Japan's Medical Device Industry & Innovation

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Points

- **Japan's medical device industry is the fourth largest in the global market (4.4 trillion yen). However, it has low competitiveness in the field of therapeutic devices and is highly dependent on imports.**
- **Most diagnostic equipment (especially endoscopes) is made in Japan, but most treatment equipment is made in Europe and the United States, resulting in an annual trade deficit of about 1 trillion yen.**
- **The market size for therapeutic devices is growing as the birthrate declines and the population ages, but increasing healthcare costs are a major challenge.**
- **A "device gap" could occur, where advanced therapeutic devices are in short supply in the country, limiting treatment options for patients.**
- **The solution is to increase domestic self-sufficiency in therapeutic devices, and startup development in particular is key.**
- **The Ministry of Economy, Trade and Industry's (METI) "Vision for the Medical Device Industry 2024" and the Ministry of Health, Labour and Welfare's (MHLW) support measures emphasize the importance of startup support and clinical trial digitization.**
- **In order for Japan's medical device industry to be internationally competitive, it needs to enter the US market and collaborate with large companies.**
- **The increasing digitization of clinical trials, such as Distributed Clinical Trials (DCTs), demands more efficient clinical trials.**

Introduction

It has been a long time since the "lost 30 years" were spoken of. Already, the times have turned to 2021, and Japan's economy has been stagnant not for 30 years, but for 40 years if things continue as they are. The situation in Japan is expected to become even more difficult in the future due to an aging society that is becoming more advanced and a declining birthrate. It is imperative that the people of Japan draw on their wisdom in their respective fields to overcome this difficult situation. I would like to take this opportunity to share my personal views on what is needed in the field of medical equipment, in which I specialize.

Global Position of Japan's Medical Device Industry

The global medical device market has reached roughly 77 trillion yen and is growing at an annual rate of about 7%. Japan's medical device market is approximately 4.4 trillion yen, or 5.7% of the global market, making it the fourth largest market in the world after the US, which accounts for 44%, Germany at 7.1%, and China at 6.6%. And what about the international competitiveness of Japan's medical equipment? Ultrasound imaging devices, with a market size of 520 billion yen, accounted for 33.1%, MRIs, with a market size of 507 billion yen, accounted for 23.5%, CTs, with a market size of 452.8 billion yen, accounted for 30.9%, PET/PET-CTs, with a market size of 155 billion yen, accounted for 3.2%, and a whopping 99.1% of endoscopes, with a market size of 120.9 billion yen, are made in Japan and dominated the global market. The total market size of diagnostic instruments in these representative fields is 1.7 trillion yen, of which 35%, or 600.5 billion yen, is accounted for by Japanese products, which is quite a strong performance *(Chart 1)*.

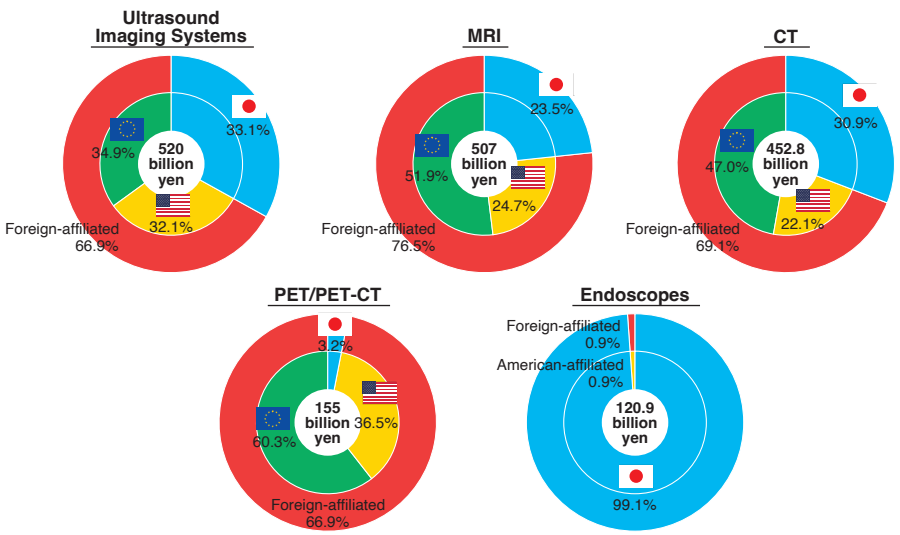
On the other hand, in the field of medical treatment equipment, Japanese-made products account for 0.0% of the market for artificial joints, which has a market size of 1,432 billion yen; 1.2% for stents, which has a market size of 653 billion yen; 1.0% for radiation therapy equipment, which has a market size of 510 billion yen; 34.8% for artificial kidney devices, which has a market size of 240 billion yen; 0.0% for peritoneal dialysis equipment, which has a market size of 212 billion yen; and 0.0% for cardiac rhythm management devices (cardiac pacemakers), which have a market size of 204 billion yen *(Chart 2)*. With the exception of artificial kidney devices, the percentage of the global market for therapeutic devices made in Japan is close to zero. The total market for therapeutic devices in these six representative fields is worth 3,251 billion yen, of which Japanese products account for only about 3% of the global market. Depending on the method of calculation, the market for therapeutic devices is about six times larger than that for diagnostic devices.

