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Development Strategy for Medical Devices and New Wearable Medical Devices

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Abstract: China is facing great difficulties and challenges in its quest to transition from the low to the high end of the medical devices industry. In the burgeoning field of new wearable medical devices, China has encountered many opportunities to catch up with the leaders in the field, despite the persistent challenges. The Chinese Academy of Engineering recently organized a major advisory project called the "Development Strategy for National Health Promotion and Medical and Healthcare Undertakings in China." The "Development Strategy for Medical Devices and New Wearable Medical Devices" is one of the eight key subjects in this project. As a result, in this study, we systematically analyzed the medical device research and assessed the requirements, characteristics, focus, and politics of this field. This paper reports the results of the project on medical device and new wearable medical device research. The paper includes suggestions and proposals to clarify critical issues affecting the development of wearable medical devices.

Keywords: medical devices; industry analysis; wearable medical devices; development strategies

1 Introduction

The field of global medical equipment and devices has witnessed an explosive development trend with a continuously expanding market size over the past few decades. According to the statistics from Evaluate MedTech, the global market sale of medical devices in 2015 reached 390.3 billion USD [1]. China has developed its own medical device market, and the sales increased from 53.5 billion CNY in 2007 to 308 billion CNY in 2015, a nearly six-fold increase, with a compound annual growth rate of 17.01% from 2010 to 2015 [2].

China's medical device industry started relatively late but has grown quickly and entered a high-speed growth track. However, large-scale medical devices are predominantly imported, which has been the case for a long time, as domestic enterprises have developed slowly and still lack the required technology and product innovation. China's medical device industry currently has more manufacturing enterprises than research and development companies and lacks core technologies. As a result, it offers few original technologies and products. Furthermore, a few multinational companies completely monopolize the high-end diagnosis and treatment device market in China.

The field of medical devices has a profound effect on the national economy and individuals' livelihood, and has a huge potential. Thus, it is necessary to urgently clarify the status quo of China's medical device industry and its key problems, requirements, and existing advantages, and the characteristics of its development process. Furthermore, implementation of strategic planning is also important for long-term development by combining China's institutional advantages, market advantages, and multidisciplinary joint research to ensure that China's medical devices break the import monopoly, form a new strategic industry, and enter the world arena.

This research reports the status quo, bottlenecks, countermeasures, and development strategies for China's medical device and new wearable medical device industries, with respect to innovation, industrial transformation, policies, and laws and regulations, providing vital decision support to the associated

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national departments. The main contents of this report can be divided into four aspects, namely the significance of the research background, status quo of the medical device and new wearable medical device industries in both China and abroad, existing problems in the medical device industry, and countermeasures and suggestions.

2 Research status and trends in the medical device and new wearable medical device industry in China and overseas

All the countries worldwide, especially the developed countries, place a high emphasis on the medical device industry, with rapid growth in total market sales. The compound annual growth rate for global sales of medical devices was 1.90% from 2011 to 2015 [1]. Looking at the global medical device market, it is apparent that the United States, Western Europe, and Japan hold absolute advantages. For example, the United States occupies the leading position in the medical device industry.

Large-scale medical device enterprises worldwide are adjusting their development strategies to address the following three aspects. First, with respect to research and development, they aim to upgrade similar products, expand product lines (especially high value-added products), develop high-tech innovative products, and research and develop localized products for low-end markets. Second, with respect to the trend of mergers and acquisitions, they are looking for opportunities to integrate similar product resources, expand product lines, and develop the global market [3]. Foreign-funded medical device enterprises in China have also started to expand from high-end products to mid- and low-end products to seize this sizeable market share. Finally, the development of this industry in the United States and European Union countries is mainly fueled by the integration pattern, including cooperation and communication among scientific research institutes, government departments, enterprises, large-scale hospitals, medical and health entities, and other related departments, with a focus on the cooperation between large-scale enterprises and small- and medium-sized professional biotechnology companies. This will continue to play an important role in the future.

