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Biomedical Industry Development in China and Japan: A Comparative Analysis of Strategic Approaches, Industry Characterization, Policies and Expected Development Strategies

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Abstract: With digitalization and globalization, the biomedical industry has become one of the new driving forces of the economy. Especially after the Covid-19 outbreak, the development of the biomedical industry has attracted much attention due to the increased awareness of the crisis and the growing demand for healthcare. China and Japan, as important players in Asia and the world, have made unique contributions to the biomedical industry. Both countries have similarities in aging trends and development potential, but more differences have been shown such as the policy environment and their respective development priorities, which also herald new opportunities and challenges. This paper aims to compare and analyze the status quo, characteristics, and policy environment of the two countries, find out the advantages and disadvantages of each country, analyze the disadvantages and propose reasonable improvement plans. Finally, based on the independent solutions of the two countries, this paper combines the complementary advantages of China and Japan, which is China's high productivity and replication technology with Japan's innovative and management technology, then puts forward a feasible direction for deep cooperation in big data which is of certain guiding significance.

Keywords: Biomedical Industry, Development Status, Industry Characteristics, Policy Environment, Comparative Analysis.

1. Introduction

With the rapid development of the global biomedical industry, the attention is also increasing. The current global biomedical sector focuses on actively developing innovative medicines and policy support, so the healthcare sector has also been emphasized in government work. Countries around the world have increased their attention to the bio-economy, and at the same time have also made strategic deployments in the biomedical industry, such as the introduction of artificial intelligence into innovative research. Among these countries, China and Japan are the two largest economies in Asia and they are playing an increasingly important role.

Both countries are currently facing the challenge of an aging population, with China's aging population (65 years and older) reaching 15.4% in 2023 and Japan's reaching 29.1% in 2022. As

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moderately and severely aging country respectively, the people's personalized demand for biomedical has grown, which has led to an increase in the status of the biomedical industry and an increase in its development potential. As maritime neighbors, China and Japan inevitably need to have trade cooperation, and China is the world's largest producer and exporter of Active Pharmaceutical Ingredients (APIs), which has a large number of exporters to Japan. However, the cooperation between the two sides only stays at a shallow level and does not make good use of their respective advantages, such as China's sufficient raw materials and mature device manufacturing and Japan's advanced research and development (R&D) technology and regulatory system. Therefore, the gaps and differences between the two sides in scientific and technological innovation and industrial complementation are also opportunities for cooperation, so how to strengthen the depth of communication and cooperation between China and Japan to achieve synergies will be explored in this paper.

In this paper, through a comparative study of the current status of biomedical development in China and Japan, the characteristics of their respective industries, and the policy environment, the current shortcomings and improvement measures has been pointed out, so as to effectively promote the development of the industry, improve international competitiveness, promote the growth of economy and trade, then ultimately successfully meet the challenges of global health and contribute to the innovation of the global biomedical industry. In addition, through the research and analysis of biomedical industry topics, the paper also innovatively proposes the possibility of in-depth cooperation in the future to achieve a win-win situation.

2. Description of China’s Biomedical Industry

2.1. Current Development of China's Biomedical Industry

China's biomedical industry is proliferating, with increases in sales, market share, and research and development (R&D) spending, although the overall market scope is still much smaller than that of traditional pharmaceuticals, and there is undeniably a huge potential for the development of the biomedical industry [1]. However, China's lack of awareness of intellectual property rights (IPR) protection and competitiveness compared to biomedical firms in countries other than China is hampering the improvement of R&D efficiency and quality.

With the increase in scale, China has also begun to segment and move closer to the top in vaccines, and a number of biomedical giants have emerged, but the shortcomings are obvious: excessive duplication and lack of concentration of talent due to a high degree of clustering. The disconnect between R&D and industrialization has also led to a lack of specialized talent, which further slows down development progress and may even lead to malicious competition [2].

