



Comparison of market environment for medical devices in Japan, China, and Korea

*Japan at a crossroads:
- The device lag and device gap in
Japan, China and Korea -*

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American Medical Devices and Diagnostics
Manufacturers' Association (AMDD)

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I. Executive Summary

To provide healthcare that meets the needs of the people, it is necessary to provide a stable supply of state-of-the-art medical technology in a way that meets the requirements of the patients and healthcare systems of Japan. For this, resolving issues such as the device lag and device gap is essential.

The device lag and device gap have been discussed from many perspectives and countermeasures have been taken. However, they have been insufficient. AMDD is gravely concerned that medical device suppliers may focus on Asian growth markets outside of Japan, and that Japan may not be able to continue to fully enjoy the future supply of advanced medical devices. Therefore, we conducted a comprehensive company survey and analysis covering three countries: Japan, China and South Korea.

What emerges from this research is that Japan is at a crossroads in its ability to continue as an important marketplace for medical device suppliers. Today, the strategic importance of Japan and China is on par. Survey data clearly demonstrates that China and Korea have closed their device gap in recent years. The number of products available in the three countries surveyed is now almost equal, and trends in regulatory submissions and approvals indicate that Japan's device lag may be worsening compared to China and Korea. On the other hand, the survey shows that even though the size of the market in China will surpass Japan in importance in the future, this change need not be viewed as a negative trend. Japan's strengths and the risk of doing business in China are perceived in a balanced way.

Based on this research, AMDD calls on key government stakeholders throughout the system to resolve the outstanding issues causing the device lag and device gap. One necessary action is the improvement of regulatory issues, especially the acceleration of the Action Program. Another necessary action is the improvement of reimbursement issues, especially the elimination of FAP, which has been an unresolved issue for many years.

. Research Background and Overview

1. Introduction

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) is an industry group consisting of 67 Japanese entities who primarily have their headquarters in the U.S. and offer advanced healthcare technologies such as medical devices and/or in-vitro diagnostics (IVD's) in Japan.

The primary aspiration of AMDD is to meet the needs of Japanese patients and medical professionals by delivering new medical technologies, both therapeutic and diagnostic. We are striving to introduce advanced medical technologies that are considered the global standards as early as possible, to provide therapies and diagnosis for orphan and intractable diseases, and to improve patients' quality of life. Further, we want to maintain a stable supply of medical devices to the field as we offer safer, more effective, and less invasive products.

In order to realize these AMDD aspirations, several structural issues in Japan must be resolved. Here we highlight three major issues [Ref 1].

Device lag

"Device lag" means that medical devices are introduced later in Japan than in Europe and the U.S., thus delaying access by Japanese patients to these life-saving and life-enhancing innovative products. Unfortunately, among Japan, the U.S. and Europe, Japan is the last place that the majority of devices are introduced. This is considered to be an important issue in the care delivery setting along with the so-called drug lag. The device lag is getting longer, and currently delays of 3 to 5 years are common. IVD's also have numerous delayed approval issues. In the 2010 research, the introduction of more than 96% of all medical devices into Japan is later than their introduction into the U.S. and Europe [Ref 2].

Device gap

"Device gap" means that medical devices used worldwide are not introduced into Japan, so Japanese patients do not have access to these innovative products. Innovative products are often not introduced into Japan because price reduction mechanisms like FAP (discussed below) do not provide for appropriate compensation in light of the investment

required because of higher regulatory hurdles[Ref 2].

Reimbursement rule that is not consistent with Japan market reality (FAP)

Foreign Average Pricing (FAP) is the scheme to reduce the price difference between Japan and foreign countries by comparing average price of the four foreign countries, including the U.S., with those of Japan. The foreign price differential was seen as an issue in the 1990's. Since then, the foreign price difference has been reduced substantially already, and some products' prices in Japan are lower than overseas. On the other hand, drastic price reductions are occurring due to foreign exchange movement, which has nothing to do with the cost of supplying the products in the Japan market, and the problems resulting from the FAP scheme are becoming more pronounced. If this scheme continues, business unpredictability will persist, and it is feared that the device lag and device gap and the risk to stable supply will worsen.

AMDD continues to provide recommendations to the government and conduct various field research projects in order to resolve these issues for the benefit of Japanese patients. In 2009, we commissioned Mitsubishi Research Institute to examine the cost differences between Japan and Europe regarding the supply of medical devices [Ref 3]. As a result, it was found that the cost of supplying medical devices in Japan was 2.2 times higher in the cardiovascular area and 2.5 times higher in the orthopedic surgery area. Despite the much higher costs in the Japanese market, the FAP rule has yet to be abolished.

2. Background

As Japan's structural issues remain unresolved, there have been discussions that, from a global management perspective, it could be difficult to keep supplying Japan with a full range of advanced medical devices. Looking specifically at Asia, there is concern that Japan could be lagging even in comparison with China and Korea, which, despite their own regulatory and approval system, are enthusiastic about fostering the medical device industry and attracting medical device technology.