The biomedical engineering industry, marked by medical devices, started relatively late but has grown rapidly and stepped into an overall high-speed growth phase. The growth rate of China's medical device market is much higher than the global growth rate. China can currently manufacture medical devices under 47 major categories with more than 3500 varieties and more than 12 000 specifications to meet the needs of disease diagnosis and treatment in China [4,5]. However, there is still a large gap between China and the developed countries, primarily in the following aspects. China still has an insufficient innovative ability in medical device research and development. More than 90% of the enterprises in China are within the manufacturing sector. Few research and development-oriented companies are strong enough to develop core technologies, which lead to the lack of original technologies and original products. Although the number of patents in the field of medical devices has increased rapidly, the number of patents focused on original core technologies is relatively small. The number of low-end products being produced has increased; key components are predominantly imported, and high-end products consist mainly of imitations and improvements of the existing products [6]. Furthermore, the medical device industry in China has a relatively low concentration; more than 12 000 medical device enterprises have a total annual industrial output value exceeding 60 billion CNY. However, none of these are influential and leading enterprises, and industrial innovation and development are restricted because of the disparity in product registration, pricing, bidding, supervision, and other aspects [7,8].

On the basis of research on the present situation and the trend of the development of the medical device industry in China and overseas, the research was focused on the following five key fields: biomedical imaging devices, medical test devices and reagents, rehabilitation devices, tissue engineering, and wearable medical devices. Based on investigation and analysis data, development in the above-mentioned fields over the next few years will have the following characteristics. The field of high-end medical imaging diagnosis and treatment devices will develop toward producing faster, more accurate, safer, and more integrated devices. Innovation and mergers and acquisitions in the field of medical test devices will primarily focus on in vitro diagnostics, whereas immune diagnostics will replace biochemical diagnostics in the mainstream market. In vitro diagnostics will develop in two directions, namely efficient, highly integrated, and automatic diagnostics; and simple, fast bedside, and family-based detections. The field of rehabilitation devices, which is one of the most rapidly developing industrial sectors worldwide, is undergoing a transition based on network, information, automation, intelligence, and human-computer interactions. Tissue engineering and regenerative medicine technology are among the most advanced biotechnology sectors worldwide. The core development direction will be three-dimensional biological printing technology, whole-tissue decellularization technology, and minimally invasive injectable microtissue therapy technology [9].

Wearable medical devices, as both a new technology and an industrial field, are of immense significance and developing rapidly. This field is both an opportunity and a challenge for China. With further development in wearable and portable testing systems, health examinations will be personalized and standardized in the future. Recent breakthroughs in core technologies are expected to energize the market beyond expectations. Here, we take the wearable, sleeveless real-time continuous blood pressure monitoring device as an example. As a large proportion of the population in China currently have hypertension, cardio-

vascular, and cerebrovascular diseases, this device will have a market share that exceeds 10 billion CNY. The development of flexible electronics will bring opportunities for new wearable sensors that will broaden the market for wearable medical devices. By 2020, the printed and flexible electronic devices and materials market is expected to reach 10 billion CNY. As this industry is promoted by technological breakthroughs, aging issues, and increasing demands for the prevention and control of major diseases and health management, wearable mobile health care could well explode in the emerging market and exceed 1 trillion CNY in the next 10 years.

3 Problems with the medical device and new wearable medical device industries

3.1 Technical innovation in the medical device industry

The medical device industry is a high-end technology industry with an impetus for technological innovation. However, the lack of technological innovation has greatly impeded its development in China. First, comprehensive innovation is insufficient and sound comprehensive innovation results are lacking. Second, insufficient efforts are being made in terms of innovation, with insufficient innovation practices. Finally, the medical technology research in China is out of step with product and industry developments, and enterprises lack the required stamina to work toward long-term development.

3.2 Market environment

A perfect market mechanism and industry regulation would be conducive to the healthy development of China's medical device industry. However, the current market competition environment has many deficiencies, primarily due to insufficient national and industry standards for medical devices, as well as flawed laws and regulations. First, the current standard of the development of the medical device industry in China is out of sync with the international standard of development of industrial technologies, which has resulted in a wide gap between the Chinese and international standards and a lag in technology development. Second, China lacks standard certification systems and agents, as well as internationally recognized third-party inspection organizations. These factors result in inadequate reliability of technologies and products among medical device enterprises in China, making it difficult to gain recognition in the market. Furthermore, these enterprises are in a disadvantageous market position, which has seriously restricted the development of the medical device industry in China.

