

Study on Sustainable China's Pharmaceutical Innovation Ecosystem

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Abstract. In recent years, China's pharmaceutical innovation has achieved remarkable results, with strong growth in innovative drug development driven by policy, talent, and investment. Through more than 20 years of development, China has initially established a relatively complete drug regulatory system of laws and regulations. At the same time, China's pharmaceutical innovation is also facing many challenges, including policy, talent, and investment. However, compared to the world's leading countries, there is still a gap in the quality of innovation in China's currently marketed pharmaceutical innovation ecosystem. By implementing the concept of scientific and risk-based assessment, this paper provides a comprehensive analysis of the current state of China's pharmaceutical innovation ecosystem and proposes future directions for development, including improving laws, regulations, policies, and technical guidelines promptly; improving the review decision-making mechanism and priority review mechanism to encourage the review of innovative drugs; optimising the organisational structure, approval process and resource allocation of regulatory bodies in a demand-driven manner to shorten the review time; and strengthening the clinical data.

Keywords: China's Pharmaceutical Innovation; Sustainable Innovation Ecosystem; Policy, Talent, and Investment; Quality Control.

1. Introduction

Chinese innovation-driven development is the core strategy of the country's 13th Five-Year Plan, and the pharmaceutical industry is one of the pillar industries for innovation. Pharmaceutical innovation not only provides a long-term impetus for economic development but also is a fundamental requirement for solving people's livelihood problems. A viable and competitive pharmaceutical innovation industry must come from a sustainable cycle of the innovation ecosystem throughout the world. Due to the special attributes of pharmaceutical innovation, such as long cycles, high risks and large investments, three elements of policy, technical capacity and investment are indispensable in the ecosystem and influence each other (Chohra. 2019). The political environment is a core element of the ecosystem. Policies that encourage innovation to ensure that market mechanisms work well and facilitate a steady flow of capital investment and technical capacity to translate science and technology into innovative products. In China, the pharmaceutical innovation ecosystem is taking shape nowadays. Over the past two years, there have been significant improvements in policy, technical capacity, and investment with an initial virtuous circle between the three elements (Clavis Nwehfor Fubah, & Menisha Moos. 2022). Benefiting from the improved policy environment, especially the reform of the drug approval system, the accelerated influx of private capital, and the gathering of high-level industrial talent, China's biopharmaceutical industry has a good momentum for innovation. In the next ten to twenty years, the key to enhancing the value of pharmaceutical innovation to economic development and people's livelihood is to build a sustainable development strategy.

Against this backdrop, four pharmaceutical industry associations have conducted research on pharmaceutical research and development (R&D) in China to promote the development of China's

pharmaceutical innovation industry, and have produced a thematic report to provide a reference and reference for promoting related efforts (D'Amato, et al 2020). Based on the framework of the pharmaceutical innovation ecosystem, this paper examines the current status and trends of China's R&D in the context of the global R&D landscape. It focuses on the development goals of China's pharmaceutical innovation industry in the next ten to twenty years and identifies the barriers to current innovation in various segments of the industry chain including top-level design, basic research, clinical research, regulatory approval, payment, and procurement, and intellectual property protection. The paper will also provide insights into the specific practices and capabilities of other countries in improving their R&D ecosystems, learning about the specific practices and outcomes adopted by other countries in improving their R&D ecosystems, and informing China's practices. Specific recommendations are given for building a sustainable pharmaceutical innovation ecosystem (Birch, et al. 2012) at the end of the paper.

2. Review of the Current Status of Pharmaceutical Innovation in China

Pharmaceutical innovation requires an ecosystem in which the three elements of policy, technical capacity, and investment work together to encourage the innovation work, active investment from multiple sources of capital as well as extensive collaboration, and professional technical capacity. After the efforts made during the 12th Five-Year Plan period, China has initially formed a virtuous cycle of the pharmaceutical innovation ecosystem, and the biopharmaceutical industry has obtained a good momentum of innovation (Ding. 2018).

