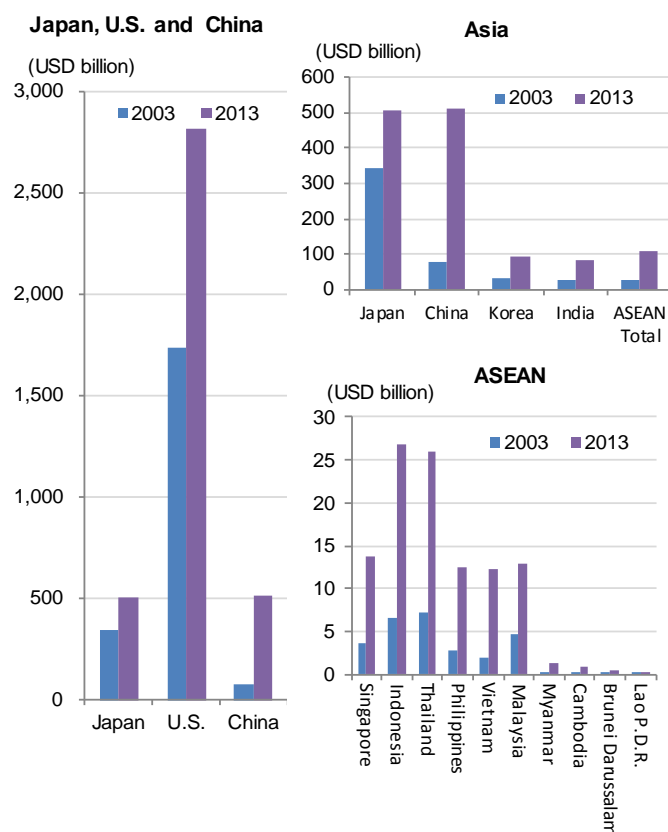


Market Circumstances of Medical Device Industry and Logic for Building a Strategy for Innovation by Japanese Companies

1. Levels of total healthcare expenditure for Japan, the U.S. and China

- In Method of Innovation for Japanese Med-Tech Industry (No.241 of this series), I referred to the medical device industry, focussing on networking with Silicon Valley. This time I summarize the market circumstances of the medical device industry in Japan, the U.S. and China, and suggest a strategy for developing Japanese company innovation.
- Fig. 1-1 shows estimated levels of total healthcare expenditure for Japan, the U.S. and China. The definition of healthcare varies quite broadly, but it is surmised that all the expenditures listed here include medical treatment and care in hospitals and nursing homes, and they also include payments for pharmaceutical products and medical devices.
- The level of expenditure in the U.S. stands out (Fig. 1-1), but in each country it has grown largely and China's position is rising. Also shown is that total ASEAN expenditure currently exceeds South Korea's expenditure. In Japan the growth has a large fiscal impact, but the rate of growth is relatively low. In the U.S. the ratio of total healthcare expenditure to GDP is higher; in Japan that ratio has grown slightly (Fig. 1-2).
- Fig. 1-3 summarizes total healthcare expenditure (THE) per capita and the physician to general population ratios of each country. As for physicians, China's ratio is a bit less than those for the U.S., Japan, South Korea and Singapore, but there is a much larger difference in its THE per capita (China's is only 7% of that of the U.S.). At this point, the countries' strategies for business development must differ because their circumstances differ.

Figure 1-1 Trend of total healthcare expenditure



Source. WHO.

Note. [Total health expenditure % of gross domestic product] × GDP.

Figure 1-2 Trend of total healthcare expenditure to GDP

Source. WHO.

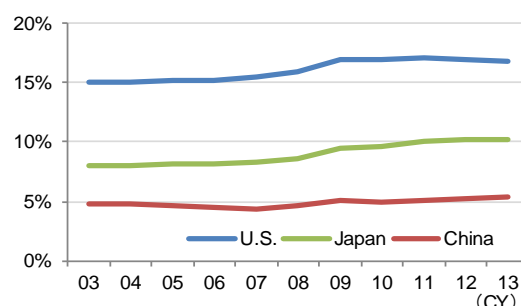


Figure 1-3 Total healthcare expenditure per capita & physicians per 10,000 population

	THE per capita (PPP int. \$)	Physicians per 10,000 population
	2013	2010-2013
USA	9,146	24.5
Japan	3,741	23.0
Korea	2,398	21.4
China	646	14.9
India	215	7.0
Singapore	3,578	19.5
Brunei Darussalam	1,812	14.4
Malaysia	938	12.0
Thailand	658	3.9
VietNam	308	11.9
Indonesia	293	2.0
Philippines	287	-
Cambodia	229	1.7
Lao P.D.R.	95	1.8
Myanmar	37	6.1

Source. WHO "Global Health Observatory" data.

