Research on the Path of Chinese Pharmaceutical Enterprises Going Public based on the Comprehensive Registration System

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Abstract. Due to the characteristics of high investment, high risk, and high return in pharmaceutical enterprises, pharmaceutical enterprises have different capital requirements from other industries. At the same time, China's pharmaceutical industry has a late start and rapid development therefore, there are few innovative projects but mainly imitation, leading to characteristics of repetitive production and insufficient stamina, as well as imperfect enterprise systems, and a relative lack of financing channels. With the recent domestic stock issuance registration system, the difficulty in issuing finance for pharmaceutical enterprises is expected to be resolved. This article reviews the financing history of pharmaceutical enterprises in China, compares the characteristics and listing conditions of A-share, Hong Kong share, and US share registration systems, and proposes relevant measures to promote the rapid development of pharmaceutical enterprises in China by using the capital market.

Keywords: Going Public; Comprehensive Registration System; Chinese Pharmaceutical Enterprises; Path.

1. Introduction

1.1. Background

On February 17, 2023, the China Securities Regulatory Commission (CSRC) issued rules related to the comprehensive implementation of the stock issuance registration system, which will be implemented as of the date of promulgation. The comprehensive implementation of the registration system is a major reform involving the overall situation of the capital market. The release and implementation of the comprehensive registration system rules mark the basic finalization of the registration system arrangement, marks the promotion of the registration system to the entire market and various types of public stock issuance, and has a milestone significance in the reform and development process of China's capital market.

1.2. Characteristics of Financing for pharmaceutical enterprises in China

1.2.1. Large demand for funds

The most important aspect of the pharmaceutical industry is the research and development stage. This stage is also the time when the demand for funds is the largest. The high cost of research and development, which involves recovering funds from sales, has led to a large demand for funds in the pharmaceutical industry.

1.2.2. High risk and high profitability

Research and development of new drugs require significant investment in the early stage, but the risk of research results in clinical trials is extremely high, with a new product success rate of almost one in 1000. Risks and benefits coexist, once a company launches a new drug, it will form a new drug in the market. With monopolistic effects, enterprises are also likely to become the leader of similar drugs and obtain high profits.
1.3. Objective

In order to explore the listing path of Chinese pharmaceutical enterprises, this study analyzes the current financing difficulties faced by Chinese pharmaceutical enterprises, compares the characteristics of A-share, US share, and Hong Kong share registration systems and the relevant requirements for stock issuance, and provides a series of suggestions for China's registered capital market to better serve medical and pharmaceutical enterprises.

2. Comparisons between China’s Stock Market and US Stock Market

2.1. The Development of China's Stock Market

In recent years, the level of biomedical research in China has gradually increased, and the degree of industrialization has also increased. In 2014, Professor Fu found by data integration of the biopharmaceutical industry that small scale and rapid growth are the characteristics of current industry development. Compared with mature foreign industries, China's bio-pharmaceutical industry has been invested in innovation to a limited degree [1]. Ding Jiaxi believes that over 80% of the investment strategies deployed by enterprises in the domestic industry are not conducive to long-term development. Research and Development investment is mainly used to improve foreign innovative drugs. Although the cost is low, it is easy to be Substituted thus enterprises on this basis are difficult to upgrade their technology [2].

In order to solve a series of problems in China's pharmaceutical industry, economists have found that the advancement of science and technology is the first key to helping biopharmaceutical enterprises achieve innovative breakthroughs. In addition, the free control of supply and demand in the capital market, the cultivation and support of national policies, and the orderly and benign competition in the industry also help the industry to move forward in twists and turns [3]. Due to the expected instability of Research and Development projects in the biomedical industry, high-intensity and sustained capital investment are needed. Scholars have put forward various methods for financing channels of the industry. In the early stage of industrial development, Rong Zhimei proposed that helping some biomedical companies with high technology content and strong ability of a sustainable operation to obtain funds through "backdoor listing", and venture capital enterprises, should help the biomedical industry [4]. In 2006, Wen Shumei considered that the possibility of cooperation between biotechnology enterprises and pharmaceutical enterprises was through enhancing competitiveness through mergers and acquisitions, integrating resources, and tapping potentials from internal development [5].