2.1 Policy, Talent, and Investment Act as Key Innovative Factors

2.1.1 Policy

The policy environment continues to be optimised and the new round of pharmaceutical review reform is beginning to bear fruit (Festa, et al 2021). The policy environment for pharmaceutical innovation development has improved significantly over the past year, with the State Food and Drug Administration (SFDA) introducing a series of policy measures to vigorously promote the reform of the review and approval system. It has had a positive and far-reaching impact on the pharmaceutical industry, including

Encouraging pharmaceutical innovation: It requests a launch of a pilot marketing licensee system (MAH) to encourage research institutions and personnel to carry out pharmaceutical R&D as well as the set up domestic clinical trial institutions to participate in international multi-centre clinical trials. Such data from trials that meet the requirements can be used in registration applications.

Optimising the review mechanism: This requests a priority review and approval system for drugs to encourage the development of innovative drugs and drugs with significant clinical value. Besides, issuing the management measures on communication and exchange between drug development and technical review may also contribute to the establishment of an expert advisory committee system which assist in validating relevant topics and providing expert advice and guidance.

Enhance technical capacity: The cooperation with APEC and Peking University to establish the APEC Centre of Excellence in Regulatory Science at Peking University to promote regulatory science research has already obtained significant output in the aspect of new drug development. Moreover, the active engagement in exchanges and cooperation with international regulatory bodies may also enhance the technical capacity and align with international standards.

Improve review efficiency: It requests to increase the overall technical capabilities of the pharmacovigilance centre by expanding its team of reviewers, speeding up the review process, and actively addressing the backlog of drug clinical and marketing applications.

Improve the quality of drugs: Carrying out self-inspection and verification of clinical trial data to ensure the quality of clinical trial data is also another important aspect. The quality of generic drugs will be able to improve through consistency evaluation.

2.1.2 Talent

In terms of innovative talents, overseas talents and scholars from top universities in China have been driven by the group effect to invest in the construction of start-ups. The Thousand Talents Programme has attracted more than 6,000 high-level innovative and entrepreneurial talents back to China since its official launch in 2009, and the growth rate is significant, with 20% of them being entrepreneurial talents (Fu, et al 2022). As more and more top foreign scientists return to China, a large number of global leading technologies are being introduced and cross-border companies are also being established. The cumulative effect of talent introduction is gradually emerging. Hence, the overall ability of innovative talents has also improved significantly, which has already been reflected in the ability to raise funds, team management, knowledge of laws and regulations, and the ability to collaborate with industry, mastery of laws and regulations, etc.

2.1.3 Investment

The influx of private investment into the biopharmaceutical sector has accelerated in recent years due to the improved policy environment (Harada, et al 2021). The number of venture capital investments and deals in the life sciences sector has been growing at a rapid pace since 2011, with a 73% increase in 2014. It has seen continued momentum in the biopharmaceutical sector in 2016, with investment in the first half of the year alone increasing by nearly 50% compared to the full year of 2015, and is expected to double in value for the next year. Tianyin Pharmaceuticals received US\$28 million. The growth of private capital investment has reduced the difficulty of raising capital, resulting in rapid growth in the number of start-ups and the volume of financing. Other than that, in recent years, biotech parks have also flourished nationwide, providing biopharmaceutical start-ups with a good software and hardware environment for development.

In the past two years, the number of biopharmaceutical start-ups in the parks has been growing rapidly, especially in some major technology parks such as Wuhan Optics Valley and Chengdu High-Tech Zone. This rapid growth is actually driven by a combination of talent in the parks and a growing number of biopharmaceutical companies. The universities in close proximity to the park are also able to provide talent and technical support for the development of enterprises. The large pharmaceutical companies located in the same park also play a leading role in terms of technology and management experience, and the pharmaceutical companies play a leading role in terms of technology and management experience. Besides, the drug regulatory authorities have piloted a direct presence in the park to provide regulatory training and direct services to the start-ups. The local government's policy and financial support will provide the inexhaustible impetus for the healthy development of start-ups (Almaainah. 2021).

2.2 Quantity and Quality of China's Pharmaceutical Innovation Output

2.2.1 Quantity Increment

According to the Nature journal index record, the number of articles that were published in high-quality life science journals in China has increased from 4,000 to over 6,500 from the 2012 to the 2015. China is in the second position which follows the heel of US, and it has already been ahead of many other traditionally developed countries. International patent applications for drugs rose from 756 in 2011 to 968 in 2015. The number of innovative drugs entering the clinical phase grew from 21 in 2011 to 69 in 2015, with the number of compounds in development reaching 656, auguring strong growth in the coming years. The number of new Class 1 drugs which get awarded of relative certificates during the 12th Five-Year Plan period has already reached 17, approximately five times the number in the 50 years since the founding of the country.