2. Trend of international sales in Japan & U.S. companies and overview of U.S and China medical circumstances (part 1)

- Fig. 2-1 shows the overall international sales trend of some major Japanese and U.S. companies. The companies captured in this analysis are basically the same as those of Fig. 5 of volume No. 241 of this series. (Some companies are excluded either because they do not specify international sales or because their definition of the category changed largely.)
- In Japanese med-tech companies, domestic sales has grown softly along with the growth of the domestic medical market. International sales has grown extensively, mainly in Asia, which gets 1/3 of the total, similar to the breakdown of U.S. companies' international sales (U.S. companies' sales to Asia include those to Japan). The amount of sales growth in the domestic market is almost the same as that in the Asian market.
- In U.S. companies, domestic market sales has grown slower than its THE growth in the past 10 years. Especially in the past five, 2009-2014, the growth rate has been slow, and the amount of growth in the sales of Asia (including Japan) is almost the same as that in the sales of the domestic market. This structure is similar to that of Japanese companies.
- Next, we look at the U.S. medical market and medical device market. Fig. 2-2 shows the trend in the patients undergoing operations (this shows only the cardiovascular field). It shows that figures of surgery are not growing in the 2000s. Growth rates for some types of diagnosis are similarly down. However, some technological progress is reflected in the growth of drug-eluting stents and endoscopy (small intestine).

Figure 2-1 International sales in Japan & U.S. mid-tech companies

	Sum of eight Japan med-tech companies (JPY 100 million)					Sum of six U.S. med-tech companies (USD million)				
	2004fy	2009fy	2014fy	2009fy/ 2004fy	2014fy/ 2009fy	2004fy	2009fy	2014fy	2009fy/ 2004fy	2014fy/ 2009fy
Sales	6,729	8,284	13,468	1.2	1.6	25,215	37,900	43,851	1.5	1.2
Domestic sales	4,419	4,840	6,072	1.1	1.3	15,335	21,433	22,913	1.4	1.1
(%)	65.7%	58.4%	45.1%			60.8%	56.6%	52.3%		
Overseas sales	2,310	3,445	7,396	1.5	2.1	9,879	16,466	20,938	1.7	1.3
(%)	34.3%	41.6%	54.9%			39.2%	43.4%	47.7%		
Asia sales (or Asia Pacific etc)	434	781	2,150	1.8	2.8	3,397	5,292	7,486	1.6	1.4
(%)	6.5%	9.4%	16.0%			13.5%	14.0%	17.1%		

Sources. IR materials of the companies listed below.

Eight Japan med-tech companies

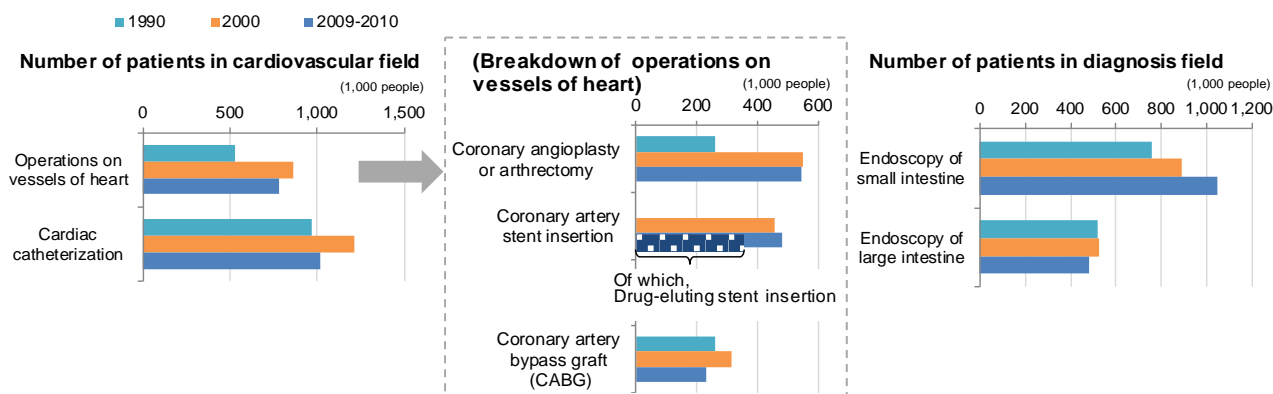
Top eight companies in 2014 in which the proportion of med-tech sales to total sales was high over the previous 10 years: Terumo, Nipro, Sismex, Nihon-Koden, JMS, Nakanishi, Kawasumi Chemical, Asahi Intecc.

