resources and production factors has resulted in a pharmaceutical innovation conversion rate of less than 8% annually in China, significantly lower than the 50%–70% range seen in developed countries.[25]

Conclusion

While China's pharmaceutical industry has made commendable progress in recent years, significant challenges remain. To bridge the gap with established pharmaceutical powerhouses, China must focus on fostering a culture of innovation that prioritizes quality and efficacy in drug development. By enhancing its research capabilities and global collaboration, China has the potential to significantly increase its presence in the international pharmaceutical market and ultimately improve healthcare outcomes both domestically and globally. As the industry evolves, ongoing evaluation and adaptation will be crucial in navigating the complexities of a rapidly changing global landscape. Looking forward, as domestic pharmaceutical companies continue to enhance their innovation capacity, buoyed by favorable policies and the expedited streamlining of new drug evaluation and approval processes by regulatory bodies, China's pharmaceutical sector is set to evolve into a more vibrant arena. Yet, amid the fiercely competitive landscape for Chinese innovative drugs on the global stage, it is evident that Chinese pharmaceutical enterprises still have a significant journey ahead.

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Disclosure

The authors declare no conflicts of interest.

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