As a result, AMDD and the Advanced Medical Technology Association (AdvaMed) commissioned LEK Consulting, which has experience and a track record of market research

globally, to conduct a comparison of the market attractiveness of Japan, China, and Korea from various perspectives.

3. Methodology

Research modality

A written survey questionnaire covering various functions of the company, and one-on-one interviews with executives who have responsibility for Asia, were conducted for this research.

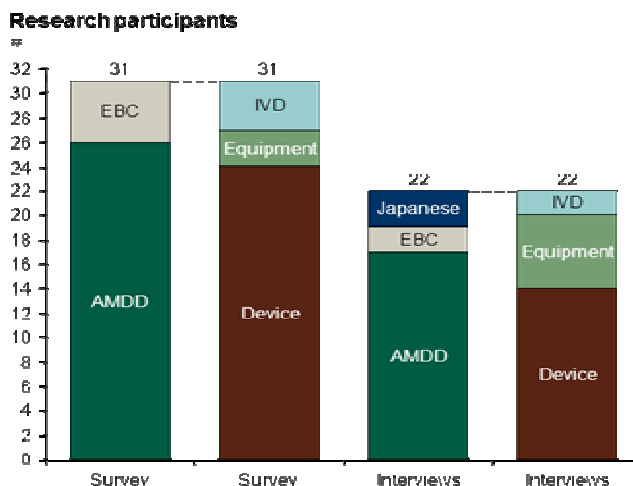
Questions covered the 'market attractiveness and resource allocation perspective', the 'strategy and marketing perspective', and the 'new product introduction and regulatory perspective'. Also, in order to understand the stable supply issue in depth, research was conducted for lone products within functional categories (The result of this analysis is shown in Appendix 1).

Participating companies

AMDD member companies were the main subjects of the research. Furthermore, some European Business Council (EBC) and Japan Federation of Medical Devices Association (JFMDA) companies also participated.

The main business segments of the participants span treatment devices (disposables, implants), capital equipment, and in-vitro diagnostics. A total of 31 companies responded to the written questionnaire and interviews were conducted with executives of 22 companies (Fig. 1).

Fig.1

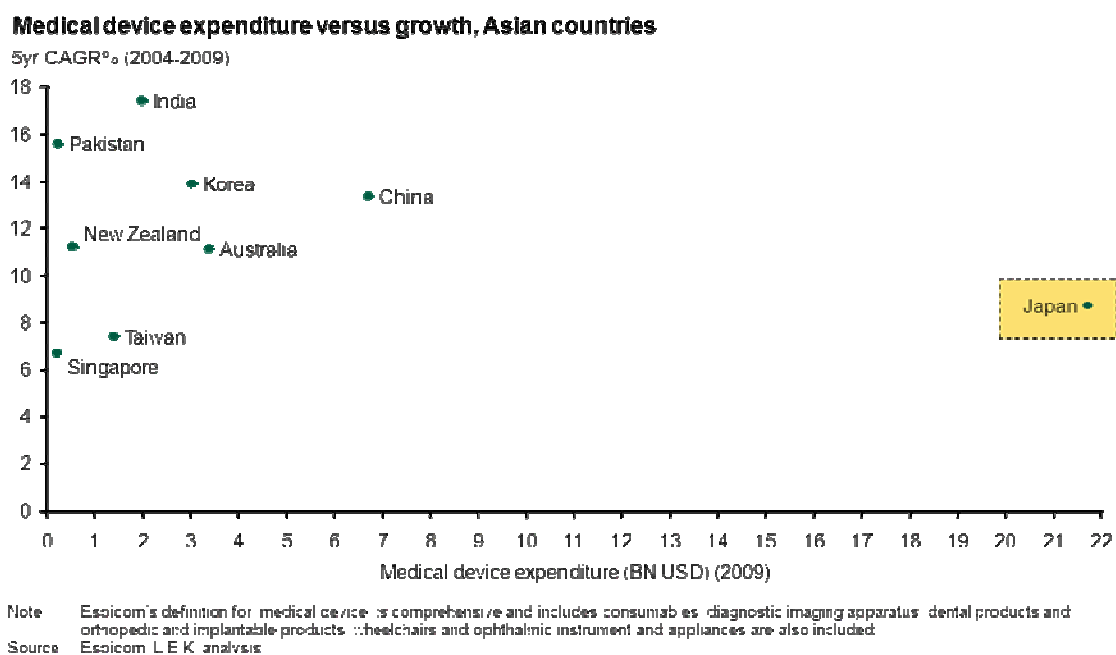


Some questions were difficult to answer as this was the first survey to bring out the situation in China and Korea, with a tight deadline. This needs to be taken into account in the future. We would like to offer sincere thanks to the participating companies' staff who responded while being mindful of accurate information exchange with their counterparts overseas of differing cultures. Individual analysis has different response numbers as we excluded incomplete or blank responses. Thus, the response numbers are mentioned in each figure.