CHART 1

International competitiveness of diagnostic equipment by sector

○In the diagnostic equipment field, Japanese companies have a certain degree of international competitiveness.

【Global market share and global market size of major medical devices by Japanese/foreign companies (2015)】



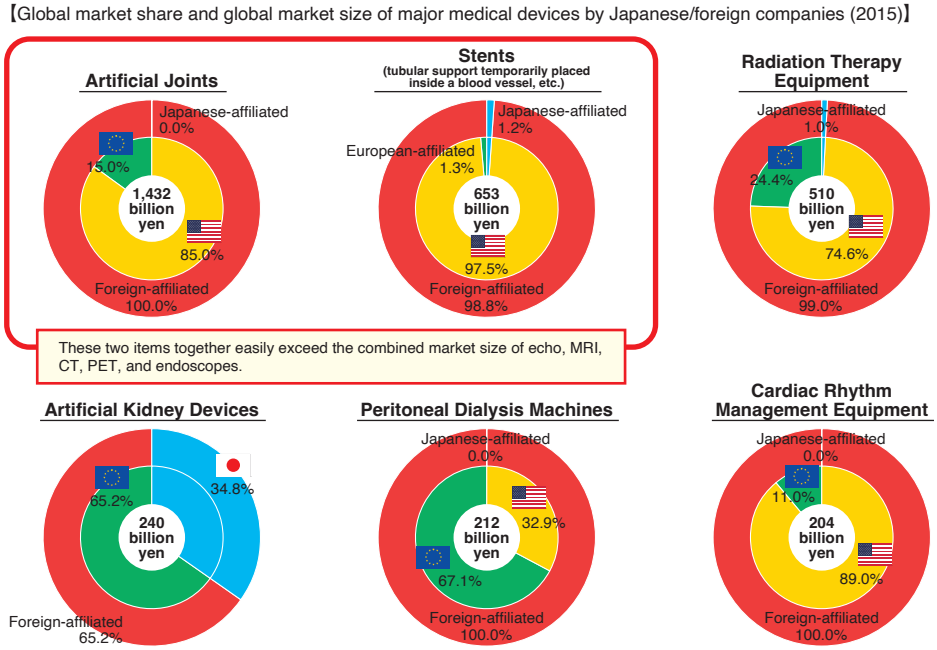
Source: "FY 2016 Information Collection on the International Competitive Position of Japanese Companies in Goods and Services and Software", New Energy and Industrial Technology Development Organization(NEDO, National Institute for Research Advancement (March 2017).

CHART 2

International competitiveness of therapeutic equipment by sector

○In the field of therapeutic devices, Japanese companies are generally weak in international competitiveness.