On how to help current industries develop rapidly and well through strategic layout, Hao Fengxia believed that the external environment of the manufacturing industry has a key impact on the technical standards of the industry because the external scale and internal demand growth have had a positive impact on the technical standards in this field. Importantly, endogenous demand drives industrial development to a great extent [6]. In 2016, Xia Yan started the supply-side reform policy and put forward the "talent - finance - innovation" three steps strategy, which is the key to solving the national economic problems [7]. In the same year, Tian Xinmin's research found that only by following the supply-side reform policy, delegating power to local governments, and allowing more market forces to freely allocate resources, could new economic growth be stimulated [8].

For more than 30 years since the establishment of the Shanghai Stock Exchange in 1990, China's stock system has gradually changed the concept of legislation and been promoted from the approval system to the registration system. Its essence is to return the right to issue shares from the government to the law, with more emphasis on "formal examination". In the early stages of the development of the securities system, academic research is more in the
On June 13, 2019, the Science and Innovation Board officially opened. The capital market reform research group (2019) believed that innovative enterprises’ capital needs should develop in a "positive pyramid" pattern, and the capital market should be adjusted to the same structure to promote the incubation process and ensure that more innovative companies are listed. The most important thing is to ignite the engine of innovation to drive the development of the national economy with high quality and uniform speed. Zhang Zongxin and Teng Junliang’s (2020) IPO in the A-share market before and after the pilot registration system of the Science and technology innovation board according to the data, the registration system inquiry reform has raised the threshold of inquiry objects, avoided excessive competition of inquiry institutions and improved the IPO pricing efficiency [10].

2.2. The difference between the registration system and the approval system

Under the registration system, securities issuance review agencies only conduct a formal review of registration documents, without making substantive judgments. The securities issuance approval system is the so-called substantive management principle. The auditing authority only makes judgments on the value of the company, which is the dividing standard between the registration system and the approval system.

2.3. The formal review is the most important feature of the registration system

Under the registration system, securities issuance review institutions only conduct a formal review of registration documents, without making substantive judgments. "With information disclosure as the core idea, only checking whether the disclosed content is complete and whether the format meets the requirements, without making value judgments on companies, adhering to the principle of free trade in a market economy, and the registration system also advocates post facto control.". The approval system not only requires administrative agencies to verify and judge the authenticity of the disclosed content but also requires administrative agencies to make judgments on the investment value of the disclosed content and to conduct substantive reviews on whether the issuer meets the issuance conditions. The approval system advocates prior control.

(1) High audit efficiency: Compared with the approval system, the registration system has the advantages of lower issuer costs, higher listing efficiency, less consumption of social resources, and rapid resource allocation functions in the capital market. The audit time is relatively short.

(2) The registration system is mainly subject to formal review by the CSRC and substantive review by intermediary agencies.

(3) The integrity of intermediaries is very important for listed companies. The approval system involves the sharing of substantive review responsibilities between intermediary institutions and the CSRC. The government's audit workload is significant.

2.4. Characteristics of the American Registration System

The US registration system includes two levels:

(1) Registration at the federal level based on formal review results: Established by the Securities Act of 1933 and regulated and enforced by the United States Securities and Exchange Commission (SEC).

(2) Based on the results of the substantive review, register at the state level: Formed before federal regulation, its history can be traced back more than 100 years ago.

2.5. Summary of Characteristics of the US stock market

First, the stock market is an important source of capital for American companies. The relatively stable and normal capital sources of American enterprises can be divided into two categories: internal funds and external funds. If profit and depreciation funds are retained; External funds mainly include loans from various financial institutions and securities financing.

Second, the stock market is the main lever for adjusting the economic structure of the United States. The economic development and structural adjustment of the United States are mainly carried out by
market mechanisms. Restricting the flow of funds through the stock market plays a role in regulating the direction of investment and has a direct or indirect impact on changes in economic structure.

Third, the proportion of institutional investors is high, and the proportion of delisting is high. Currently, the proportion of shares held by residents in the US stock market is around 30% (once as high as 90% in the 1950s), mainly through various means institutions invest, including mutual funds, pension funds, asset management companies, and so on.

2.6. Comparison of stock issuance systems between China and the United States

Compared to the US stock issuance system, the China - Registration System emphasizes information integrity, the current situation of the enterprise, the balance sheet and the income statement. By contrast, the American capital market pays more attention to the future of the enterprise, strict information disclosure requirements and income statements. Furthermore, China - Approval System weighs on strict procedures, while China - Registration System focuses on the ask and answering questions through a discretionary mechanism (Table 1).

Table 1. Differences in stock issuance systems between China and the United States.