About China and Korea, the comparators

China and Korea were chosen as comparator countries because they have their own regulatory requirements, are keen to grow the medical device industry and are close geographically. Their medical device markets are less than 1/3 of Japan in size, but are nevertheless sizable in Asia and have high growth rates (Fig. 2). Because we used Episcom data as the source, a wide range of medical devices are included in the statistics and numbers may be different from other AMDD statistics.

Fig.2



Australia, with a market size larger than Korea, was not included this time as their product introduction processes by and large follow the European rule and the entry barriers are lower than in the three countries surveyed.

The research was conducted between November of 2010 and March of 2011. With respect to 2010 data, companies were given the discretion of providing forecasts or actual results.

. Research Results

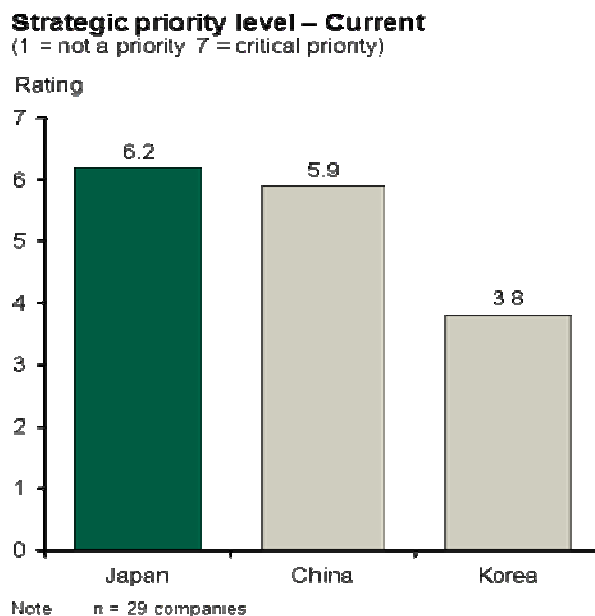
Throughout the research, same questions were asked of Japan, China and Korea. Overall, it can be said that China is Japan's rival for investment by the companies, and that Korea is a somewhat less significant competitor. Therefore, even though we show the results for the three countries in figures and tables, the narrative often focuses on the comparison between Japan and China.

1. Japan and China sharing strategic importance in Asia

Historically, Japan was the only strategically important market for medical devices in Asia. However, the research results show that today, because of the emergence of China, there are two strategically important markets in Asia.

Figure 3 shows the result of rating the current strategic importance of the countries on a scale of 1 to 7. Both Japan (6.2 pts) and China (5.9 pts) have high rankings and are positioned as very important markets.

Fig.3



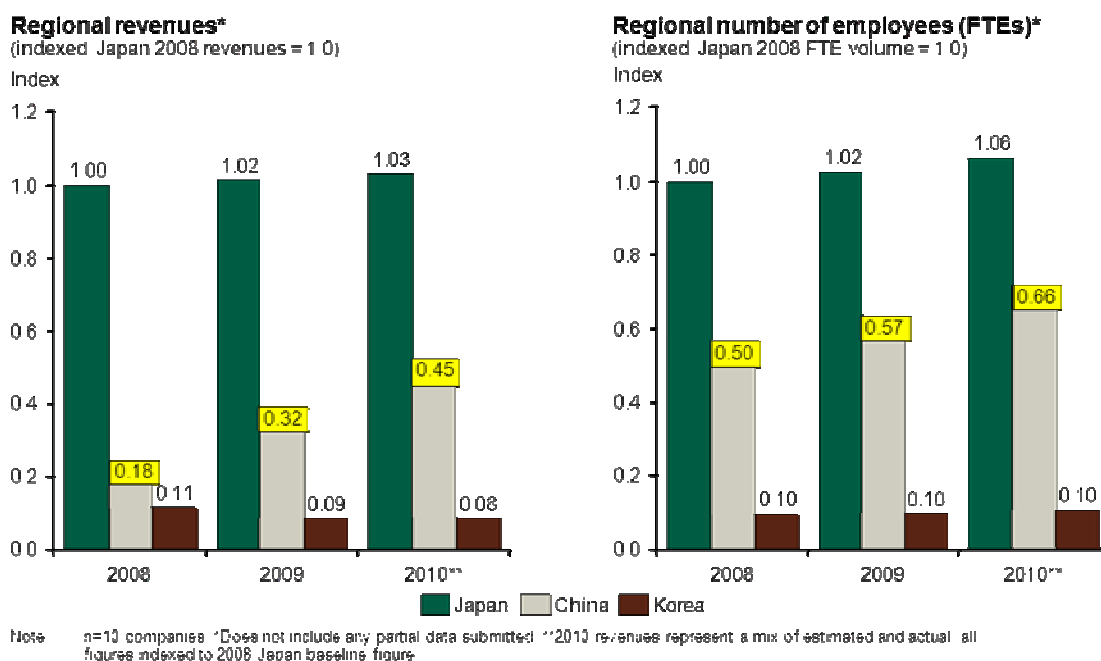
Further analysis of individual companies' responses about which country was rated higher is as follows:

- Companies who rated China as more important than Japan. 11 (38%)
- Companies who rated Japan as more important than China. 9 (31%)
- Companies who rated them equally. 9 (31%)

So there were slightly more companies who rated China higher. Also in the ranking, 13 companies put China at the top and 11 companies put Japan at the top.