2.2. Characteristics of China's Biomedical Industry

China's biomedical industry has distinctive characteristics. China started to build on its strengths as early as 30 years ago, constructing an innovation system oriented to “government-led, resource integration, and long-term planning”, and dynamically changing with policy and environmental changes to meet public requirements, and ultimately forming a nationwide industrial cluster [3]. The growth potential of China's biomedical market is huge, with the market size expected to exceed RMB 800 billion by 2025 with an annual growth rate of more than 20%, and China's capabilities in manufacturing, clinical development, and other areas have been assessed to be at a medium level and continue to progress [4]. However, although the innovation system has been constructed, its overall level of network density and frequency of synergy is still not significant, and this is particularly large in the gap between developed and less developed regions. This system, however, will dynamically change in response to changes in policy and environment to meet public demand and eventually form

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a national cluster. In addition to continuous technological innovation, the digital transformation of the biomedical industry is also accelerating, as reflected in the comprehensive and in-depth application of artificial intelligence in biomedical, as well as the direction of next-generation research.

2.3. Public Health Policy and External Environment

The biomedical industry is the first national strategic emerging industry in China and the government has put forward a number of policy recommendations through the development plan, including the establishment of a new drug registration and approval channel to speed up the approval process, policies to encourage the research and development of bio-innovative drugs, and the construction of a support system for talent and financial innovation, and other measures, which have also achieved certain results so far. However, it takes about three years for both new and generic drugs to be approved, so the State Council implemented the marketing authorization holder (MAH) system for drugs, the China Food and Drug Administration (CFDA) also adopted new regulations, all aimed at speeding up the approval process to reduce the difficulty of approval [2].

The cost issue remains acute due to the significant increase in healthcare costs associated with China's aging population. In response to the three major problems: high generic drug prices, high expired patent drug prices and high expired patent drug shares, the government launched a volume-based purchasing (VBP) in 11 cities in 2018, which showed significant price reductions (for example one manufacturer reduced the price of entecavir by 94%). VBP also reduced marketing costs and shifted the focus of research to critical issues such as drug quality [2].

The government is a strong driver of innovation in China's biomedical industry. As a visible hand, the government is gradually shifting its paradigm to a sustainable innovation mechanism by changing its own functions. To improve independent R&D capability, the government is trying to transform from government-driven to market-oriented [3].

3. Description of Japan’s Biomedical Industry

3.1. Current Development of Japan's Biomedical Industry

Japan was a global leader in the biomedical industry during the 1980s, which is thought to have been driven by a highly regulated market and key health policies [5]. Now the leadership position has changed but Japan still remains ahead of most countries, for example, 33 out of 363 new drugs approved in the U.S. between 2011 and 2021 came from Japan [6]. It is estimated that the market size of biomedical will grow by 7.98% in 2024 and over the next eight years. Eight years thereafter, the market size of biomedical in Japan is growing at a rate of 7.98%, which can be considered as a steady growth rate [7]. The growing demand for personalized therapies, including biomarker discovery, pharmacogenomics, and precision medicine, which customizes medicine based on an individual patient's genetics, is a major driver for the market.

Currently, Japan has begun to show weakness in developing innovation due to the three main characteristics of irrational drug prices and strict control of payment rates, insufficient government investment and attention, and relatively weak industry-academia relations, as evidenced by the lack of thriving biotechnology and localized biotechnology systems (with the main investment locations overseas), coupled with an unsupportive attitude of traditional scholarship on innovation, which has resulted in the majority of patented technologies are in the hands of traditional large companies, further hindering the transformation and upgrading of Japan's biomedical industry into the biological field [6].

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3.2. Characteristics of Japan's Biomedical Industry

Japan's biomedical market is relatively small but technology is advanced and focused on innovative drugs and gene therapy. In terms of transformation in the domestic market, against a backdrop of patent expiration and growing generics, coupled with increasing personalization and aging, Japanese biomedical companies are also looking to transform themselves. Including digitally transformation, especially when stimulated by the Covid-19, Japanese biomedical have begun to introduce AI digital technologies in order to increase market growth and improve output efficiency [8].