Six US med-tech companies

Top six companies in 2013 in which the proportion of med-tech sales to total sales was high over the previous 10 years: Medtronic (Irish at present *), Becton Dickinson, Boston Scientific, Zimmer, C.R. Bard, Edward Lifesciences.

*Medtronic is an Irish company now, but was a US company during almost all the period above; thus, we analyze the company as a US company for this report.

Figure 2-2 Trend in number of patients (nonfederal short-stay hospitals in U.S.)



Sources. Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics (NCHS) "National Hospital Discharge Survey" and U.S. Census.

Note. "Discharges with at least one procedure in nonfederal short-stay hospitals, by sex, age, and selected procedures" (per 10,000 people, 18 years of age and over) multiplied by population estimates of the U.S.

3. Overview of U.S. and China Medical Circumstances (part 2)

- U.S. medical device industry has continued to grow over the past 10 years (Fig. 3-1). In particular, shipments of surgical and medical instrument products have grown largely, and some of them must be high value added. Export and import trends (which are about equal, as shown in Fig. 3-2) are not so meaningful because U.S. companies' production is globalized.
- As for the China market, over the past 10 years the inpatient figure has grown more than 300% (Fig. 3-3). From death-toll estimates broken down by cause of death, most patient deaths are due to 1) malignant tumor, 2) heart disease and 3) cerebrovascular disease. This structure is similar to that of Japan, and the number of deaths related to heart disease stands out.
- In China, on the other hand, sales of medical devices has grown largely, compared with growth of inpatients. Exports and imports have had balanced growth; there has not been an excess of imports over exports (Fig. 3-6).
- China has both 'production factory' and 'growth market' characteristics. Compared with the number of inpatients, the medical device industry has grown greatly over the past five years. It obviously indicates an upgrading of medical care. Who leads such upgrading? Is it by foreign companies or by Chinese companies? I guess that high-end product growth has been led by U.S. and European companies. However, it is estimated that domestic Chinese companies have grown fast in terms of middle-level products. This situation would represent a barrier to growth by Japanese companies.
- Fig. 3-7 shows 10 years of medical device industry growth in Japan, the U.S. and China. China's progress is huge compared to that of the other two countries.

Figure 3-1 Product shipment value of medical devices in the U.S.

(USD billion)	2004	2010	2011	2012	2013	2014
Electromedical equipment (including diagnostic, therapeutic, and patient monitoring equipment), excluding ionizing radiation equipment	15.8	22.0	22.0	24.0	24.2	24.4
Surgical and medical instruments	22.3	34.7	36.0	36.6	38.9	38.8
Surgical appliances and supplies, including orthopedic, prosthetic, and therapeutic	19.7	25.5	25.0	23.1	25.0	24.1

Source: US Census Bureau, "Annual Survey of Manufacturers (ASM)".

Figure 3-2 Export and import of medical devices in the U.S.

(USD billion)	2004	2010	2011	2012	2013	2014
Export	17.9	29.8	32.1	33.6	34.1	34.9
Import	19.3	27.4	30.4	31.6	32.5	34.4

Source: US Census Bureau, "U.S. International Trade in Goods and Services".

Figure 3-5 Sales revenue of new medical devices in China

(CNY 10 billion)	2004	2010	2011	2012	2013	2014
Manufacture of Medical Equipments and Meters	1.3	7.2	13.0	15.9	17.4	20.4
Manufacture of Medical Equipment and Appliances	0.2	0.9	1.5	2.5	3.0	3.4
Manufacture of Measuring Instruments	1.1	6.4	11.5	13.4	14.4	17.0

Figure 3-6 Export and import of medical devices in China

(USD billion)	2004	2010	2011	2012	2013	2014
Export	1.4	5.5	6.5	7.3	8.2	8.8
Import	2.0	4.6	6.0	7.1	7.9	8.3

Source for Figs 3-3, -4, -5, -6: National Bureau of Statistics of China.