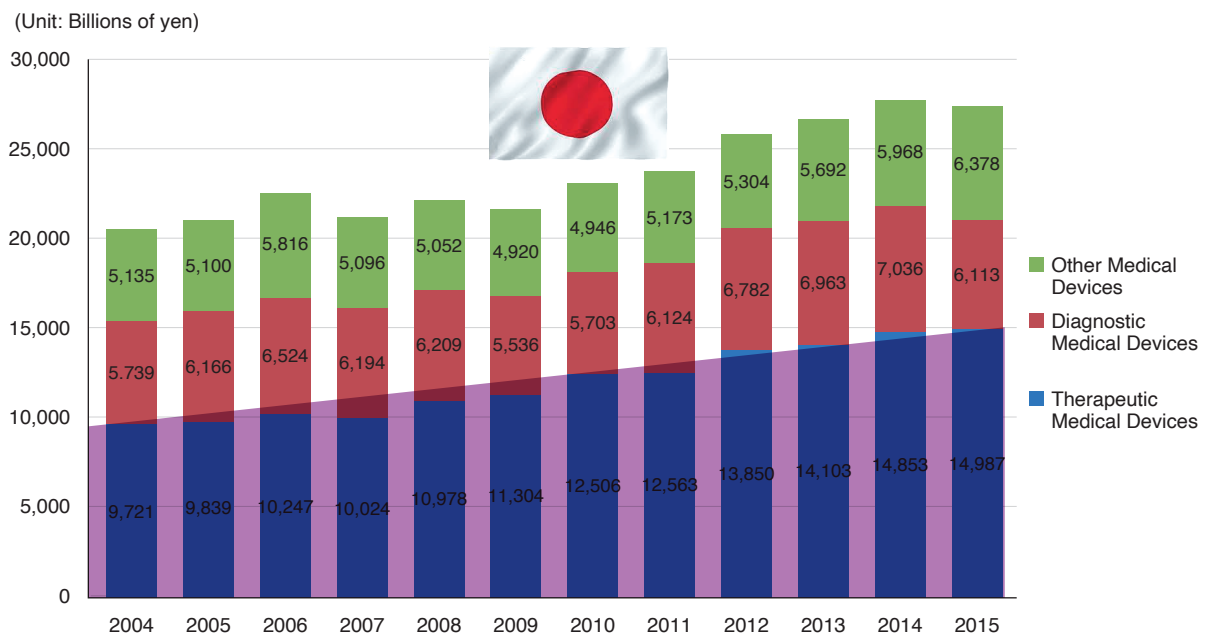
【Global market share and global market size of major medical devices by Japanese/foreign companies (2015)】



Source: "FY 2016 Information Collection on the International Competitive Position of Japanese Companies in Goods and Services and Software", New Energy and Industrial Technology Development Organization (NEDO, National Institute for Research Advancement (March 2017)).

CHART 3

Size of the medical equipment market in Japan



Source: Japan Agency for Medical Research and Development (AMED, "Social, Technological, and Industrial Trends Surrounding Medical Device Development").

Why, then, are Japanese medical device companies strong in the diagnostic field and weak in the therapeutic field? I imagine this is probably due in large part to the national character of the Japanese people. For example, there is an urban legend that Konosuke Matsushita once said, "Matsushita Electric would like to enter the medical field and contribute to people, but we must never touch therapeutic devices." We speculate that behind the spread of such rumors is the idea that therapeutic devices could endanger the lives of patients if something goes wrong with them, and if such a thing should happen, products such as home appliances would lose sales. In fact, Matsushita Electric Industrial Co. (formerly Matsushita Electric Industrial Co., Ltd., now Panasonic Holdings Co., Ltd.) has made inroads into diagnostic-related medical devices, but not into any therapeutic devices. The reason why Japan has not been able to expand into the high-risk, high-return therapeutic device field may be due to the Japanese corporate culture that fears the risk of failure.