We further analyzed the companies' activity in terms of sales and number of employees. This is shown in Fig. 4.

Fig.4



In this figure, the companies' sales and number of employees in three countries for the past three years are shown. Both the sales and employee numbers are normalized with 2008 Japan value set to '1'. First of all, both the sales and the number of employees are growing in Japan. In China, the number of employees is growing at 15% per annum over the last three years, and is more than a half that of Japan in 2010. Similarly, sales in China


grew 2.5 times in 2010 compared to 2 years earlier and are close to a half those of Japan.

Looking 10 years into the future, we asked whether the attention given to each country will increase or decrease. For both Japan and Korea, the opinions were almost evenly split between 'increase' and 'decrease', but for China, more than 90% replied that attention will 'increase'. The comment, *“China is seen as key to global relevance and success,”* is no different from those voiced by other industries.

In Table 1, we extracted, from the perspective of the Japanese market, the key issues contributing to the result that attention is shifting from Japan to China.

Table 1 Issues for medical device market in Japan

Concerns	Description	Quote
High investment costs	<ul style="list-style-type: none"> ● Heavy investments especially on a global comparative basis are required in clinical development and for regulatory approvals in Japan 	<p>“... Clinical investments can be cost prohibitive ...”</p> <p>“... No one wants to invest in Japan’s regulatory [requirements] ...”</p> <p>“... As soon as you put anything in the body it gets so difficult ...”</p>
Significant time requirements and lag	<ul style="list-style-type: none"> ● Particularly for regulatory approval time requirements are long in Japan <ul style="list-style-type: none"> - but a degree of improvement was noted 	<p>“... By the time you gain approval a lot of products are obsolete which then adds costs for support ...”</p> <p>“... Ongoing delays to bring product to market and the costs are a major issue but it’s getting better ...”</p>
Degrading reimbursement	<ul style="list-style-type: none"> ● Systematic and long-term cuts in pricing particularly for STMs are raising concerns of long-term economic viability 	<p>“... By far the biggest issue is the eroding value of the market and reimbursement cuts are driving a lot of this ...”</p>



High concern exists among executives regarding the eroding economics and value of the Japanese market
 “... The government cannot assume that Japan will remain important ...”

The concerns of participating companies can be summarized into three points regarding the Japanese market: the high cost of business; an environment which requires long lead-times for product introduction and results in a device lag; and reimbursement that gets worse with every revision. As a result, long term attractiveness and recovery of investment are questioned. The quote, *“government cannot assume that Japan will remain important (just because global players have not yet exited Japan)”* symbolizes the

concern about the device lag that persists, and the persistent issues with respect to reward for innovation.

In particular, companies whose main business is Special Treatment Materials (STMs) voiced opinions that are more pessimistic because the FAP rule, described in 1.1, has not been abolished (Table 2).

Table 2 Issues of companies whose main segment is STMs

<ul style="list-style-type: none"> ● Overall, multinationals relying on STM reimbursement expressed the greatest concern about the future in Japan <ul style="list-style-type: none"> - ability to gain a return on investment - ability to bring products to market 	<p>“... The current business model is not sustainable ...”</p> <p>“... No growth is the prevailing view at corporate ...”</p>
<ul style="list-style-type: none"> ● Executives from cardiology/cardiac-focused multinationals expressed particular concern and described Japan as a blockbuster-only market <ul style="list-style-type: none"> - only situation where time and investment will result in sufficient ROI - limited to no growth or return for evolutionary product improvements 	<p>“... The current model in Japan only will work for blockbuster products ...”</p> <p>“... The biggest risk is for next generation products. With these products you have to rely on market growth for success. All the focus will be on China, and Japan will be bypassed ...”</p>
<ul style="list-style-type: none"> ● While clinical development costs and regulatory were noted as drivers, particular emphasis focused on systematic cuts in reimbursement 	<p>“... Reimbursement price cuts are affecting the availability of products being brought to Japan ...”</p> <p>“... It takes tremendous effort to tread water ...”</p>



STM executives, especially those from cardio/cardiac companies, expressed that new technology is already bypassing Japan in favor of other Asian countries

Notably, we heard from multiple executives in the cardiovascular segment that *“The current model in Japan will only work for blockbuster products.”* This kind of comment arises because the prices granted to newly approved devices, with certain improved features, will be based on predicate prices already reduced by the FAP without regard to the cost of business in Japan.