Note: Figure 3-4 data is determined by multiplying the major disease death rates by the population of China.

Sources for Fig 3-7: US Census Bureau, "Annual Survey of Manufactures (ASM)" and "U.S. International Trade in Goods and Services"; National Bureau of Statistics of China; Ministry of Health, Labour and Welfare, "Statistics of Production by Pharmaceutical Industry".

Figure 3-3 Number of inpatients in China

(10,000 people)	2004	2010	2011	2012	2013	2014
	6,669	14,174	15,298	17,857	19,215	20,441

Figure 3-4 China's trends in patient deaths, by main disease

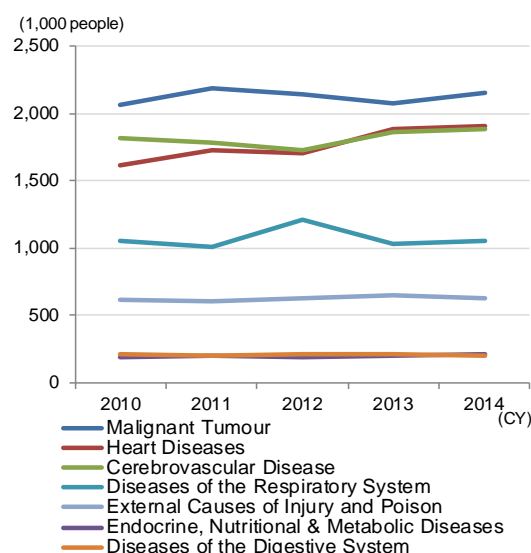


Figure 3-7 10-year growth of medical device industry in Japan, the U.S. and China

	2014/ 2004	Reference Export	Import
U.S.			
Products shipments value	1.5	2.0	1.8
China			
Sales revenue of new medical devices	15.7	6.4	4.3
Japan			
Market size	1.8	1.3	1.4
Amount			
2014 (JPY trillion)	2.8	0.6	1.4
2004 (JPY trillion)	1.5	0.4	1.0

4. Medical needs & device supply in Japan (part 1)

- In the Japanese market, the 'with surgery' portion of patients (estimated number of outpatients) has grown over the past 20 years. On the other hand, the patients 'without surgery' number has stayed steady (Fig. 4-1). The number of abdominal operations is going down, whereas patients with minimally invasive surgical procedures (endoscopic surgery, laparoscopic surgery and percutaneous transluminal angioplasty) has been increasing. As for diagnosis, there has been growth in all four types represented, but especially in CT scans (Fig. 4-2). In addition, other than in the malignant tumor category, there has been a lack of increase in the 'without surgery' portion of patients (Fig. 4-3), and 'with surgery' patients are the key drivers of the growth of all patients. This trend is especially characteristic of digestive disease and heart disease, and minimally invasive surgical procedures is the leading reason. Another observation is that dialysis treatment is still growing in Japan.
- As for data on medical devices in Japan, Fig. 4-4 lists products (big volume, middle classification products that I selected) in which the total of 'output and imports' is more than 50 billion yen.

