

Analysis and Reflection on Investment Status of Innovative Drugs in China

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Abstract. At present, China's innovative drug support policies and market volume are good, but China's innovative drug research and development(R&D) success rate and market share still need to be improved. This is related to the unreasonable investment direction of innovative drugs and the low utilization efficiency of R&D resources. Therefore, the objective of this paper is to evaluate China's present state of investment in innovation drugs and explore how to promote the effectiveness and sustainability of innovative drug investment. Through data analysis, this paper found that the scale and frequency of investment and financing of innovative drugs in China are declining. The problem with China's innovative drug investment is that the valuation of hot projects is too high, the allocation of funds is unreasonable, the investment is not in line with the actual needs of the industry, and only the pursuit of short-term returns. Given the various problems in China's innovative drug investment, the government needs to create a long-term stable environment for the innovative drug investment market and prudently formulate relevant policies to strike a balance between stimulating the market and regulating the market. Entrepreneurs should choose the direction of R&D according to their areas of expertise combined with cutting-edge scientific research progress rather than adjusting the direction of R&D to cater to the preferences of investment institutions. Investment institutions should avoid risks caused by unreasonable capital allocation by strengthening the layout of the pre-investment track and prudently carrying out project valuation analysis.

Keywords: Innovative drug; Investment status; China policy; Investment market.

1. Introduction

1.1. Background

In recent years, China's share of the innovative drug market has increased. According to the National Medical Information Center, China's innovative drug market will reach 678.5 billion yuan (\$92.9 billion) by 2022. At the same time, the Chinese government has taken active measures to encourage research and development(R&D) and investment in innovative drugs, including simplifying the approval process and speeding up the registration and listing of innovative drugs to improve the market competitiveness of innovative drugs and attract investment from domestic and foreign enterprises. The huge demand for innovative drugs in the Chinese market and the government's supportive policies for innovative drug research and development provide opportunities for investment in innovative drugs.

The total R&D investment of the pharmaceutical industry reached 102.617 billion yuan (\$92.9 billion) in 2022, with a year-over-year growth rate of +14.66%. From 2018 to 2022, the R&D expenditure of Chinese pharmaceutical businesses grew year over year. China has advanced in recent years in novel medicine R&D thanks to the expansion of investment scale. The number of new Class I drugs approved by China in 2022 has increased from the previous single digits to more than 50 innovative drugs, including innovative drugs treating cancer and rare diseases.

Although China's innovative drug investment has increased year by year, the success rate of China's innovative drug R&D is still at a low level compared with other countries, and the return rate of R&D investment is not good enough. In addition, the market share of China's innovative drugs only accounts for about 15% of the entire pharmaceutical market, which is still low compared with the considerable volume ratio of China's pharmaceutical market. As a long-term investment project with high risk and high return, if the lack of scientific evaluation criteria and reasonable resource

allocation, it will cause problems such as unreasonable investment direction and low utilization efficiency of R&D resources. Therefore, it is necessary to analyze the current situation of innovative drug investment in China and explore how to promote the effectiveness and sustainability of innovative drug investment.

1.2. Related Research

Chen analyzed and summarized the changes in phase I clinical trials of new drugs in mainland China between 2011 and 2020. The study discovered that phase I clinical trials have advanced significantly in mainland China over the last ten years as a result of modern design and drug innovation strategies. Nonetheless, further work is required to increase the success rate of novel medication phase transitions in the future [1]. Takao used the database of the U.S. Securities and Exchange Commission to analyze the R&D investment required by future successful biotechnology companies during the financial crisis. It highlights the significant differences in R&D investment characteristics between potentially successful and unsuccessful biotech companies during the financial crisis [2]. The study, which gathered information from the top 20 global pharmaceutical corporations between 2011 and 2021, discovered that China engaged in far fewer novel anticancer medicine clinical trials than did South Korea, Japan, the United States, or the European Union. Over the past ten years, China's share of worldwide pharmaceutical companies' clinical development of novel anticancer medications has increased, although there is still a sizable difference when compared to these nations [3].