2.2.2 Quality Increment

Compared to the world's leading countries, there is still a gap in the "quality" of China's currently marketed innovative drugs, which is reflected in the lack of originality of the new drugs as well as limited clinical value. And most of the new drugs have not yet fully entered the international market.

Due to limited R&D capabilities, the majority of new drugs currently on the market and under development in China are improvements on known drug targets and mechanisms of action. In contrast, of the 66 new molecular entities approved in the US from 2012 to 2014, nearly half were breakthrough innovations based on new targets or technology platforms. Of the 19 new chemical drugs first marketed in China in the last decade from 2007 to 2015, no new drugs have yet been marketed in ICH member countries (including the US, Europe and Japan), and only three varieties are in clinical trials. In comparison, up to 85% of the innovative drugs first marketed in the US were approved in Europe or Japan, and Japan debuted 25% of its new drugs globally. The internationalisation of China's innovative drug industry is gradually increasing, with the emergence of many innovative pharmaceutical companies with strength and international vision that are beginning to locate overseas and conduct clinical development. In addition, technology transfer and collaboration with foreign companies are becoming an important source of pharmaceutical innovation in China. Among all the 64 Class 1.1 drug molecular entities that applied for clinical trials in 2015, 13 were developed by Chinese companies that acquired development rights from abroad or co-developed with multinational pharmaceutical companies, and 2 were new drugs developed by multinational pharmaceutical companies in China. Addressing unmet clinical needs is the fundamental purpose of drug development. In recent years, Chinese companies have also increased their focus on the clinical value of drugs in the R&D process, demonstrating a clinical value-based drug development strategy. For example, Etaan (Apatinib), a small-molecule targeted drug for advanced gastric cancer, which was developed by Hengrui and launched in December 2014, provides a new treatment option for the majority of advanced gastric cancer patients in China. In addition to large pharmaceutical companies, many start-ups have also targeted the medical needs of Chinese and global patient populations, such as the development of novel treatments for type 2 diabetes by Hualin Pharmaceuticals, oral treatment options for hepatitis C by Gloria Pharmaceuticals, and new drugs for advanced lung cancer and many other cancers by Baekje Shenzhou. All these cases show that innovative drug development in China is increasingly focused on the clinical value of the drugs themselves.

3. Why does China Need to Develop Pharmaceutical Innovation?

3.1 The Importance of Pharmaceutical Innovation

The fundamental aim of pharmaceutical innovation is to improve the health of the nation, and there is still a huge unmet medical need in China. China has a large population base and has a different disease spectrum from that of Europe and the US, such as liver cancer (e.g. 420,000 deaths from liver cancer in China each year), stomach cancer, and hepatitis B, which are seriously endangering the nation's health. Besides, China also has had a high incidence rate and accounts for a significant proportion of the total number of patients worldwide. These diseases lack innovative drugs and are becoming the main focus of pharmaceutical R&D in Europe and the US. China has a large patient base, and with an ageing population, changing lifestyles and environmental changes, the number of patients will continuously increase, including some chronic and serious diseases such as diabetes and cardiovascular diseases. With an ageing population, changing lifestyles and environmental changes, the number of patients is increasing every year and the economic burden is increasing. Innovation in these disease areas shall be unlocked. In addition, as the economy develops and income levels rise, some patients with financial means are no longer satisfied with the access to basic medical care only, but are eager to be the first to use the world's most advanced treatment. The availability of innovative medicines in China At present, the accessibility of innovative medicines in China does not meet the health needs of the public. The gap between patients' escalating medical needs and the domestic supply of innovative medicines is highlighted by phenomena such as overseas medical treatment and illegal drug substitution.