Figure 4-1 Number of patients

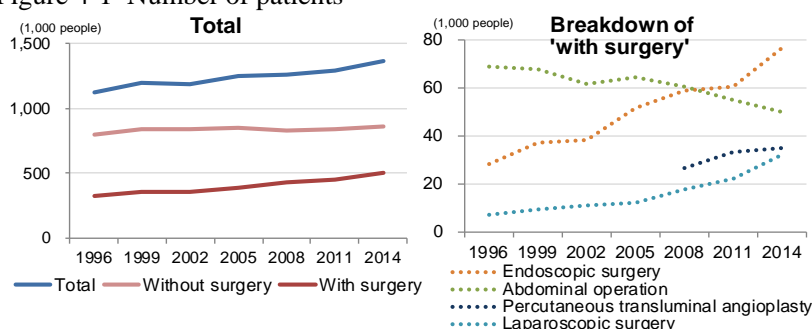


Figure 4-2 Number of diagnoses

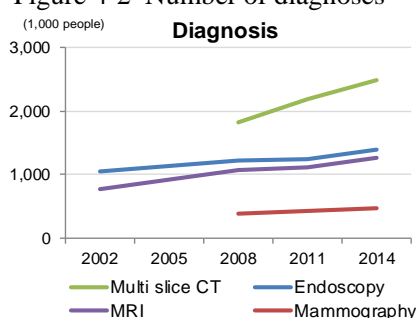
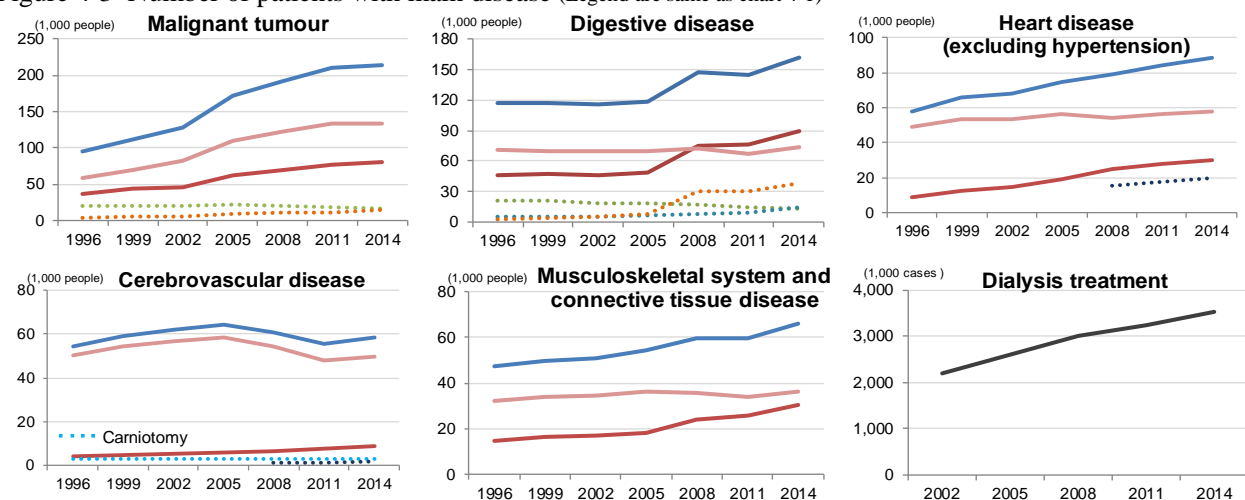


Figure 4-3 Number of patients with main disease (Legend are same as chart 4-1)



Source for Figs 4-1 and 4-3 (excluding dialysis treatment): Ministry of Health, Labour and Welfare, "Patient Survey".

Sources for Figs 4-2 and 4-3 (only dialysis treatment): Ministry of Health, Labour and Welfare, "Survey of Medical Institutions" and "Hospital Report".

Note. The data is the monthly data for September of each survey year.

Figure 4-4 Output + Import (2014)