<table>
<thead>
<tr>
<th>Angle</th>
<th>U.S. Securities and Exchange Commission</th>
<th>China - Approval System</th>
<th>China - Registration System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information disclosure requirements</td>
<td>Strict and meticulous</td>
<td>Emphasize information integrity</td>
<td>Emphasize information integrity and detail</td>
</tr>
<tr>
<td>Audit focus</td>
<td>Facing the Future of the Enterprise</td>
<td>Emphasize the history and current situation of the enterprise</td>
<td>Emphasize the status quo and future</td>
</tr>
<tr>
<td>Review position</td>
<td>Biased towards investor positions</td>
<td>Bias toward government positions</td>
<td>Biased towards investor positions</td>
</tr>
<tr>
<td>Discretionary space</td>
<td>Greater flexibility and diverse questioning methods</td>
<td>Strict procedures</td>
<td>Ask and answer questions</td>
</tr>
<tr>
<td>Financial Focus</td>
<td>Focus on the income statement</td>
<td>Focus on the balance sheet</td>
<td>Focus on the balance sheet+income statement</td>
</tr>
<tr>
<td>Language readability</td>
<td>Plain language</td>
<td>No specific requirements for readability</td>
<td>Clear and appropriate language and text</td>
</tr>
</tbody>
</table>

Selected from the "Administrative Measures for the Registration of Initial Public Offerings of Stocks" and “NASDAQ Initial Listing Guide”.

3. Financing channels for Chinese pharmaceutical companies in the US stock market, Chinese A-share market, and Hong Kong stock market

3.1. Characteristics of the Hong Kong Stock Exchange

The reform of the listing rules of the Hong Kong Stock Exchange in 2018 is more conducive to the listing of "new economy" enterprises, further increasing the attractiveness of the Hong Kong stock
market. Before 2018, Hong Kong stocks-imposed listing restrictions on companies with unprofitable structures or characteristics such as the same stock with different rights. Some startup companies with different corporate governance and equity structures, as well as some emerging industry companies that have not yet made profits and have huge financing needs to support their research and development investments (such as biopharmaceutical companies), had to go to the United States for financing. However, this situation changed after the reform of the listing system by the Hong Kong Stock Exchange in 2018.

(1) Allowing unprofitable biotech companies to list in Hong Kong: Exempting from other financial requirements based on meeting the following main conditions: 1) possessing at least one core product and having passed the concept stage; 2) Market value greater than HK $1.5 billion; 3) Has been operating in the current field for over 2 years; 4) Working capital can cover at least 125% of the company's costs in the next 12 months; 5) At least one senior investor has provided a certain amount of investment six months before the offering.

(2) Restrictions on the opening up of the same stock with different rights: companies with such equity structures that meet the conventional requirements of other main boards are allowed to list but with the following criteria: 1) they are "innovative companies"; 2) A market value greater than HK $40 billion, or a market value greater than HK $10 billion and a profit of not less than HK $1 billion in the most recent financial year; 3) The voting power of special voting shares shall not exceed 10 times that of general voting shares, and the total voting power of general voting shares shall not be less than 10%(Table 2).

(3) Accepting secondary listing of companies with a business focus in the Greater China region in Hong Kong: The Hong Kong Stock Exchange has established new secondary listing channels for overseas issuers, attracting emerging industry issuers listed on the New York Stock Exchange, Nasdaq, and London Stock Exchange to list in Hong Kong. According to the newly revised "Listing Rules" that came into effect on January 1, 2022, the threshold for secondary listing is further lowered: 1) Greater China issuers with the same shares and the same rights and need not prove to be "innovative industry companies" can also make a secondary listing, that is, noninnovative Greater China issuers who do not adopt different voting power structures can also apply for a secondary listing on the Stock Exchange. 2) To reduce the minimum market value requirement for a secondary listing, an issuer may choose to meet one of the following two criteria: at least HK $3 billion (with a good regulatory compliance record for five full accounting years of listing); Or at least HK $10 billion (with a good regulatory compliance record of at least 2 complete accounting years after listing). Companies with the same stock, different rights, and VIE structure, they can choose to apply for dual primary listing directly, without changing the structure in order to fully comply with the listing rules and guidelines of the Stock Exchange.

(4) Reform of GEM listing rules: Strengthen listing requirements and raise the threshold for transferring to the main board, making the listing requirements of the GEM closer to those of the main board; Positioning the GEM as a market that serves small and medium-sized enterprises independently of the main board.