Domestic Market for Medical Devices

Japan's medical device market is worth a total of 4.4 trillion yen and is growing at an annual rate of 5.5%. This is due to the rapid aging of the population and advances in medical care. While the expansion of the medical device market is good news for medical device manufacturers, it is a headache for those who pay for the devices. Although the discussion should normally be conducted comprehensively from the perspective of medical economics, this time we will consider the issue from the standpoint of industry. If we divide the medical device market into diagnostic devices, therapeutic devices, and others, therapeutic devices account for about 56% of the total, diagnostic devices account for about 25.2%, and other medical devices such as contact lenses make up the remainder *(Chart 3)*. In addition, according to the MHLW's Current Survey of Pharmaceutical Production, the average growth rate of Japan's medical device market by structure is 4.3% for therapeutic devices, 0.17% for diagnostic devices, and 2.3% for others, indicating a remarkably high growth rate for therapeutic devices. This implies that the number of patients requiring treatment is increasing with the aging of the population and that the price of treatment equipment is rising as treatment becomes more sophisticated. Furthermore, this is due to the fact that the price of treatment equipment is higher than that of diagnostic equipment.

In order to bring a therapeutic device to market, clinical trials must be conducted in advance, and development and introduction costs are much higher than those for diagnostic devices. In addition, most of the therapeutic devices that are implanted in patients are basically single-use devices due to the risk of infection, which is different from diagnostic devices that are used for many years. In any case, it is understandable that the market in the field of treating diseases is

very important.

Increased Trade Deficit in Medical Devices

So, are most of the medical devices used in Japan domestically produced? The answer is no. Currently, Japan's trade deficit in medical equipment is approximately 1 trillion yen. And this trade deficit is increasing at a double-digit rate annually. As mentioned, Japan's medical device industry is strong in diagnostic devices, but not in therapeutic devices. Although the market size for therapeutic devices is increasing in the domestic market, most of the value-added and particularly invasive therapeutic devices used in Japan are made in Europe and the US, and since Western medical device companies do not manufacture medical devices in Japan in the first place, they must inevitably rely on imports. Japanese medical equipment companies also manufacture their products at factories in Vietnam, China, Thailand, and other countries with low labor costs and import them into Japan, so the trade deficit cannot be attributed solely to Western companies. However, a large share of imported medical equipment in value terms comes from Western companies that develop and sell particularly expensive medical equipment.

By way of comparison, what about the pharmaceutical market? The global pharmaceutical market is worth 228.778 trillion yen, about three times the size of the medical device market. The growth rate is about 6%, the same as that of medical devices. The Japanese domestic pharmaceutical market is 11.9 trillion yen, or about 5.2% of the global market, which is almost the same as the medical equipment market, but with an average annual growth rate of 0.88%, showing slower growth than the medical equipment market. The balance of trade also shows an annual deficit of approximately 4,558.5 billion yen, the same as for medical devices. Because of the size of the market, the deficit for pharmaceuticals is much larger than that for medical devices. Also, as with medical equipment, the trade deficit has been growing at a double-digit rate. The reason for this is that, unlike medical devices, most pharmaceuticals are therapeutic drugs. The cost of developing a new therapeutic drug is tens to hundreds of billions of yen, which is 10 to 100 times more than the cost of medical devices. In addition, the period from the start of development to the launch of a new drug is usually 10 years or more, and the price of a new drug is high to recover these development costs.

But what is the definitive cause of the trade deficit? There are currently 165 new drugs, called "blockbusters", that sell more than 150 billion yen per year for a single drug. Of these, only 13 are sold by Japanese companies, and most of these are products of Western companies. Drugs with particularly large sales are said to be biopharmaceuticals, which are used to treat malignant tumors, immune disorders, and rare diseases, but this area is almost exclusively dominated by products from Western companies. Japanese companies had previously demonstrated strength in small molecule pharmaceuticals, but their shift to biopharmaceuticals has been delayed, and their presence in the global market is currently waning. Against this background, the trade deficit in pharmaceuticals in Japan is large and increasing.