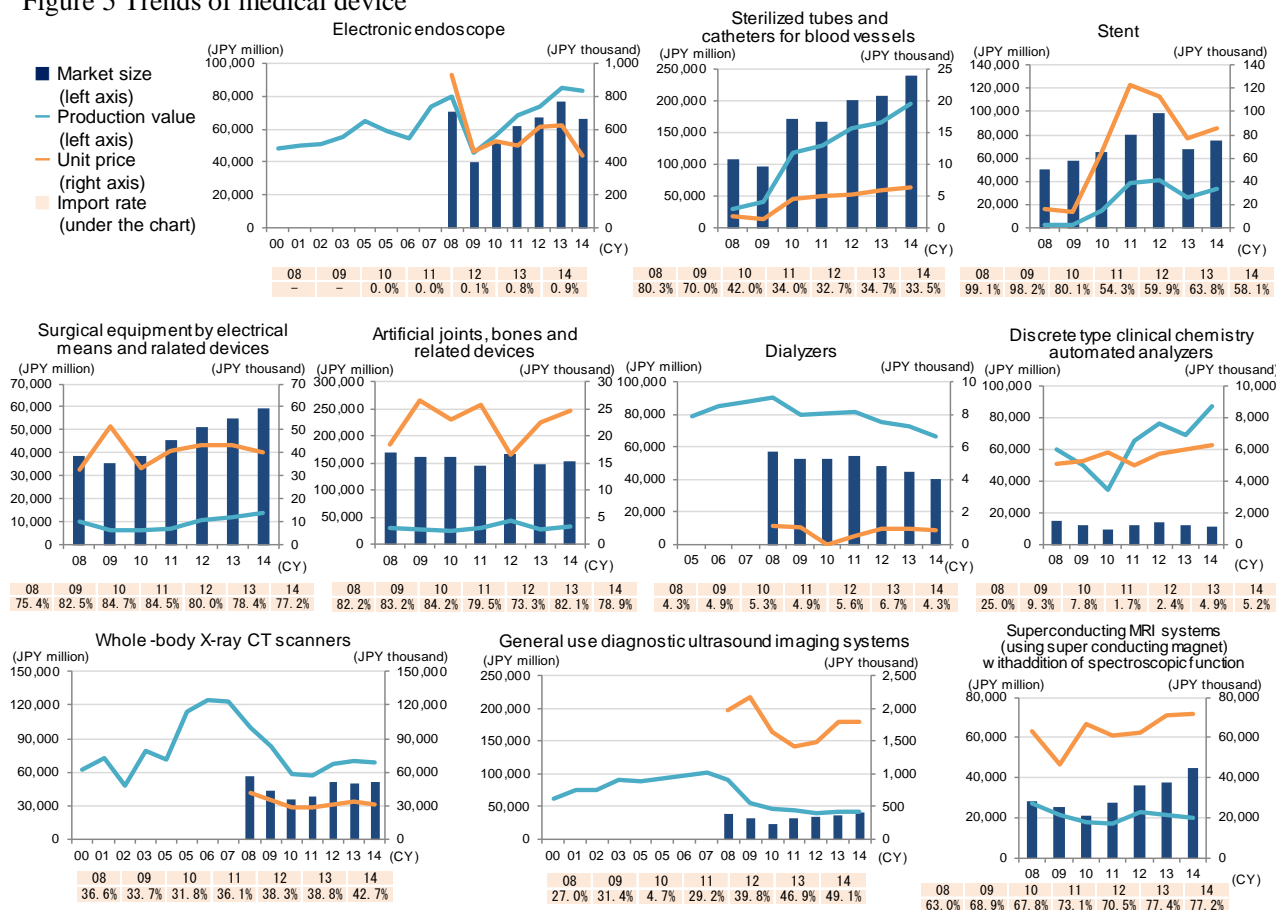
Therapeutic instrument		JPY million	Products picked up in Fig. 5	JPY million	Diagnostic equipment		JPY million	Products picked up in Fig. 5	JPY million
Tubes and catheters		404,226	Of which, Sterilized tubes and catheters for blood vessels	276,048	Endoscopes		200,459	Of which, Electronic endoscopes	84,174
Implantable devices and materials		365,281	Of which, Stents	76,625	Medical X-ray CT scanners		97,432	Of which, Whole-body X-ray CT scanners	90,065
Contact lenses		210,826	Of which, Artificial joints, bones and related devices	153,306	Diagnostic ultrasound imaging systems		90,160	Of which, General use diagnostic ultrasound imaging systems	62,549
Blood donor and transfusion devices, infusion devices and infusion apparatus		170,856			Diagnostic X-ray systems		74,354		
Extracorporeal blood circulation equipment		170,799	Of which, Dialyzers	68,249	Magnetic resonance imaging (MRI) systems		66,682	Of which, Superconducting MRI systems (using superconducting magnet) with addition of spectroscopic function	54,630
Injection and puncture devices		103,769			Testing equipment for biophysical phenomena		53,323		
Artificial internal organ control apparatus		64,790			Radiographic X-ray equipment		51,824		
Dental metals		84,520			Clinical chemistry test equipment		130,822	Of which, Discrete type clinical chemistry automated analyzers	87,379
Apparatus for ligature and suture		71,479							
Surgical equipment by electrical means and related devices		72,052	Excluding Operation microscopes	59,726					

Source. Ministry of Health, Labour and Welfare, "Statistics of Production by Pharmaceutical Industry".