3.2 China Contributes Less Than 5% to Global Pharmaceutical Innovation

When measuring a country's overall level of pharmaceutical R&D and its contribution to innovation, two indicators are normally analysed: the number of products in development and the number of first-to-market new drugs worldwide. The number of products in development refers to the number of molecules with preclinical, clinical phase I-III and market registration status at the end of 2015, categorised by the country where the R&D company is based. The number of global first-to-market new drugs refers to the number of new molecular entities marketed from 2007 to 2015 that made their debut in a particular country. Using this as a criterion, the world's major pharmaceutical R&D countries can be broadly classified into three echelons according to their contribution to innovation: the first echelon is the United States, which is in a distant lead and accounts for about half of the global innovation contribution; the second echelon includes pharmaceutical powerhouses such as Japan, the United Kingdom, Germany and Switzerland, with an innovation contribution of about 5-10%, which have a good drug R&D base and are striving to become global or regional innovation hubs; many countries, including some countries, including China, are in the third tier, contributing less than 5%. Among other countries in the same echelon as China, some still are taking a generic-based pharmaceutical strategy (e.g. India), while others are focusing on pharmaceutical R&D and aiming to reach global leadership in some areas (e.g. South Korea and Israel) (Hui, et al 2020). China, on the other hand, aspires to be a world power in science and technology innovation and to become a major scientific centre and innovation hub in the world. The vision of China's pharmaceutical innovation industry moving towards the second and first echelons inevitably places higher demands on the construction of innovation ecosystems. higher requirements.

4. Profound Challenges in the Drug Discovery Phase

Success in the basic research and drug discovery segments is necessary to achieve breakthrough original innovations. The emergence of original innovation requires a long-term investment in basic research and the accumulation of extensive work to gain an understanding of disease mechanisms and drug targets that can be used to guide the development of innovative therapies (Jennifer Markarian. 2020).

Basic research is the foundation of industrial innovation, but basic research is inherently open and uncertain, and this stage is usually supported by long-term and sustained government funding. This phase is often supported by long-term and sustained government research funding. Then, starting with early drug discovery, industry and venture capital (Ahmed, et al 2021). The key role of government in this process is not only to provide direct funding, but also to establish a mechanism that can catalyse private capital investment and accelerate technology transfer, thereby facilitating a specialised and efficient innovation chain. While basic research and drug discovery are not the most significant constraints on the development of innovative medicines in China in the short term, they are critical to the industry's long-term development. The success of basic research and drug discovery requires a strong talent pool, adequate research funding, a well-developed technology exchange market and a translational infrastructure. China still faces several challenges in the following areas.

4.1 Pharmaceutical Industry Still Lacks Experienced Industrial Leaders

In the academic community, China's high-level research talent programme has achieved remarkable results. On the one hand, more than 30,000 PhD students in science and engineering have been graduating locally each year; on the other hand, the national talent programme is accelerating the return of talented people from overseas, and the overall quality of the researchers returning to China has improved significantly in recent years. However, although there are now a few talented people in academia who are capable of leading breakthrough innovations, they are not yet large in number (Ma, et al 2019). A large number of researchers are engaged in research that is not sufficiently original, mostly following international frontier hotspots, to drive far-reaching innovations. Also, due to the relatively short history of innovative drug development, the industry still lacks leading talents

with a track record of successful drug development. Returnees are usually only experts in one part of the new and always lack end-to-end successful experience in the development of innovative medicines.

4.2 Low Proportion of National Investment in The Basic Research Phase

The total and percentage of gross domestic product (GDP) invested in R&D (including basic research, applied research and experimentation) is used as an indicator of the intensity of a country's investment in innovation. China's total R&D investment (including pharmaceutical and non-pharmaceutical sectors) ranked second in the world in 2014, behind only the US. However, the proportion of basic research funding for all R&D investments in China is low at around 5%, lower than the 18% in the US, 16% in the UK, and 12% in Japan (Rosendal, 2006). Current R&D investment in China is more skewed towards applied research. Moreover, the government intervenes too much administratively in the allocation of research funds, often setting strict criteria and conditions, and in the biological, some funds in the biomedical sector are even earmarked for research on specific targets, which is not conducive to encouraging innovative results. This is not conducive to encouraging the production of innovative results. In addition, the composition of expert committees is still dominated by experts from academic institutions and universities. In addition, the composition of expert committees is still dominated by experts from academic institutions and universities, and there is a lack of participation from pharmaceutical industry experts and investment professionals who have participated in the development of new drugs.