Huang has investigated the effects of supply chain strategies for pharmaceutical manufacturing subsidies on the R&D decisions, earnings, and social welfare of pharmaceutical firms, taking into account spillover effects both within and beyond the industry. The findings indicate that the patient medical insurance subsidy method is thought to be the most effective one, and that the government subsidy strategy can encourage R&D investment, enhance business profits, and improve societal welfare [4]. Joshua investigated how creative companies react to unfavorable shocks to their goods using project-level data from drug development companies. According to the findings, impacted companies have boosted their R&D expenditures and are more likely to buy innovations in response to external disruptions than to launch new initiatives from scratch. The findings show how route dependence is formed by specialized business capital investment and how it alters the direction of R&D expenditure [5]. According to Lai's research, China's pharmaceutical manufacturing sector is trapped in a U-shaped efficiency trap, and innovative efficiency can only really boost industrial competitiveness in high- and low-level technical groups. In order to boost competitiveness, the region should concentrate on standardizing centralized procurement and making effective use of creative resources and industrial transformation. Furthermore, the government ought to bolster laws in order to eradicate substandard innovation. [6].

Research by Lee points out that low - and middle-income countries continue to face unequal disease burdens, including a lack of drug R&D and poor access to essential medicines. The Health Impact Fund proposes collaborative solutions that will consider working with pharmaceutical companies in Brazil, Russia, India, and China to expand reach, spur local innovation, and promote a more equitable path to drug discovery [7]. Li analyzed the delays in drug development in China from the start of clinical trials to the regulatory process and identified critical underlying factors. The study found that while shortening the approval process could reduce approval delays, the start time of clinical trials in China was more important in reducing the impact of drug delays. In addition, strengthening domestic R&D capacity remains the key to lowering drug delays. The China National Drug Administration should also pay attention to the accumulation of experience in the supervision of innovative drugs and transform the supervision of generic drugs into new drugs [8]. Alexander conducted a comparative analysis of the R&D efficiency of 14 leading pharmaceutical companies between 1999 and 2018 and found a strong positive relationship between R&D investment and two parameters of R&D outcomes. In other words, higher R&D input correlates with higher R&D output. Second, analysis results show that there are "economies of scale" in pharmaceutical R&D that the

larger the scale, the more efficient the R&D [9]. Annapoornima found that biotech and pharmaceutical companies invest heavily in new drug discovery, but returns are falling. The study found that failure to terminate projects with poor prospects on time is an essential cause of declining R&D productivity. As a result, companies need to restructure the new drug discovery process and consider the impact of project and company characteristics on project downtime to redeploy resources promptly [10].

1.3. Objective

This paper takes China's innovative drug investment as the research object and mainly explores the current situation and problems of China's innovative drug investment. Firstly, data will be used to analyze the changes in policies and markets related to innovative drugs in China in recent years and the status quo of investment and financing. After that, this paper will analyze the main problems faced by China's innovative drug investment through the current investment and financing situation. Finally, in response to these problems, relevant recommendations for the government, investment institutions, and entrepreneurs will be put forward.

2. Current Situation and Problems

2.1. Current Situation of the Innovative Drug Industry in China

China's innovative drug-related policies are favorable. In recent years, China's innovative drug industry has received significant attention from the Chinese government and critical support from national industrial policies. The state has introduced several policies to encourage the development and innovation of the innovative drug industry. In March 2023, The State Council issued the "Opinions on Further Improving the Medical and Health Service System" policy, proposing to strengthen the capacity building of clinical medicine-related disciplines and develop cutting-edge medical technologies such as omics technology, new vaccines, and precision medicine.

China's innovative drug market continues to expand. With the introduction of the review and approval policy of innovative drugs and the acceleration of the marketization of innovative drugs brought about by rapid economic development, the structural proportion of innovative drugs in the medical market has gradually increased. The market size of innovative drugs will reach 630.6 billion yuan in 2021 and 678.5 billion yuan in 2022. Due to favorable policies, medical insurance adjustments, and other reasons, the market size is expected to rise to 778.9 billion yuan in 2023, as shown in Fig. 1.