5. Medical needs & device supply in Japan (part 2)

- Based on the medical needs mentioned in part 1, Fig. 5 shows the trend of medical device supply in Japan. There are variations in terms of 'needs', 'level of unit price', and 'import rate'. I make some short comments on each product type. (As for Fig. 5 and unit price, for some products, large movements of the unit itself make it difficult to find obvious correlations.)
- Endoscopy: Growth is almost entirely in domestic shipping. Compared to growth in the number of patients, growth of the endoscopy market is slow.
- Catheters: Growth of domestic shipping is very large. This category has near-parallel, but little, growth of market size, unit price, and domestic shipping. Along with the growth in patients, the products are getting value-added and unit price increases.
- Stents: The import rate is still very high, as is the unit price. However, the unit price has not risen recently; it is leveling off.
- Surgical electrical machines: The import rate is high, similar to that for stents. The market size has grown steadily.
- Artificial jaws: In contrast with the growth in patients, the artificial jaw market size has diminished. The import rate is high, similar to that of surgical electrical machines.
- Dialyzers: Domestic production is large in this market, and patient numbers are still growing, but the overall market size has diminished. Some of the assumed reasons are 1) down-trend of the unit price and 2) saturation of the products.
- Automatic analyzers for clinical chemistry: Compared to other products, total output is much higher than that for domestic shipping. The model is based on export, and the production value has grown steadily.
- Diagnostic equipment: Growth in supply of equipment for CT scans and diagnostic ultrasounds has not been as strong as the growth in the number of these procedures. In contrast, growth in the production value of MRI equipment seems to be outpacing growth in their usage, but an increase in the import rate is contributing to this situation.

Figure 5 Trends of medical device



Sources. Ministry of Health, Labour and Welfare, "Statistics of Production by Pharmaceutical Industry".

Note. Market size = Production value + Import - Export; Unit price = Production value / Production volume; Import rate = Import / Market size.

6. Supplement: Trend of product development

- This chapter is supplementary, to show new medical device products relative to the FDA and PMDA. Here I note the activity levels of various fields (2005-2015), using FDA and PMDA approvals of new products.
- Firstly, in Fig. 6-1 I note the PMA trends of the FDA. The highest number of approvals is in cardiovascular. A second tier in terms of approvals comprises microbiology and pathology. A third consists of orthopedics and surgery (general and plastic). As for VC investments in medical device (2014-15), cardiovascular and orthopedics still seem to be active, based on Silicon Valley bank report Trends in Healthcare Investments and Exits 2016. Of course, FDA approvals are often preceded by approvals elsewhere, be it the CE in Europe or approval in an emerging country; thus, this number doesn't show the latest trend. However, as this is the largest market of the world, its new approvals trend is important.
- On the other hand, as Fig. 6-2 shows, new approvals in Japan are most active in the cerebrovascular, respiratory and neuropsychiatric fields. A second tier consists of orthopedics, plastic surgery, and dermatology. However, what is most important is that 80% of the new approvals are from overseas; new approvals of Japanese developed products are just 20%. Thus, it is correct to surmise that FDA approval has a direct effect on PMDA approval.
- As for FDA approvals relative to Japanese companies, PMA approval (all categories, including with-predecessor type) has increased recently, but is still about 30 in the 2010s. As for the 510(k) category, an appropriate number of Japanese products have been approved, but such approval does not equate to a good presence of Japanese companies in the global market, because 510(k) products of Japanese companies are a small fraction of the overall products.

Figure 6-1 Numbers of PMA approvals (non-predecessor type only)