3.3 Industrial policy and government support

In recent years, the Chinese government has recognized the importance of the development of the biomedical engineering industry, which is considered both strategic and emerging and is being given high attention and sufficient policy support. Investment in this industry is increasing annually, promoting its rapid development in China. However, many deficiencies persist. First, the policy is not perfect, as it lacks long-term effectiveness and is insufficient to ensure the sustained and healthy development of the biomedical engineering industry. Second, although the government has gradually increased its investment in and support to the biomedical engineering industry, a large gap remains between the current investment and the actual demand with respect to China's market scale and the industry's current state. In addition, the government needs to change the way it supports the biomedical engineering industry; specifically, it should not only be an "investor" and lead the industry's development, but should also be a bridge connecting enterprises, research institutes, and investment agencies to enable wide cooperation. With these efforts, we can ensure healthy development of the biomedical engineering industry in China.

4 Countermeasures and suggestions

Here, we present suggestions for the technical, market, and policy aspects of the problems faced by the medical device industry.

4.1 Building research and development system and boosting product transformation

The research and development of medical devices in China is relatively low, and middle- and low-end products tend to occupy the market. Technology and product innovation ability are insufficient, and original technologies and products are few, especially in case of core components, as they are predominantly imported [10]. Thus, China should establish a research and development system across the industry chain as soon as possible and promote product transformation. Some concrete suggestions are as follows: An innovative research and development system must be developed for new medical devices, and a national demonstration center for medical device research and development must be built. Innovative strategies for medical device development should be designed and formulated, and budget allocation in the field of medical devices must be further unified. Furthermore, a research and development platform for innovative medical devices must be constructed and integrated efforts from all aspects of scientific and technological innovations should be made. Hard work on key technologies of core components is needed to promote transformations and upgrades in the medical device industry and ensure its sustainable development. Evaluation centers for the clinical application of innovative medical devices should be established and managed to develop a brand-new status quo in research and development and for the

application of domestic medical device products. Efforts should be doubled to cultivate key technologies in the field of wearable medical devices, promote the fusion and transformation of core technologies, and establish testing methods and product standards for China. Based on this system, unified medical information, electronic standards, and usage rules must be established for innovative products that are rapidly developing in the field of wearable medical devices.

4.2 Normalization and standardization of market management

Although China has an established standard system for quality and technical indicators in medical devices with over 1000 existing standards, the main problem lies in the slow updating of standards and introduction of new standards. As a result, it is necessary to implement a strategy for technical/quality standardization of medical device products and formulate a comprehensive national technical/quality standard system for medical device products in accordance with international requirements. The new medical device regulations have taken the quality system as a requirement for enterprises to obtain licensing and registration, focusing on the equal treatment of domestic and foreign products. However, domestic enterprises still suffer from unfair pricing of medical products. There are huge differences in charges for the same inspection between domestic and foreign products. China should bridge the existing gap between domestic and foreign medical device products and issue policies to promote the application and development of domestic products in the clinical area. Finally, China should expedite the establishment of more strict and effective standard detection methods as well as the development of a rigid evaluation management system.

4.3 Diversified policy support

To avoid repeating the limitations of the earlier government support to achieve the expected results, China should increase its support for leading medical device enterprises with competitive strengths in the industry, scientific research and innovation ability, and an industry demonstration role. Key enterprises should be encouraged to grow stronger and expedite the construction of innovation systems. The improvement of product technology and the research and development of new products should be accelerated. Therefore, these enterprises can play a leading role in the future to achieve the goal of "yielding twice the result with half the effort" and to provide funds and market channels for innovative domestic products through financial support policies. Furthermore, the construction of a medical device registration review and supervision team must be expedited, the evaluation and supervision levels must be improved, and the innovation of the medical device examination and approval process must be accelerated. Thus, national-level, third-party medical device clinical trials must be established to consult institutions to help enterprises and medical institutions develop clinical programs, track clinical compliance, and perform statistical analyses to match medical devices with actual clinical needs. Finally, the focus should be on the intellectual property rights system and strategy, legislation to protect patents in high-tech fields should be ensured, the protection of intellectual property rights and handling of infringement must be strengthened, and an international intellectual property protection and response system must be actively established.

Overall, many key problems persist in the development of medical devices in terms of technology, market, and policy in China. These key problems can be tackled on the basis of the above-stated countermeasures and suggestions; long-term plans should be made to ensure a break in the import monopoly for China's medical devices, form a new strategic industry, and approach a new era in this key development period of the medical device industry.

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