2. Device lag in Japan is greater than in China or Korea

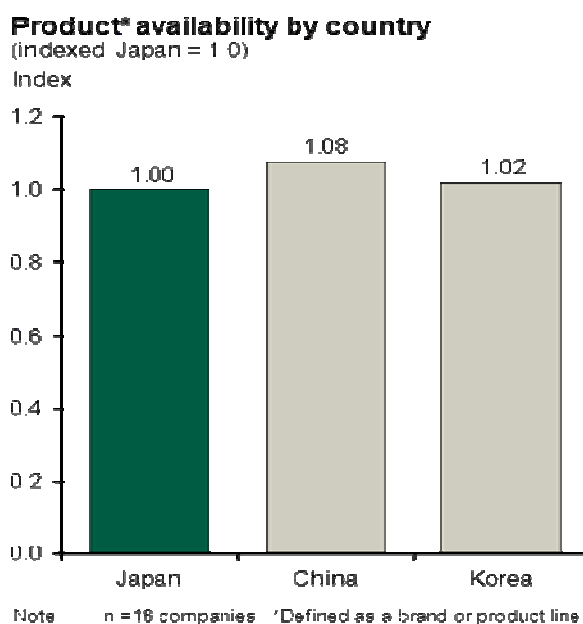
Let us now turn to the comparison of product introductions in these three countries.

Since 2008, AMDD has been surveying product variety (the number of brands) available in various countries. The survey is conducted for Japan, the U.S. and Europe. The

results show that the “Number of products available in Japan is roughly 1/2 of Europe or the U.S.” In the latest 2010 survey, if we normalize the products available in Japan to 1, then the U.S. is 2.3 and Europe is 1.9 [Ref 2]. In another words, the U.S. has 2.3 times the variety of medical devices as Japan.

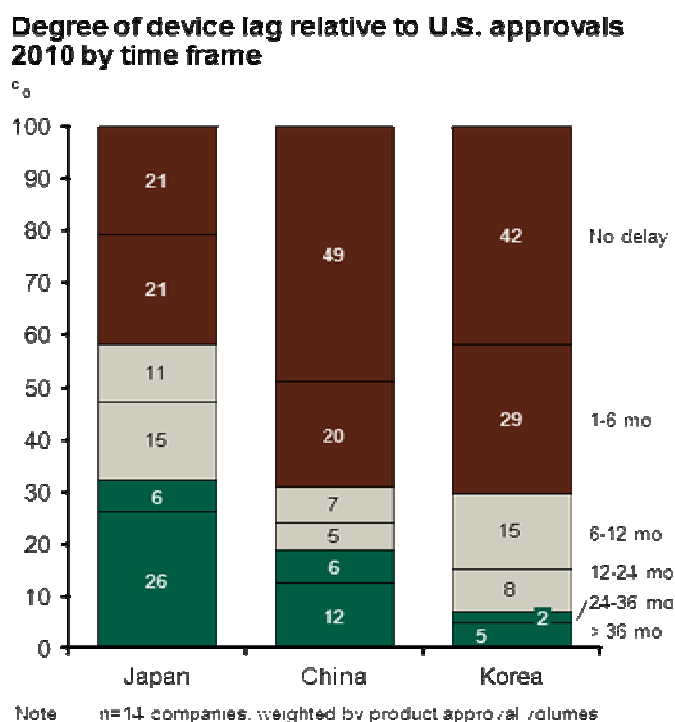
In our research, the same comparison was carried out for Japan, China and Korea (Fig. 5). Compared to 1 for Japan, China has 1.08 times as many products, and Korea has 1.02 times as many products. According to this result, the number of products supplied by the participating companies is already slightly higher in China and Korea than in Japan. Roughly similar numbers of medical devices are available in China and Korea.

Fig.5



In this analysis, the number of products may be roughly the same, but we cannot determine whether or not the portfolio is equally advanced. So in order to observe from a different angle, we analyzed the products that were approved in each country in 2010, in terms of the delay in approval in each country compared to the approval timing in the U.S. of the same product. The results are shown in Fig. 6.

Fig.6



Of the products approved in Japan in 2010, 42% had a device lag of less than 6 months compared to the U.S. The comparable ratio for China was 69% of the approved products and for Korea was 71%. Stated another way, approximately 2/3 of the products approved in China and Korea have little device lag with the U.S. as compared to only 42% for Japan. Percentages of products with zero device lag were 49% for China and 42% for Korea, more than twice the 21% performance for Japan. In Japan, 1/3 of products are still being approved with more than a 2 years device lag.