Serious Issues in Japan

A serious issue threatening Japan's medical care has become apparent. It is known as "drug loss", or the inability to use new drugs in Japan that are used as standard in the rest of the world. This is because many of the new drugs are developed by Western pharmaceutical companies, and these companies are not considering the introduction of these drugs to Japan. So, why don't they consider introducing them to Japan? There are various reasons, but the most important reason is that the reimbursement price is not commensurate with the cost of entry. In the past few years, the rapid rise in medical costs due to the aging of the population has caused a wrinkle in the reimbursement prices of drugs and medical devices. In particular, major pharmaceutical companies in Europe and the US have shifted from developing new drugs from scratch on their own to acquiring startups that have developed attractive drug seeds, placing them under their control, and using their financial strength to conduct clinical trials and other activities that require huge development funds. In other words, it is important to make the Japanese market attractive not only to large pharmaceutical companies but also to startups. At present, the Japanese market is not very attractive to startups with few resources, as seen in the drug loss problem. What about medical devices, then? The inability to use medical devices in Japan that are routinely used in Europe and the US is called the "device gap", which is the same as the drug loss in the pharmaceutical industry.

Although not as pronounced as with pharmaceuticals, a small device gap does exist. In particular, with regard to therapeutic devices, which is a weak area of Japan's medical device industry, in the unlikely event that a Western company does not enter the Japanese market, it would mean that, like pharmaceuticals, patients would no longer be able to be treated. This could be a very dangerous situation for the security of Japan. In fact, according to my estimate, Japan's domestic self-sufficiency rate for therapeutic devices is only 20%, meaning that most value-added advanced medical devices are made in Europe and the US. This domestic self-sufficiency rate is lower than the current problem of food self-sufficiency, which is 38%. There have been cases in the past where this problem has manifested itself: in the early 2000s, drug-eluting stents were routinely used in foreign countries as the then newest medical devices for coronary artery disease, but unfortunately they

were not available in Japan. This led to patients traveling to South Korea to receive treatment. At that time, the Pharmaceuticals and Medical Devices Agency (PMDA) had not yet been established, and the delay in regulatory approval was the primary cause. Once approved in Japan, the higher reimbursement price than the US price was an incentive for major Western medical device companies to follow suit and introduce similar products to Japan one after another. In this case, since approval was obtained in Japan later than in the US and Europe, it is not exactly a device gap but rather a "device lag", but ideally such a case should not occur in the future.

Where Should Japan Start?

So where should we start to prevent the device gap described above? The first step is to increase domestic self-sufficiency in medical devices, especially therapeutic devices. To this end, we can only hope for the efforts of existing medical device companies, but it will take about 10 years to develop a new type of therapeutic device that does not infringe on patents. The only way to prevent a device gap from occurring during that time is to rely on Western companies. What Western companies expect from the Japanese market is its attractiveness as a business. In other words, profit. As explained earlier, it is easy to predict that raising reimbursement prices will be quite difficult given Japan's current healthcare finances. One solution would be to lower the cost of entry into the Japanese market.

Background of Increased Cost of Entry

So what can be done to actually lower the cost of entry into the Japanese market? A major part of the entry cost is the cost of clinical trials. While many diagnostic devices do not require clinical trials, almost 100% of therapeutic devices do. It is extremely risky to launch a product on the market before its efficacy and safety have been proven in Japanese patients, especially for highly invasive therapeutic devices, so clinical trials are essential, even for a small number of cases. In this context, the key issue is how to reduce the cost of clinical trials. The cost of clinical trials in Japan is relatively high, said to be nearly three times that of the US per case. The reason for this is that there are many hospitals in Japan that have fewer cases than in the US and Europe, which leads to a larger number of hospitals participating in clinical trials. On the other hand, the format of medical records differs from hospital to hospital, and there is a delay in digitization and compatibility problems with electronic medical records. In order to deal with this situation, they would need to dispatch monitoring staff to each hospital from the Contact Research Organization (CRO) and thus the costs of the CRO would increase. This is one of the reasons for the rise in the cost of entry.