3.2. Comparison of listing requirements for A-shares, Hong Kong shares, and US shares involved in the Pharmaceutical industry

In order to seek out reasonable financing methods for the pharmaceutical industry, it is necessary to compare the difference in listing requirements for A-shares, Hong Kong shares and US shares. Firstly, A-shares attach importance to the proportion of cumulative Research and Development investment of Chinese pharmaceutical companies, while Hong Kong Stocks pay great attention to large product market space, excellent results of core products in phase II clinical trials and obvious technical advantages (Table 2). In addition, capital companies in the NASDAQ global market value the market capacity and future profit of core products in the pharmaceutical industry (Table 3 and Table 1).
Table 2. Differences of listing requirements for A-shares and Hong Kong shares involved in pharmaceutical industry.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>A share</th>
<th>Hong Kong Stocks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Science and technology innovation board</td>
<td>motherboard</td>
</tr>
<tr>
<td>General enterprise</td>
<td>Standard 1</td>
<td>Profit test</td>
</tr>
<tr>
<td>market value</td>
<td>No less than 1.5 billion yuan</td>
<td>Market value/earnings test</td>
</tr>
<tr>
<td></td>
<td>No less than 4 billion yuan</td>
<td>Market value/earnings/cash flow test</td>
</tr>
<tr>
<td>Profitable level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>operating income</td>
<td>The operating income in the latest year shall not be less than 200 million yuan, and the proportion of cumulative R &amp; D investment in the past three years shall not be less than 15% of the accrued operating income in the past three years</td>
<td>The cumulative profit for the first two years shall not be less than HK $45 million, and the last year shall not be less than HK $35 million (the cumulative profit for three years shall not be less than HK $80 million).</td>
</tr>
<tr>
<td>cash flow</td>
<td></td>
<td>At least HK $500 million in the most recent fiscal year</td>
</tr>
<tr>
<td>other</td>
<td>The main business or product market space is large and has achieved stage results. Enterprises in the pharmaceutical industry should have at least one core product approved for phase II clinical trials, and other enterprises should have obvious technical advantages and meet the corresponding conditions.</td>
<td>Management remains unchanged for at least the first three fiscal years; ownership and control for at least the last audited fiscal year.</td>
</tr>
</tbody>
</table>

Selected from the "Administrative Measures for the Registration of Initial Public Offerings of Stocks", “Nasdaq Initial Listing Guide” and “Listing Rules of the Stock Exchange of Hong Kong".
Table 3. Listing requirements for US shares involved in pharmaceutical industry.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>American stock</th>
<th>NASDAQ</th>
<th>Global market</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Standard 1</td>
<td>Standard 2</td>
</tr>
<tr>
<td>General enterprise</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>market value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>stockholder's equity</td>
<td>Not less than US $15 million</td>
<td>Not less than US $30 million</td>
<td></td>
</tr>
<tr>
<td>Profitable level</td>
<td>During the latest full meeting year or 2 of the last 3 meeting years, the</td>
<td></td>
<td>For the most recent full fiscal year (or 2 of the last three), total assets and total income are not less than $75 million</td>
</tr>
<tr>
<td>operating income</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cash flow</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Selected from the "Administrative Measures for the Registration of Initial Public Offerings of Stocks", "Nasdaq Initial Listing Guide" and “Listing Rules of the Stock Exchange of Hong Kong”.

3.3. Problems in A-share Listing of Chinese pharmaceutical companies

Analysis of the current financing situation of pharmaceutical enterprises in China

3.3.1. There is a widespread funding gap in Chinese pharmaceutical enterprises

The scale of Chinese pharmaceutical enterprises differs greatly from that of foreign pharmaceutical enterprises. The main reason for this phenomenon is that there is a widespread funding gap in Chinese pharmaceutical enterprises, which do not have sufficient funds to research and develop new drugs, leading to enterprises being unable to break through the scaling bottleneck.

3.3.2. The system of pharmaceutical enterprises in China is not perfect, and they are generally faced with financing difficulties.

Corporate financing is generally conducted in the order of internal financing, equity financing, and debt financing. Listed companies can conduct equity financing on the stock market. However, most enterprises are not perfect in terms of system, and various indicators cannot meet the listing conditions, especially the supervision and management mechanism of pharmaceutical enterprises is not perfect. Therefore, most pharmaceutical enterprises mainly rely on bank loans. Banks are very strict in approving loans to pharmaceutical companies. Pharmaceutical companies are unable to raise funds in the capital market or obtain funds from banks due to inadequate systems, resulting in a difficult situation for financing.