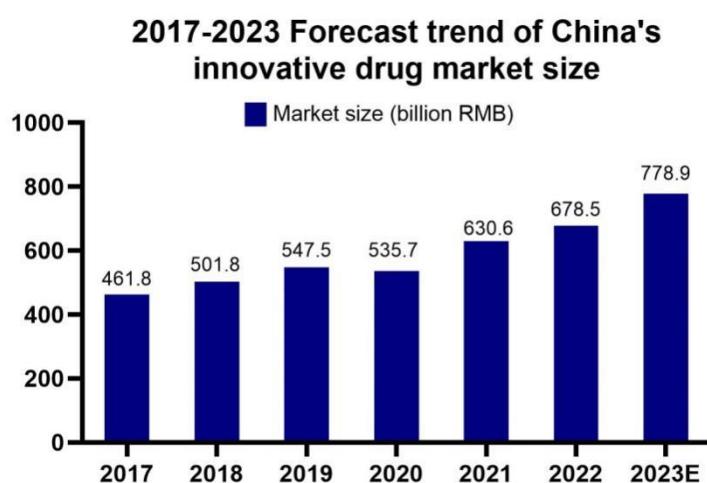


Fig. 1 2017-2023 Forecast trend of China's innovative drug market size

The number of applications for approval of innovative drugs in China has increased rapidly. The number of investigational new drug applications (IND) increased from 236 in 2017 to 600 in 2022,

with an average annual growth rate of 20.5%. In 2022, 64 New Drug Applications were submitted for marketing approval (NDA) in China, of which the number of domestic innovative drugs reached 24, a significant increase compared with 2018, as shown in Fig. 2.

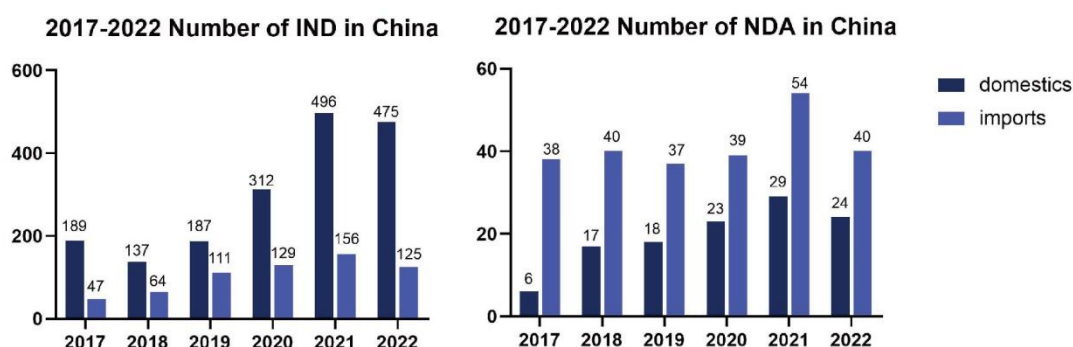


Fig. 2 2017-2022 Number of IND (left) and NDA (right) in China

2.2. Investment and Financing Status of the Innovative Drug Industry in China

Contrary to policy signals and market trends, the size of China's innovative drug investment market has continued to decline in recent years. In 2019, China's new drug investment market began to show a downward trend. Still, the outbreak of COVID-19 in 2020 has attracted unprecedented attention to the medical investment industry, making the industry that was initially in a downward trend suddenly pick up and continue to grow for two years. From 2022 onwards, the market for innovative drug investment began to decline again. The total financing of China's innovative drug primary market in 2022 was about one-third lower than that in 2021, and the total financing was less than half of that in 2021, a significant decline. As of the end of August 2023, there were only 135 innovative drug financing events this year, with a total of 18.14 billion yuan, less than half of the past two years, as shown in Fig. 3.