Digitization of Clinical Trials

It is not surprising that streamlining clinical trials is effective not only when medical devices are introduced into the country from overseas, but also when domestic companies bring them to market in Japan. This was triggered by the pandemic of the new coronavirus that began in 2020, when the entire US went into lockdown starting in March 2020, forcing the public to stay out of the country and restricting all but minimal activities for an extended period. Under such circumstances, the challenge for US pharmaceutical companies was not only to develop new vaccines, but also how to proceed with clinical trials of new drugs under the pandemic. In particular, a one-day delay in the launch of a new drug, known as a "blockbuster", would result in a lost opportunity of approximately 400 million yen, so a way to continue clinical trials was sought. This is where decentralized clinical trials (DCT) came into the spotlight. In conventional clinical trials, patients visit the hospital where the trial is being conducted and undergo follow-up examinations at the same hospital. DCT services had been offered by startups and others before the pandemic, but during the pandemic, pharmaceutical companies, CROs, and others began to pay attention to the system. In many cases, conventional clinical trials are only available to patients living in the vicinity of the hospital where the trial is being conducted, or at most within a two-hour drive. However, the DCT system, using digital technology, not only allows patients to take part in clinical trials remotely from the comfort of their own homes, but also offers the possibility that patients living anywhere in the US can participate in clinical trials. This can provide a ray of light not only to pharmaceutical companies, but also to patients suffering from illnesses.

However, the implementation of DCT requires service innovations that are not bound by various existing concepts. For example, in DCT, a qualified medical nurse must actually go to a patient's home to perform blood collection tests on the patient and to administer intravenous infusions at home. However, due to the pandemic, patients who had been receiving routine outpatient care were no longer able to visit outpatient clinics, and the need to draw blood and administer intravenous infusions at home quickly became apparent, leading to the birth of a startup that dispatches nurses to provide home healthcare services. The service, in which registered nurses go to patients' homes to provide medical care, already became widespread. One senses the dynamism of the US in that when social issues arise, startups find business opportunities in these issues emerge with a sense of speed and change society. And these nurse staffing services accelerated the spread of DCT.

However, there is an absolute requirement for the widespread use

of DCT. That is, without a doubt, the digitization of medical care. In particular, the digitization of patient medical information is urgently needed. If clinical trial systems and medical information databases such as electronic medical records can be compatible, the risk of human error in transcribing clinical trial data for each patient will be reduced, and information can be accurately and quickly consolidated into clinical trial systems. In addition, a database of patient information can contribute to the speeding up of clinical trials by finding the most suitable patient for a clinical trial as quickly as possible, thereby speeding up the inclusion of patients in a clinical trial.

While DCT is a good thing in this way, the biggest obstacle is the high initial investment required for digitization. This is not a problem in countries where digitalization of medical care is already widespread. Unfortunately, for other countries, including Japan, DCT will increase rather than decrease expenditures, even though one of the goals of DCT is to reduce the cost of conventional clinical trials.

However, I believe that DCT is not only for clinical trials. The digitization of medical information is essential for the realization of precision medicine, which is referred to as predictive medicine, preemptive medicine, and personalized medicine. In the past, US President Barack Obama declared by presidential decree that he would promote "Precision Medicine". As a result, startups with various technologies, such as genetic analysis, have been established in the US. If all of this medical information is digitized and managed, the realization of precision medicine will no longer be a pipe dream. This is also important for preventive medicine. If personal medical information can be used to formulate individualized preventive strategies, it will be possible to provide more reliable preventive care on an ongoing basis, and this may help to reduce the growth of the nation's overall medical costs. We hope that future medical care in Japan will be wonderful through the optimization of medical care and the realization of personalized medicine using digital technology and medical information.

Strengthening the Global Competitiveness of Japan's Medical Device Industry

I have discussed how to introduce the latest medical devices approved in foreign countries to Japan quickly, safely, and appropriately. From a long-term perspective, a major issue will be how to generate innovative therapeutic-related medical devices from within Japan. Since the development of innovative medical devices usually takes about 10 years from start to market, there is no immediate effect on improving the trade deficit. However, it is clear that if it is not done now, the trade deficit will continue to increase forever, and immediate action is required. It goes without saying that existing medical device companies must make efforts to develop their own products, but just as most innovative medical devices in the US and Europe are born from startups, it is clear that startups will be the key to success in Japan as well. The Japanese government has designated 2022 as the first year of the startup era and has launched a policy to create a second boom in business startups.