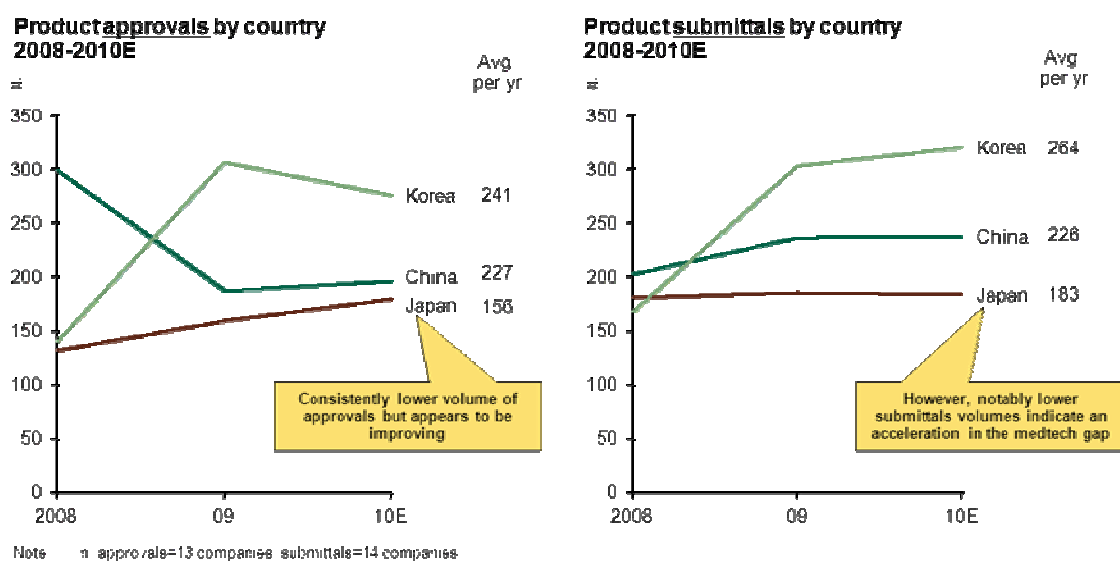
Based on the data in Fig. 6, the device lag in Japan appears to be more serious than in China or Korea. At the same time, if we take into account the result that the numbers of devices available in these three countries are similar as shown in Fig. 5, the medical device portfolio in China and Korea could become more advanced than that of Japan.

In the past, Japan's device lag has been discussed within the context of Japan-Europe-the U.S. And there was some acceptance of the fact that global companies

obtain approval first in markets where they develop the products. However, the analysis this time shows that same kind of lag exists compared to China and Korea.

In order to predict the number of products available to patients in these countries in the future, we show the three year trend data of submissions and approvals in Fig. 7. The number of submissions and the number of approvals in Japan are fewer than in China for all three years. The numbers are close between Japan and Korea for 2008, but the gap widens in subsequent years. If this trend continues, Japan’s device lag and gap with China and Korea could accelerate and become wider.

Fig.7



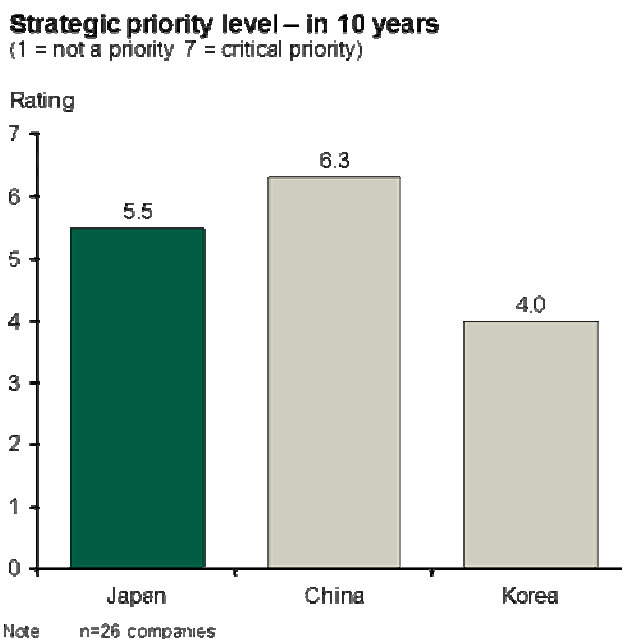
In the current research we also quantified the ease of product introduction on a scale of 1 (Difficult) to 7 (Easiest). The result shows Korea at 4.3 being the highest (easiest), followed by China at 3.5 and Japan last at 3.1.

3. Japan's strengths

As the analysis up to this point shows, Japan and China are approximately on par with respect to strategic importance in Asia and the advanced medical devices supplied by global companies. However the regulatory trends indicate that China will become the country with better access to advanced medical devices.

As if to confirm this, survey results indicate that China will surpass Japan in strategic importance in 10 years (Fig. 8). This response should be interpreted within the context of 'if Japan does nothing to resolve the issues and concerns.'

Fig.8



In Fig. 3 showing the 'current importance', 38% of companies ranked China higher than Japan. In this Fig. 8 which shows the importance 10 years into the future, 15 out of 26 companies (58%) ranked China higher than Japan. 5 companies (19%) ranked Japan higher than China 10 years into the future.

As a prelude to discussing what should be done so that Japanese patients will continue to benefit from advanced medical devices, we explain here the survey results regarding Japan’s strengths. First the characteristics of each country that emerged from the research are shown in Table 3.