3.3.3. Chinese pharmaceutical companies usually have a single research target, leading to serious homogenization of pharmaceutical products and a low investment return rate.

Lots of domestic pharmaceutical companies are focused on the research and development of few disease targets, resulting in excessive investment by venture capital funds, increased investment risk, and low capital return. In the recent decade, CAR-T cell research and development projects have focused on blood tumors and lymphoma, however, solid tumors rarely made breakthroughs. As a result, a large number of funds have been invested in a few tumor targets such as CD19, CD20, and BCMA, resulting in severe product homogeneity [11]. Another monoclonal antibody generic drug targeting PD1/PDL1 is also a competition between more than ten domestic pharmaceutical companies, including Junshi Biological, Xinda Biological, Hengrui Pharmaceutical, Baiji Shenzhen, and Kangfang Biological, and international pharmaceutical companies such as MSD, Bristol-Myers
Squibb, AstraZeneca, Roche, etc[12]. As a result, the actual sales of domestic generic drugs are lower than market expectations, and the investment returns rate has decreased. If we want to reverse this vicious competition, we need to improve from the following three aspects; Firstly, the government needs to establish strict intellectual property protection mechanisms and patent protection laws. Secondly, the country needs to establish a free-market pricing mechanism to ensure a high rate of return for pharmaceutical investment funds, and finally, the country needs to invest heavily in basic scientific research to lay a solid foundation for the early research and development of innovative drugs.

3.4. Solution

3.4.1. The core of the comprehensive registration system is to strengthen information disclosure and comprehensive supervision

Although the registration system may make more adjustments and optimizations in terms of profitability and pricing, it does not mean that there can be room for breach of trust, financial fraud, and fraudulent listing. The registration system will impose stricter requirements on the completeness and accuracy of information disclosure by enterprises.

3.4.2. The penalties imposed by regulatory agencies have been further strengthened

From the perspective of ensuring the steady progress of the reform of the registration system, regulatory agencies are expected to further strengthen comprehensive supervision and strengthen the fight against fraud, counterfeiting, and other violations.

3.4.3. Responsibility of compaction intermediaries

The Chairman of the Securities Regulatory Commission has repeatedly mentioned the responsibilities of intermediary institutions. To promote the reform of the registration system, it is necessary to continue to establish and improve the investor protection system, place greater emphasis on compacting the responsibilities of intermediary institutions, strengthen the role of "gatekeepers" of intermediary institutions, and consolidate the foundation for high-quality development of the capital market.

3.4.4. Strengthen the function of survival of the fittest in the capital market

Implementing a comprehensive registration system and enhancing the pricing ability of the capital market can help the capital market play a good role in optimizing the allocation of resources and the functional mechanism of survival of the fittest, improving the quality of listed companies, and reshaping the ecology of the capital market. Taking the registration system as a guide, comprehensively promoting the reform of all elements and chains of the capital market, including the judicial system, delisting mechanism, market-making system, and multi-level market construction, will further stimulate market vitality and enterprise competitiveness, and will further enhance market vitality. Under the registration system, the function of survival of the fittest in the capital market will be better played, which will better serve the high-quality development of China's economy.

3.4.5. Increase investment in basic scientific research and encourage enterprises to conduct scientific research innovation.

The value of medicine lies in its clinical effectiveness. Only by developing new drugs with intellectual property rights can a company's products become internationally competitive and obtain high profits. Currently, most pharmaceutical companies in China conduct follow-up research, producing ME too or Me better drugs, lacking original innovation. Therefore, it is urgent to encourage original and innovative administrative means.

3.4.6. Strengthen intellectual property protection and take legal measures to protect investors' economic returns.

In the past many years, due to the neglect of intellectual property rights by Chinese people, pharmaceutical companies have shown little interest in the research and development of original
Drugs. These measures have seriously hindered the development of China's pharmaceutical industry. Only by increasing the penalties for plagiarism of intellectual property rights and using legislative measures to protect the economic interests of investors can the rapid development of medicine in China be promoted.

4. Conclusion

It is time to conclude that the comprehensive registration system can play the core role of market mechanisms in company evaluation and resource allocation, facilitating the financing and development of Chinese pharmaceutical companies. In order to give full play to the advantages of the registration system, it is necessary to strengthen supervision over intermediary institutions, and actively encourage pharmaceutical companies to conduct innovative research, strengthen intellectual property protection and legislation, safeguard the economic interests of investors, give play to the survival of the fittest function of the capital market, and promote the rapid development of China's pharmaceutical industry.

Reference