In particular, startups that develop products and services that use science and technology to solve social issues, known as "deep tech", were seen as important for Japan, a country with a strong science and technology base. Recently, government strategies for medical-related startups were announced by the relevant ministries and agencies. The "Medical Device Industry Vision 2024" released by METI and the "White Paper on Promotion and Support of Healthcare Startups" released by the MHLW explain the government's strategy for medical device startups. Currently, the number of medical device startups established in Japan is about 30 per year. Compared to the approximately 300 companies in the US, the number is low even as a percentage of GDP. Under these circumstances, the government's strategy becomes important.

Below are the policies of METI and the MHLW.

(1) "Vision for the Medical Device Industry 2024"[1]

"Vision for the Medical Device Industry 2024" is a strategy for the medical device industry developed by METI that emphasizes the importance of innovation, research, and global expansion. The main contents of the vision are as follows.

a) Current issues

It is emphasized that the Japanese medical device market is shrinking compared to the global market, especially the US market, and that Japan needs to grow out of its dependence on the domestic market.

b) Global market growth

The importance of the US market was emphasized, and the need to create globally competitive products. It also pointed to the growth of digital technologies such as artificial intelligence (AI) and software as a medical device (SaMD).

c) Innovation and research

R&D investment is needed to promote innovation, and collaboration between startups and large companies is critical to the development of new medical devices. In particular, there is an urgent need to promote the development of medical devices that utilize AI and digital technology.

d) Support for entry into the US market

The vision aims to strengthen the competitiveness of products in the global market by providing support for clinical trials and evidence building necessary to enter the US market. Support is also proposed for companies that leverage government assistance to promote their

expansion in the US market.

e) Cooperation and collaboration

Strengthen partnerships with startups, large companies, and research institutions to develop new products and achieve success in the marketplace, both domestically and internationally.

By implementing these measures, we aim to strengthen the international competitiveness and sustainable growth of Japan's medical device industry.

(2) White Paper on Promotion and Support of Healthcare Startups[2]

The "White Paper on Promotion and Support of Healthcare Startups" released in June 2024 provides recommendations on measures to promote and support startups in the health, medical, and long-term care sectors in Japan. The main contents of the paper are as follows.

a) Current Issues

Although Japan is a country of longevity and health, there are many restrictions on the activities of healthcare startups, and global expansion has not progressed. The digital accumulation of domestic medical data and the potential of healthcare technologies for an aging society have not been fully exploited.

b) Recommendations

- Strengthen the functions of the Medical Innovation Support Office (MEDISO), a startup support organization, and establish an ongoing support system.
- Establishment of the Health Tech Challenge (tentative title), a milestone-based development support program.
- Establishment of a request window for reimbursement revisions, and improved English-language support for healthcare startups.
- Improving clinical trial efficiency by promoting clinical trial Digital Transformation (DX) such as DCT.
- Strengthen collaboration with overseas venture capital to support global expansion.

c) Support approach

- Global direct approach: in addition to the Japanese domestic market, we (the government) support strategic business development with an eye toward overseas expansion from the beginning.
- Phased Overseas Development Approach: we provide support for phased overseas expansion after achieving success domestically.
- Domestic Enrichment Approach: developing the domestic market and strengthening the ecosystem to promote sustainable growth.

This white paper aims to improve the international competitiveness of Japan's healthcare startups through government initiatives. To improve international competitiveness, it is necessary to strengthen domestic development of therapeutic medical devices in particular and to capture overseas markets, particularly the US.

It is clear that the Japanese government's policies are aimed at strengthening startups, co-creation between large companies and startups, strengthening Japan's weak therapeutic devices, and expanding overseas, especially into the US market. We hope that these policies will be incorporated into concrete policies in the future, and that Japan's medical device industry will make great strides.

Conclusion

It has been 24 years since I left Japan. In 2001, when I left Japan, I went to an electronics store in the US and saw Japanese-made flat-screen TVs still proudly displayed on the shelves. Unfortunately, we no longer see Japanese-made televisions. It is extremely difficult to find not only TVs but also other electrical appliances made in Japan. Living abroad, one can easily realize that the Japanese economy's position in the world is not a bright one. However, there is no reason for Japan to simply sit back and watch its economy continue to decline. Now is the time for the Japanese people to innovate in the fields in which they are involved, to go out into the global marketplace, and to revive the Japanese economy. I believe that Japan can achieve this.

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