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REVIEW

Brief Talking about the Development of Medical Device Industry in China

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ABSTRACT

With the continuous development of China's economy and the improvement of Chinese' living standards, people's awareness of health care has gradually increased, so the demand for medical devices products is also strengthen. In addition, China is gradually entering an aging society and policy support for the medical device industry. China's medical device industry is developing rapidly.

1. Introduction

In recent years, whether the State Council promulgated the "Healthy China 2030" Program Outline or "China-Made 2025", the trend of promoting biomedicine and high-performance medical devices in China is obvious. With the remarkable improvement of people's living standard, people pay more attention to the health field. With the support of policy dividend and market dividend, China's medical device industry has developed rapidly.

2. Text

According to the "China's medical device industry competition pattern and leading enterprises analysis report" released by perspective industry research institute, statistical data show that the market scale of China's medical device industry reached 212 billion yuan in 2013, and broke through 300 billion yuan in 2015, up to 2017, t By 2017, the market size of China's medical device industry has grown to 445 billion yuan, with a year-on-year growth of 23.3%.. In 2018, the market size of China's medical device industry exceeded 500 billion yuan, reaching 525 billion yuan, an 18% increase over the previous year. The compound growth rate was 20% in 2013-2018.[1] From 2011 to 2017, the scale of China's medical device market has been expanding at a rate more than twice the world level, but there is still much space for

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development compared with the world level. Although we expanded capacity in the market for medical device industry speed, but because of the relevant basic science and manufacturing technology, medical device industry is relatively backward, leading to domestic enterprises engaged in medical equipment industry is relatively low in the link, medical device products are still concentrated in low and middle-end varieties, and the competition pattern is diversified. China's medical equipment industry mainly relies on imports of high-end products. Although there are more than 2000 export-certified enterprises in China, most of them have relatively weak competitiveness in terms of scale and brand, and lack of core technology. OEM is the main form of export, lacking of their own brand, it is at a disadvantage in the international market competition. At present, the basic composition of China's medical device market is 25% of high-end products, 75% of low-end products; while in the international medical device market, the basic composition of medical device products is 55% of high-end products, 45% of low-end products. In addition, 70% of the high-end products market, which accounts for 25% of China's medical devices, is occupied by foreign capital. These 70% of foreign enterprises occupy more than 80% of the market in areas with high technical barriers, such as medical imaging equipment and in vitro diagnosis, while Chinese medical devices enterprises mainly produce low-end products.[2]

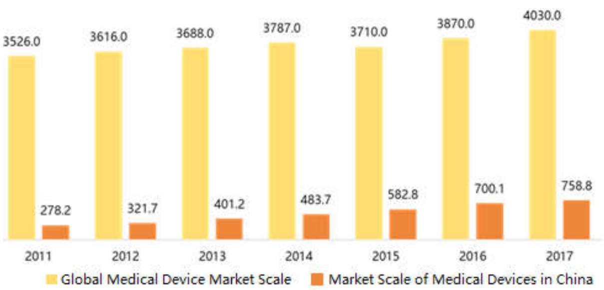

Figure 1. Contrast the Scale of Medical Device Market between China and the World from 2011-2017 ($100 million)

In terms of the product structure of China's medical device market in 2018, medical imaging, in vitro diagnosis and low-value consumables account for a relatively high share in the domestic medical device market, accounting for 16%, 14% and 13% of the market share respectively. and the top seven subdivisions including cardiovascular equipment, accounted for 68% of the market share.[1]