Table 3 The characteristics of 3 countries

Characteristics	Japan	China	Korea
Survey indications	<ul style="list-style-type: none"> ● Significant and strategic market ● Low growth market ● Product entry barriers significant 	<ul style="list-style-type: none"> ● Currently significant and strategic market ● Continued high growth expected ● Ease of product entry not favorable but few delays experienced 	<ul style="list-style-type: none"> ● Ease of product entry most favorable among the 3 countries ● Highest volume of product submittals and approvals ● But growth and corporate visibility expected to remain flat or decline
Descriptive terms used	<ul style="list-style-type: none"> ● Stable / mature ● Aging society ● Replacement market ● Sophisticated market ● Fight for share ● Traditionally high revenue 	<ul style="list-style-type: none"> ● Emerging ● Young demographics ● High volume ● Significant investments by govt ● IP risk exists ● Strong future revenue potential 	<ul style="list-style-type: none"> ● Mature ● Unstable reimbursement dynamic ● Small market
Executive comments made	<p>"... Japan is the largest in Asia but with slow growth ..."</p> <p>"... Japan is a direct marketing country rather than an emerging market..."</p> <p>"... Very challenging environment ..."</p>	<p>"... Level of growth is astounding ..."</p> <p>"... Unlimited potential but complex market ..."</p> <p>"... But the Chinese government is hard to predict ..."</p>	<p>"... Mature market with single digit growth ..."</p> <p>"... Market size is almost the same as Kansai ..."</p>
	A large market with limited growth prospects and notable market challenges	Still emerging with immense market potential that outweighs risks/uncertainty	Relatively favorable environment but too small to be a strategic priority

Although Japan is still a large market, a high growth rate cannot be expected in the future and barriers to product introduction remain high. On the other hand, China is already recognized as a sufficient-size market and the high growth rate and relative ease of product introduction are seen as attractive. However, the government’s unpredictability is viewed as a risk in China.

Furthermore, since the participants of this research are mostly companies with long business histories in Japan, they regard Japan highly. Their views on the attractiveness inherent in Japan’s business, practice, culture, human resource, and science and technology are summarized in Table 4.

Table 4 Attractiveness of Japan market for medical devices

"Japan has a lot of positives"

"There are a lot of good things about this market"

Business/ cultural values	Highly developed	Human resources
<ul style="list-style-type: none"> ● Strongly value fairness ● Service orientation ● Strong IP protection 	<ul style="list-style-type: none"> ● Mature / clean healthcare system ● High savings by public 	<ul style="list-style-type: none"> ● Great scientists ● Well-educated and trained physicians
<p style="text-align: center;">Technological sophistication</p> <ul style="list-style-type: none"> ● Robotics ● Stem cell research ● Recognize value of technology ('break through') 	<p style="text-align: center;">Business environment</p> <ul style="list-style-type: none"> ● Still the second largest in the world ● Supportive demographics ● Regulatory process improving (but still lags) 	

. AMDD Proposal

1. Japan is at a crossroads

For years, AMDD and its predecessor organization (the ACCJ Medical Devices and IVD Subcommittee) have been raising concerns about issues concerning medical devices in Japan. In particular, we have been pointing out that the cost of supplying medical devices in Japan is substantially higher than in the U.S. or Europe and therefore FAP, the rule regarding referencing foreign prices, is unreasonable. Our appeal has not been heard to date, but Japan remains the 2nd largest medical device market as a country globally, and its strategic importance has been paramount in Asia in spite of the continuation of FAP. However, as in other industries, China is about to overtake Japan in attractiveness based on substantial market potential and the large growth rate that it will deliver. Our research showed the possibility that Japan may already trail China in terms of the device lag.

At about the same time as our research took place, PwC published a report titled “Medical Technology Innovation Scorecard” [Ref 4]. This report discusses the fact that the innovation paradigm for medical device is changing, with the implication that the superiority of the U.S. in medical technology is eroding. It also discusses the emergence of China. Low scores are given to Japan for its regulatory systems and market attractiveness, which are the causes of the device lag. On the other hand, high scores are given to Japan’s medical technology and intellectual property protection environment. These findings parallel the views of our research participants and are insightful. Japan is at a crossroads. The scenario for Japan could change substantially by improving the negatives while continuing to enhance its core competencies. There is still a chance, since the industry sees Japan as more attractive than China today, albeit by a small margin.

2. To continue supplying advanced medical technology in Japan

In order to maintain the strategic importance of the Japanese market and to continue ensuring the supply of advanced medical technology to its population, Japan must make improvements in the following areas while maintaining and enhancing its strengths.

Rectify high entry cost and reduce the device lag

- ✓ Acceleration, monitoring and disclosure of progress under the regulatory “Action Program” [Ref 5] by MHLW and PMDA, as well as further clarification of testing and

review criteria, must be carried out.