Japan has a low level of exports, its pharmaceutical trade deficit grew from $2 billion in 2000 to $21.3 billion in 2019 due to its special standards and access restrictions, so domestic companies are largely uncompetitive in the international market [5]. In addition, Japan's innovation system is based on the “in-house development principle,” and the system provides a comprehensive model of health care by integrating traditional and modern medical practices, with a special focus on the elderly population, and is an example of what can be achieved in primary health care. But also severely hampers the transition between academia, industry, and capital, and the weak industry-academia linkage leads to low mobility of researchers and insufficient venture capital, leaving Japan's funding budgets lagging far behind those of comparable countries, which undoubtedly limits its biomedical entrepreneurship [5]. Japan's weakness in entrepreneurship is also a testament to the irrationality of the current system (basically all innovations come from traditional firms), which has led to a large portion of investment going to traditional firms rather than to new firms with innovative potential.

3.3. Public Health Policy and External Environment

The irrationality of the previous policy and the changes in the existing population (aging) and disease structure also make policy change a necessity. Japan launched its 2030 Bioeconomy Strategy in 2023, and as an important part of it, the biomedical industry has also proposed a three-step strategy: research, technological innovation, and commercial viability [9]. Among other things, in response to the over-controls arising from the Drug Pricing Standard (DPS), Japan introduced the Price Maintenance Premium (PMP) program in 2010 to create a stable and reliable pricing strategy. This accelerated cost recovery and a new round of R&D investment, even if the new pricing rules do not currently solve the problem of low research incentives [5]. In addition, Japan has utilized the three pillars of sustainable resources, biotechnology innovation, and leadership in the global bioeconomy to guide the country's sustainability process, strategically aligning biomedical, environmental sustainability, and economic development.

However, effective solutions have yet to be found to the problems of insufficient investment in R&D and incentives, regulatory delays such as drug lags, policy incoherence like Japan's attempts to address social security issues and the sustainability of innovative medicines by lowering the price of medicines [5].

4. Comparison of Chinese and Japanese Biomedical Industries

4.1. Comparison of Industrial Development, Characteristics and Policy

4.1.1. Advantages of China

China is now well ahead of Japan in terms of market size, which is $75.679 billion in 2022 for China and $24.2 billion in 2023 for Japan, and has a significant advantage in terms of growth potential due to a higher market growth rate than Japan [10]. In addition, China's biomedical are catching up with Japan’s developing early-stage innovative drugs, especially in the number of clinical trial activities and new drug development. China's market growth rate is increasing steadily, with a compound

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annual rate of over 20%. In addition, the Chinese government is encouraging companies to innovate, expand, and internationalize. It has also introduced a series of policies to support this, as well as an innovation system that is more in line with current developments.

4.1.2. Weakness of China

China's biomedical industry is currently characterized by talent shortages and fragmentation, with significant disparities across regions (developed and undeveloped). Due to China's serious aging problem, healthcare costs have also remained high, coupled with a lack of market orientation due to over-reliance on government decision-making, there has been a lack of motivation to pursue profits [3]. This is also reflected in the lack of upstream innovation capacity and weak innovation value chain capabilities. At the international level, China's biomedical has not yet adapted to overseas regulatory systems and data disclosure requirements, making it more difficult to enter overseas markets. This has led to increased difficulty in overseas market access [11].

4.1.3. Advantages of Japan

Japan already has a mature market, ranking third globally in the pharmaceutical market. Its biomedical technology is still in the world's leading position, derive benefit from its strong regulatory and health policies, a steadily growing market that is smaller than China's, and rich experience as well as unique advantages in the combination of traditional and modern medicine and pharmacogenomics.