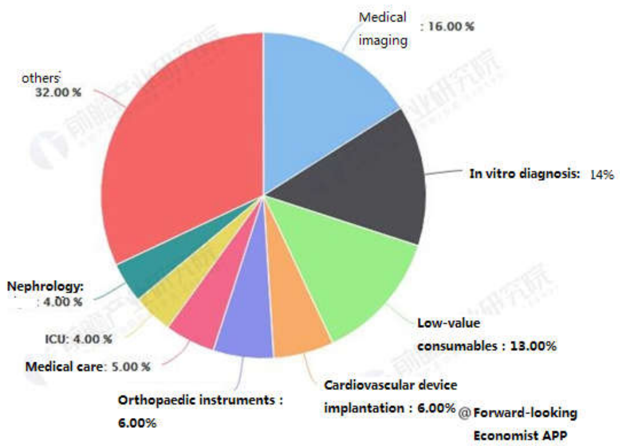

Figure 2. Statistics on the Product Structure of China's Medical Devices Market in 2018

From the perspective of consumption structure of medical devices, medical imaging, in vitro diagnosis and consumables (including low and high value) account for the highest proportion, while high-value consumables such as cardiovascular and orthopaedics are in a relatively high growth stage. Overall, CT, nuclear resonance and ultrasound occupy 16% of the market share in the field of medical imaging. Domestic enterprises mainly focus on low-end products, with market share between 10% and 20%. In the field of in vitro diagnosis, foreign enterprises still occupy the country because of their technical advantages and closed system strategy of "equipment + reagent", medium and high-end markets for in vitro and in vivo diagnostics.

Since March 2014 and January 2017, CFDA has opened a special review channel for innovative medical devices and a priority approval channel for medical devices. By the end of May 2018, 161 projects had been selected into the special approval procedure for innovative medical devices, 15 projects had been selected into the priority approval procedure for medical devices, and a total of more than 30 varieties of devices had been approved.[3] With the accumulation of technology and the acceleration of approval over the years, a series of domestic high-end equipment products were released, and domestic enterprises gradually have the conditions to import and replace them in high-end hospitals.

In 2019, the market scale of the whole industry not only focuses on breakthroughs in quantity, but also on the research and development of innovative devices and high-end devices. China is accelerating the import substitution and independent innovation of medical devices. In order to accelerate the development of medical device science and technology industry, the Office of the Minis-

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try of Science and Technology formulated and issued the "13th Five-Year Plan for Scientific and Technological Innovation of Medical Devices" (hereinafter referred to as the "Plan"). According to the framework and content of the "Plan", the new strategic opportunities and objectives facing the development of medical device industry were defined, and the medical device was put forward. Focus on the development of cutting-edge technology and major products. The specific development goals pointed out in the Plan include: breaking through 1-3 original innovative technologies, 10-20 frontier key technologies and forming more than 300 core patents; developing 10-20 frontier innovative products, leading screening and early warning, early diagnosis, micro/non-invasive treatment, individualized diagnosis and treatment, artificial intelligence diagnosis, intraoperative precise imaging, medical wisdom. The development of new medical products and health service technologies such as medical treatment and preventive treatment of diseases by traditional Chinese medicine; Focus on cultivating 8-10 large-scale medical device enterprise groups with strong competitiveness in domestic and international markets, establishing 8-10 medical device science and technology industry clusters, 80-100 furniture with independent core intellectual property rights and a certain scale of innovative high-tech enterprises.[4]

From the content of the above plan, we can see that the government has made great efforts to promote innovative equipment and advanced products, and paid more attention to the development of diagnostic screening, intelligent medical treatment, home rehabilitation equipment and surgical equipment. In a good economic, social, technological and policy environment, China's medical device industry continues to develop. Many medical device enterprises have been recognized by capital. Intelligent household medical equipment has become a new direction for China's medical devices.