Improve reimbursement rule

- ✓ Abolish the FAP rule which does not take into account the high cost of supplying medical devices in Japan and which can lower prices mechanically based on just the foreign exchange movement.

- ✓ Ensure that medical device reimbursement reflects the proper value and innovation of these devices.

If these issues are appropriately resolved, both the existing device lag and device gap compared to Europe and the U.S., as well as the emerging device lag/gap compared to China and Korea will go away and stable supply of advanced medical devices to Japan will be maintained. This is precisely what AMDD is aspiring towards, and would truly benefit Japanese patients. Moreover, as the market becomes attractive, more domestic companies could create advanced medical devices and the domestic medical device industry can be expected to grow.

3. In closing

As we finished data gathering and began our analysis, the East Japan Earthquake occurred.

We would like to offer our deepest condolences and sympathy to the families of those who lost lives in this catastrophe. We have been deeply saddened by the continued suffering of the survivors who now have to contend with the loss of their homes and property, sheltering in uncomfortable surroundings and the struggle to find missing family members, relatives and friends. AMDD member companies are working to ensure a stable supply of medical products to hospitals in these areas.

The government has the great responsibility to rebuild Japan from the disaster and revive the competitiveness of the nation. It is essential that there exists an attractive market for medical devices so that the medical device industry can grow and take part in the recovery of the disaster-affected areas and Japan as a whole. For this, as well as for

the advanced medical technology to be provided to Japanese patients, we ask that stake-holders in the government, policy arenas and agencies to consider and carry out the proposals mentioned above.

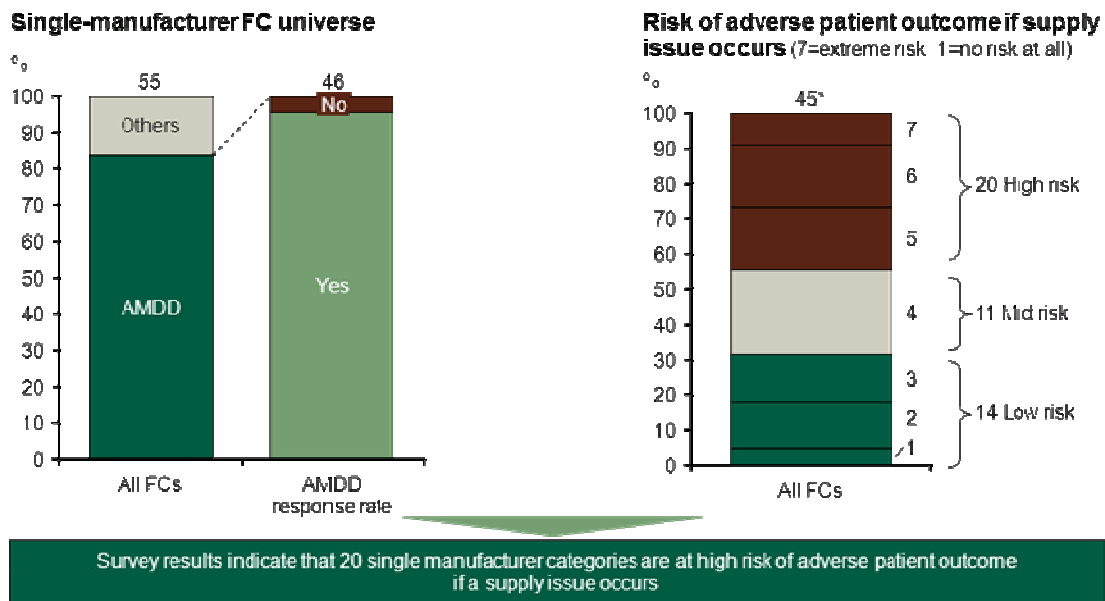
Appendix

1. Analysis results on the stable supply issue

We tried to compare the stable supply issue of medical devices among Japan, China and Korea. At the time of the research, there were 55 functional categories of Special Treatment Materials in Japan that had only one brand and for which no obvious substitute exists. Among the 55, 46 categories are single-sourced by an AMDD member company and we assessed the risk to patients if the supply were to be interrupted.

Unfortunately we could not obtain sufficient information from China and Korea about the supply situation of these products, so only the Japan result is described. If the supply is interrupted for some reason, such interruption for 40% of the products would pose a high risk to the patient.

Fig.A1



Note: *45 of 55 single manufacturer functional categories
 Respondents could not provide sufficient information regarding comparative competition levels across other geographies

2. References

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- [Ref 2] L.E.K. Time Clock Survey, 2010. L.E.K、医療機器タイムクロック調査。2010年
- [Ref 3] AMDD position paper, Jul., 2009. 米国医療機器・IVD工業会(AMDD)、「医療機器提供コストの日欧比較調査」2009年7月
- [Ref 4] PwC、"Medical Technology Innovation Scorecard: The Race for Global Leadership." 2011年
- [Ref 5] MHLW link to the Action Program, Dec., 11, 2008.
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