4.3 Imperfect Technology Transfer System Hinders Technology Flow and Transformation

China still lacks a sound technology trading market and a phased return mechanism. Universities and academic institutions usually do not set up technology transfer offices. The technology transfer offices in universities and academic institutions do not usually set up technology transfer offices, and the support for researchers in terms of intellectual property protection, evaluation and related legal and commercial procedures involved in the process of technology transfer is weak. Support for researchers in the process of technology transfer is weak. In addition, administrative approvals also hinder the granting of patents and the transformation of results. Under the job invention Under the regulations, the intellectual property rights obtained from government-funded university research projects are owned by the research project's undertaking unit. However, in terms of the disposal of intellectual property rights, the university, as the owner of the intellectual property rights, is the owner (Aguilar, et al. 2019). However, in the disposal of intellectual property rights, universities, as owners of intellectual property rights, are still subject to the intervention of administrative approvals, such as the financial department, and lack the autonomy to transform their achievements. They lack the autonomy to transform the results.

4.4 Infrastructure and Capital Investment to Support The Transformation of Results Needs Re-Adjust

The current mode of support for start-ups in industrial parks and start-up incubators around the world is still relatively homogeneous. Supported and encouraged by policies, over 100 technology industrial parks and start-up incubators have been established across the country (Saneja, et al 2020). However, a significant number of them just provide low value-added services and support, only providing office and laboratory space but lacking key professional guidance in the early stages of a start-up's development (e.g. technology development, business cooperation, legal and taxation). For private capital, the biggest bottleneck is the single exit model. Domestic RMB funds typically have a 3-5 year investment horizon, and the current lengthy regulatory approval process coupled with the requirement for three consecutive years of profitability before IPO financing makes it impossible to invest in early-stage R&D of innovative medicines and exit within the required time frame, and only for very late-stage projects. In addition, the ability of VCs to assess high-risk early-stage R&D

projects still needs to be improved, and there is still a lack of experienced talent in China to evaluate early-stage R&D projects.

5. Recommendations for China's Pharmaceutical Innovation

The pharmaceutical innovation industry chain is complex, with a highly detailed division of labour and a wide range of subjects involved. A viable and competitive pharmaceutical innovation industry must come from a healthy and virtuous cycle of pharmaceutical innovation ecosystem (Wadovski, et al 2020). First of all, the research and development of innovative medicines involve several ministries and regulatory bodies, covering regulation, health, health insurance, finance and taxation, scientific research and other aspects. The top-level design at the national level is crucial. Secondly, all aspects of the R&D chain, including basic research and drug discovery, clinical research, regulatory review and procurement and payment, need to be supported by scientific concepts, sound policies and mechanisms, and the technical capacity of all parties involved. Intellectual property protection and capital investment mechanisms are essential across all parts of the chain.

All major pharmaceutical R&D countries have a top-level design to guide the development and innovation of the pharmaceutical industry. The traditional technological pharmaceutical powerhouses, represented by the United States, have focused on optimising the regulatory process and policy environment to enable their innovations to reach the market as quickly as possible to benefit patients and create value. For latecomer countries such as Japan, South Korea and Israel, the focus is not only on promoting domestic innovation, but also on lowering policy barriers, making the latest global medicines available to their citizens as soon as possible through an internationalisation strategy, and bringing domestic products to international markets. A key mechanism in the development of top-level design is how to incorporate the views of multiple parties, including business, academia and government departments, to develop practical policies that encourage innovation. For example, the US Presidential Science and Technology Advisory Council formed during the Clinton administration and the UK Life Sciences Advisory Council both bring together leading experts from relevant industries to regularly advise on national pharmaceutical development. In the US, the FDA has established a Scientific Committee, which brings together experts from government, industry and academia to provide expert advice to the FDA on complex scientific and technological issues and cutting-edge scientific developments, ensuring that regulation keeps pace with technological development.

China, as a large country, faces complex and daunting issues in healthcare and medicine, and the goals pursued are diverse. The decision making and resolution of these issues often involve several government departments, including at the central level the Health and Welfare Commission, the General Administration of Food and Drug Administration, the Development and Reform Commission, the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology, the Ministry of Science and Technology, the Ministry of Finance and the Insurance Regulatory Commission (Yao, et al 2021). Moreover, China's current pharmaceutical policy system is still mainly based on the generic drug landscape. In order to restructure the industry and upgrade from generic production to innovation-driven, top-level design and strategic planning are needed at the national level to promote the change of concept and the establishment of a better system.

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