In 2017, there were only four companies with revenue exceeding 5 billion yuan, including Merry Medical, Weigao Stock, Xinhua Medical and Dean Diagnosis. In 2017, Top10 accounted for only 12.58% of the total sales revenue of the medical device industry, while Top50 accounted for 31.71% of the total sales revenue of the medical device industry. Compared with Top10 sales revenue of the global medical device industry, 37.55% still has a lot of space to improve.[5]

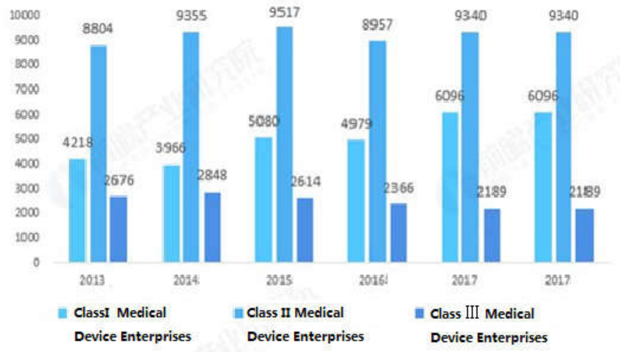

Figure 3. Number of Manufacturing Enterprises of Medical Devices in China from 2013 to 2017

In recent years, many reports showed that in medical imaging, medical informatization, in vitro diagnostic, consumables, patient care, health care equipment and so on six big niche, in China's medical equipment market share rising. In advanced medical equipment, there are a lot of high-tech products such as: multiple row helical CT, DSA system, digital color B ultrasonic and high intensity focus ultrasonic therapeutic apparatus, digital X-ray machine, auxiliary body parts, repair and replacement products and materials, electrical control prosthetic limbs, and other products,[6] (prospective net the economist in 2018, the China medical equipment industry technology development trend analysis focus on high-end medical equipment technology) Production of the products effectively increased with independent intellectual property rights innovation, make the medical equipment industry in our country have more new products and new economic growth point.

Taking yuwell medical for example, based on the high performance base completed in the first half of 2017, the company maintained a performance growth of nearly 20% from January to June 2018.[7] (yuwell medical first three quarters' performance report of 2018) The enterprise continuously increased the speed and intensity of new product promotion, consolidated the market share of old products, and continued optimization of core elements such as brand, marketing network and product structure, strengthened the integration and sharing of merger resources, and constantly increased comprehensive competitiveness.

Jiuan medical is a high-tech enterprise focusing on the development and production of health electronic products and intelligent hardware. Its products cover personal health wearable devices in the fields of blood pressure, blood sugar, blood oxygen, ecg, heart rate, weight, body fat, sleep, sports and other fields. In recent years enterprises to "Internet + medical field transformation, establish a mobile Internet" smart hardware + mobile + cloud service

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"personal health management cloud platform of mobile medical service innovation management model has basic forming, and explore new retail offline mode in France, and access to Xiaomi $25 million strategic investment in science and technology, as Xiaomi cooperation partner.

For another example Mindray medical, is a large company with annual revenue of more than 5 billion yuan. Its main business covers three fields: life information and support, in vitro diagnosis and medical imaging. The advantage is that, through cutting-edge technological innovation, we can provide more perfect product solutions, such as integrated first-aid solutions, perioperative integrated solutions, and integrated solutions for severe diseases. By using intelligent medical concepts, innovative products, integrated information mode, high-quality first-aid and efficient information interconnection, we can improve the efficiency of diagnosis and treatment.

Large enterprises have a complete development system, specific product direction, and sufficient experience. For small and medium-sized enterprises, on the one hand, they have to resist the pressure from foreign medical device companies and domestic large enterprises; on the other hand, they have to deal with the policy changes brought by medical reform. In the rapidly developing medical industry, how could they survive and develop?

According to the CFDA, most of the companies are small, with more than 90 percent being small and medium-sized enterprises. Nanjing runfengyuan medical device technology co., ltd. is a small enterprise, which was established in 2014 due to the introduction of nanjing government. It focuses on the research, development and production of rehabilitation medical devices, focusing on the medical anti-bedsore pad and medical temperature controller. Improve traditional mattress to clinical application in the process of research and development, such as sound, vibration, interfere with sleep problems, has developed the first use of the water cycle through the tiny vibration and water can make patients comfortable warm effect 24 hours of continuous use, has now been extended to the major national hospital feedback effect is good. Such small enterprises exert their advantages in the team of Chinese medical device enterprises, and devote themselves to solving patients' pain, innovating medical device products, and finding their own way of survival.