4.1.4. Weakness of Japan

Japan's incoherent policies have led to excessive control over pricing and payment, and a combination of lack of investment in R&D and weak industry-academia relationships have resulted in insufficient incentives for innovative medicines. Japan's large corporate and academic traditions have a negative attitude toward new ventures, resulting in patents and investment funds being largely in the hands of traditional large corporations, further reducing innovation.

4.2. Feasible Recommendations for China and Japan

4.2.1. Analysis and Recommendations for China

The most important is to ensure the supply and concentration of talented people, which can be achieved by strengthening university-enterprise cooperation to increase industry-academia linkages. Through international exchanges, policy tilts and subsidies to ensure that talents can return to the country based on adequate learning of advanced technologies, and a more targeted knowledge of overseas regulation and data disclosure. Industry demand as the core driving force of the biomedical industry, should be the core to accurately position the direction of talent training, the focus of talent training on the cultivation of practical and innovative capabilities, such as participation in industry-university research or scientific research projects. Furthermore, it is also crucial to strengthen faculty construction and improve the quality assurance system in the resource-poor central and western regions [12]. The government should incentivize collaborative innovation between hospitals and enterprises to break through the limitations of low connectivity and strengthen collaborative innovation networks. Finally, when learning from Japan, government is able to set up health policies that encourages researchers and companies then link finance and biomedicine to achieve commercial viability.

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4.2.2. Analysis and Recommendations for Japan

A cost-effectiveness analysis of innovative medicines could be conducted through stakeholder participation, linking policy to finance and giving more autonomy to firms so that a clear and enforced industrial policy (partial disclosure of patented technologies, preference guiding of investments) could be established, which may improve the competitiveness of potential new firms as well as to mitigate policy incoherence.

5. Conclusion

In conclusion, a comparative analysis of the biomedical industries of China and Japan shows that both countries have their unique endowment of advantageous elements and deficiencies. China has shown great potential in both generic and innovative drug markets. The rising demand for personalized therapies from a large population base and the aging population are driving the rapid growth of the biomedical market. However, the lack of human resources, weak regulation, sluggish innovation, and insufficient awareness of intellectual property rights are obstacles that must be addressed. As a country with a mature biomedical market, has excelled in R&D infrastructure and original drugs, Japan's technological advantage is still evident even though it is no longer the leader. However, Japan is also facing problems such as excessive price control, insufficient funding, and regulatory delays due to policy incoherence, it is crucial to set up new policies and strategies for the future to address these problems.

International cooperation is essential for both two countries to strengthen global competitiveness based on the solution of national problems. The strengths can be fully utilized to strengthen industry-academia cooperation and promote innovation and technology transfer. This allows synergies effect to be realized by combining China's high productivity and replication technology with Japan's innovative management technology.

To promote cooperation and enhance the competitiveness of both countries in the field of biomedical, it is important to capitalize on the strengths of each country. The two countries can create a synergistic partnership that will benefit their biomedical industries. Continued dialogue and cooperation in research, development, and market access will be critical to meeting the evolving healthcare needs of the people of both countries and achieving sustainable growth in the global biomedical sector. In the context of increased competition between China and Japan, through the new Third Party Market Collaboration (TPMC), the two countries can reduce competition and achieve common goals and mutual benefits.

In addition to this, improvements and cooperation between China and Japan in biomedical research, development, and market access can be a powerful catalyst for meeting the growing needs of the people of both countries and for sustainable global biomedical growth.

In addition, the results of this study will facilitate the improvement and cooperation between China and Japan in biomedical research, development and market access, which will help to promote and meet the growing needs of the people of both countries and ultimately contribute to the sustainable development of biomedicine globally. However, due to the limitation of data timeliness, policy changes and the uncertainty of technological development, the current study is only a reasonable analysis and prediction of the current status quo. The further study will be combined with more accurate and authoritative data, as well as the introduction of big data models and economics and finance-related content to conduct more in-depth analysis in the future.

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