2014-2023 Financing events and amounts of innovative drugs in China

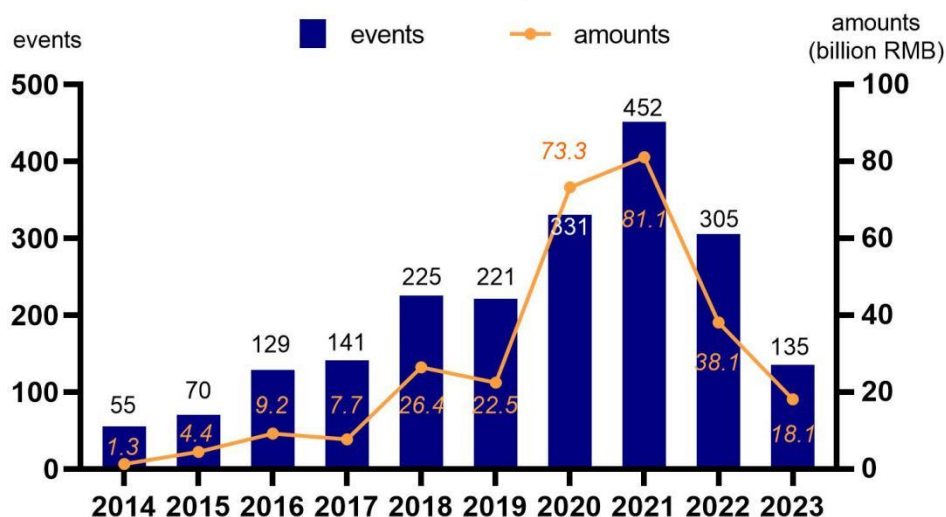


Fig. 3 2014-2023 Financing events and amounts of innovative drugs in China

The cooling of China's innovative drug investment market is not due to the decline in the level of innovative drug R&D in China or the decline in the prospect of the innovative drug market. This is because investors are gradually returning to rationality and no longer regard innovative drug investment as a short-term return market with rapid speculation and rapid liquidation. China's new drug investment market is relatively young and has experienced a period of rapid development and

inflated valuations caused by COVID-19, and now China's innovative drug investment may return to its actual level. This year, investment institutions began to spend more time on industry research and understanding technology, paid more attention to post-investment planning, and repeatedly polished more reasonable R&D plans with founders. Some investors even set up their experimental teams to verify R&D data to reduce investment risks. These phenomena show that China's innovative drug investment market has begun to return to rationality and return to the essence of drug R&D, which is a good thing for entrepreneurs who want to do new drug R&D.

2.3. The Problem of China's Innovative Drug Investment

Investors are overvaluing popular projects. In the past few years, China's average biotech companies were able to obtain financing successfully, and some hot biotech companies even raised financing three times in a year, accumulating 1 billion yuan of capital. Once listed, most of them were valued at more than 20 billion yuan (\$2.9 billion). By comparison, biotech in the United States will be worth only \$200 million to \$300 million when it goes public. After the successful listing of these Chinese enterprises, the market value soared, and investors quickly obtained several times the return. Over time, investment institutions and investors have taken this fast profit model to the extreme: they don't care about the success of developing drugs. They want to cash out as quickly as possible. For some enterprises, from the establishment to the listing but 2-3 years, investors only rely on listing arbitrage, without considering the success of R&D. These companies were overvalued in the primary market and began to bite back in 2021. Some companies have seen their share prices fall sharply on their first day of trading, with some dropping as much as 50 percent below their offering price. As the bad news of stock price collapse increases, China's innovative drug investment has entered a trough.

China lacks a stable and hierarchical investment ecology to allocate investments at different stages and positions rationally. In the past three years, the popularity of early-stage projects in the capital market has also continued to rise, and investors have even gone to significant universities to compete for professors, staff with teams, and start companies. This is a result of anxiety about investment risk: valuations of early-stage projects are relatively low, and lower capital investment can obtain a higher shareholding ratio; In contrast, middle and late-stage project financing is complex because the valuation is high, but also easy to decline because of the emergence of R&D results. However, early-stage projects are not a good place to hide from risk, it is very uncertain, and the success rate is the lowest.

Investment does not consider the actual needs of the industry, only chasing the latest technology. Some diseases have been treated well with traditional drug forms (such as small molecule antibodies), and there is no need to introduce new technologies to make duplicate drugs. Even if the new technology is finally verified to be feasible, it still costs unnecessary costs and has commercialization problems. However, many investors don't have in-depth industry research or do not understand pharmaceutical research, are attracted by the gimmicks of new technologies, and prefer innovative forms of medicine (such as gene therapy). However, some foreign large pharmaceutical companies introduced BD projects, and most of them carefully consider too fancy therapies but tend to be more stable technology drug forms.