China's medical device industry has a weak foundation for development, medical device supervision started late, and the phenomenon of small, large, scattered and low-level competition of medical device enterprises has not been fundamentally changed, so it has become a top priority to accelerate the improvement of China's medical device industry's technological innovation ability, and strengthen the joint production, study and research of medical device research and development.

At the beginning of the enterprise development, small and medium sized medical equipment enterprises should according to their own characteristics, opening up new road, can put the energies on the following goals:

Focus on low-value consumables: choose primary hospitals, which have a large number, wide distribution, insufficient procurement funds and are sensitive to price, so they purchase and use many domestic medical devices, especially low-value consumables. But the basic-level hospitals use less, influence is small, only depend on the basic-level hospitals enterprises difficult to become bigger and stronger.

Attention to private hospitals: at present, there are 15,000 private hospitals in China, and the annual purchase amount of medical equipment reaches more than 300 billion yuan.[8] (electronic audiophiles network medical electronics) the private hospital market is relatively easy to achieve profits, because compared with public hospitals, private hospitals do not need bidding for equipment procurement, procurement time is short, cost is relatively low, and in the later stage, mass procurement can be formed.

Establishment of independent brand: if an enterprise wants to develop continuously in the long run, it must take the road of independent research and development and establishment of independent brand. In the market, we should stand at the height of being a brand, integrate dealer resources and expand influence with the help of academic activities. Branding is a long-term process that requires enterprises to spend a lot of time, energy and investment. To increase sales volume, we can cooperate with distributors to explore county-level hospitals, quickly achieve sales and realize payment collection, and lay a good foundation for the subsequent development of the enterprise.

Emerging technologies such as mobile medicine, telemedicine, surgical robot and gene sequencing make miniaturized and intelligent medical devices the future development direction. Foreign markets may be put off by protectionist and patent policies for a while, but it is only a matter of time before cost-effective Chinese manufacturing challenges big international brands on a global scale. The bottleneck limiting the development of medical devices in China may be the gap in clinical research, new materials and technologies and other basic subjects.

Driven by national policies, no matter large or small enterprises, the scale of China's medical device market will continue to expand at a rate more than twice that of the world level. During the 13th five-year plan period, China's medical device industry will focus on five areas, including digital diagnosis and treatment equipment, tissue repair and renewable materials, molecular diagnostic instruments and reagents, artificial organs and life support equipment, and health monitoring equipment. [8] under the guidance of national policies and the upgrading demand of equipment in domestic medical and health institutions, medical devices will have a huge domestic consumer market.

Market is huge, but China's medical device companies can seize the market and dividend policies, whether on domestic consumer market and is very good to complete the import substitution, must be in the product technology research and development, originality, core technology, team construction, key components procurement, quality system, and constantly improve and perfect the company's operations. Some traditional enterprises are in urgent need of transformation and upgrading. Many provinces and cities have also made important arrangements for the transformation, upgrading and development of medical device enterprises in their respective regions in "made in China 2025", and put forward their own development goals of domestic devices in 2020 and 2025. Therefore, while the industrial scale is growing rapidly, the proportion of domestic devices, especially in county hospitals, will be greatly improved.

3. Conclusion

"Idle boast the strong pass is a wall of iron, with firm strides we are crossing its summit". Looking to the future, domestic import substitution is an inevitable trend for the domestic market, and domestic policies are also supporting the big health industry. At the same time, the trust of domestic medical institutions to national brands is steadily improving, and the market outlook continues to be good. Our enterprises should grasp the policy trend, enhance their awareness of the importance of the rule of law, set up the height of the national brand of confidence, actively break industry deeply, reform of power supply side, increase the supply quality, and the effect of medical treatment service, satisfy the people's growing health care needs.

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