China's innovative drug investment market is fickle, and investors are pursuing a quick return of funds. The R&D of innovative drugs requires long-term and stable investment, but in China's venture capital industry, the capital raised is due to various considerations and pressures, and there is a need for rapid withdrawal of funds, which cannot truly realize long-term value investment. The innovative drug environment has experienced a period of rapid development in the past. In such an immature market, there have been numerous arbitrage opportunities, leading to investors having a common short-term return idea. In addition, the long-term also requires a specific and relatively mature market environment, which is also the weakness of China's investment market.

3. Suggestions and Inspirations

3.1. Government

To avoid problems such as investment overheating and resource waste caused by excessive stimulus policies, the government needs to create a long-term stable environment for the innovative drug investment market and carefully formulate promotion policies. Long-term regular support policies include innovative drug evaluation systems, research-related funding allocation, personnel training, and other aspects to maintain a steady policy direction. On the other hand, the government's regulatory system for the innovative drug industry has a more significant impact on the profits of innovative drugs. It is necessary to continuously optimize the system to ensure the compliance and sustainability of R&D, production, pricing, and intellectual property protection and to avoid overly strict regulatory systems to discourage investors. In recent years, the emergence of the medical insurance bargaining system has brought some challenges to the profitability of pharmaceutical companies. The relevant system should be stable and regular so that price reduction negotiations are relatively predictable and provide a relatively stable environment for the marketing and profit of innovative drugs. At the same time, the government should pay close attention to the situation of the innovative drug investment market and make some timely adjustments to some deviations and unreasonable situations in the market. In short, the Chinese government should make multiple predictions about the possible impact of each policy on the investment market and strike a balance between encouraging and regulating the market.

3.2. Entrepreneur

Entrepreneurs should have a cutting-edge vision, a clear understanding of the field of innovative drugs, and precise clinical and market needs. In particular, entrepreneurs should not be biased by the preferences of investment institutions and the gimmicks of new technologies. They should not arbitrarily adjust the direction of R&D to cater to the investment market to obtain financing. When choosing the direction of R&D, enterprises should carefully formulate R&D strategies according to their fields of expertise and cutting-edge scientific research progress and take the success of drugs to clinical practice as the primary goal. In addition, to seize the market and obtain more investment, enterprises should also develop as fast as possible in the chosen field. For each type of innovative drug, generally, only the top three companies in R&D progress are expected to gain the favor of investors and eventually seize the market. Speeding up R&D as much as possible will help reduce future market competition.

3.3. Investment Institution

Investment institutions should avoid risks caused by unreasonable capital allocation by strengthening the layout of the pre-investment track. Innovative drug investment is a high-risk field, and China's innovative drug investment ecology also has the problem of imbalance. The concentration of funds in early projects will lead to increased risks. Investment institutions can carry out a variety of track layouts by studying market trends and establishing extensive partnerships. A diversified investment portfolio can better monitor and control the performance and risk status of each investment variety in the portfolio, adjust the portfolio weight in time, maximize the portfolio performance, and help investment institutions reduce risks. In addition, investment institutions should be more careful to conduct project valuation analysis. Overheated investment projects and projects with inflated valuations should be stopped in time. Finally, good post-investment management, especially formulating a reasonable R&D strategy and capital use plan, can effectively promote investment efficiency.

4. Conclusion

This paper studies the status quo and main problems of China's innovative drug investment market in the last five years through data analysis. Through the analysis, it is found that the current policies related to innovative drugs in China are very favorable, and the innovative drug market is also expanding. However, the scale and frequency of investment and financing of innovative drugs in China have been declining because the investment market has returned to rationality. Among them, the problems of China's innovative drug investment are: the overvaluation of hot projects, improperly allocating funds in the industrial ecosystem, chasing the latest gimmicks without considering the actual needs of the industry, and only pursuing short-term returns rather than long-term investment.

Under such circumstances, the government needs to create a long-term stable environment for the innovative drug investment market and carefully formulate relevant policies to achieve a balance between stimulating the market and regulating the market. Entrepreneurs should choose the direction of R&D according to their areas of expertise combined with cutting-edge scientific research progress rather than adjusting the direction of R&D to cater to the preferences of investment institutions. Investment institutions should reduce risks by strengthening the layout of the pre-investment track and more cautious project valuation analysis.

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