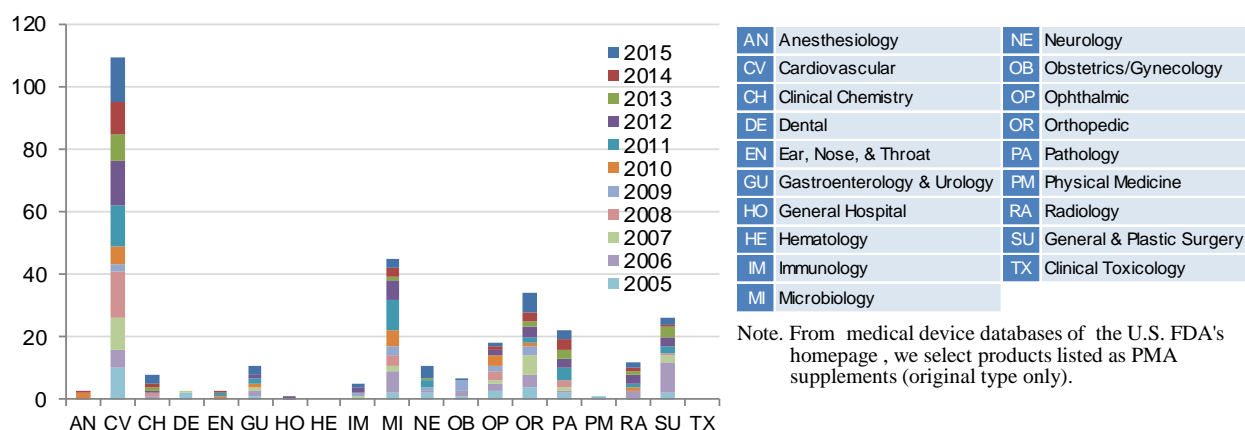
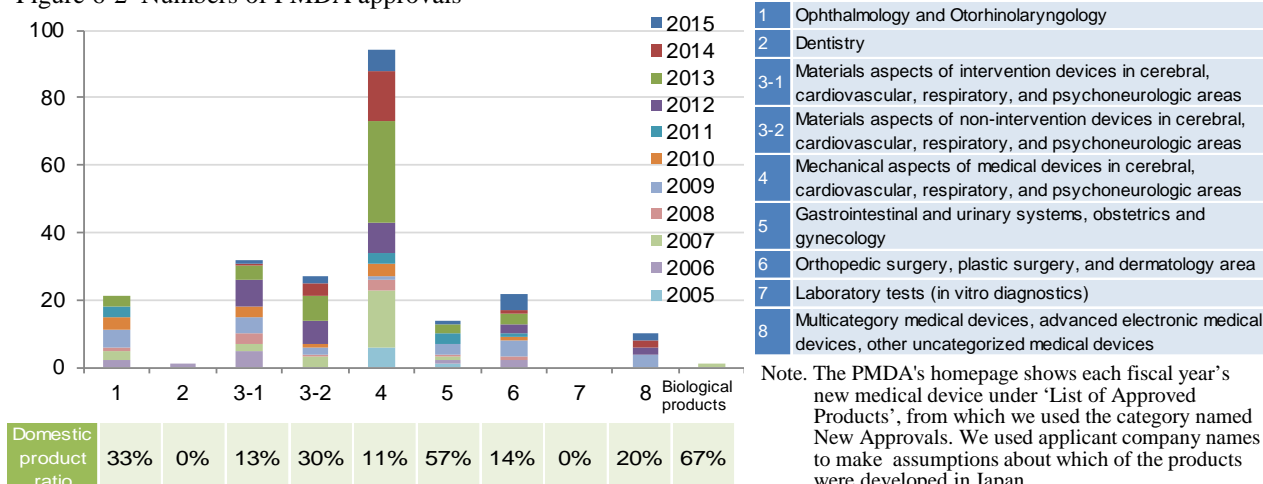


Figure 6-2 Numbers of PMDA approvals



Notes. Premarket Approval (PMA) application is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

Premarket Notification 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective as (that is, substantially equivalent to) a legally marketed device that is not subject to PMA.

In its approval of medical devices, the PMDA (Japan) evaluates the quality, efficacy, and safety of high-risk medical devices (mainly classes III and IV) in light of current scientific and technological standards.

7. Building logic to properly match the 'business development' function with the global market

- The previous pages outline the Japan, U.S. and China markets. Here, and summarized in Fig. 7-1, we cite characteristics of each market. For the U.S., the major issue is to reorganize healthcare systems due to levels of total healthcare expenditure. For China, the major issue is to meet their rapid growing medical needs. At the same time, both markets have volume; therefore, they each have a base cargo function in global trade. Of course, the overall Asian market, including ASEAN, is important but, individually, the country markets are still small, as is apparent on page 1. Other considerations include the increasing trends in acquisitions (see Abbott and St. Jude Medical).
- On the other hand, in Japan's market, social welfare spending is negatively impacting national finance and there are complications in various relations between medical care and products. However, it is obvious that the need for minimally invasive surgical procedures has increased along with the aging of the population, and we can say that these trends constitute a significant market size in Japan.
- One of the more important issues, other than market size, is the number of high value-added products that are developed and utilized. As seen on page 5, many of the high unit price products, such as stents and electrical surgical machines, are foreign product imports. Also, abundant supply, which has suppressed unit prices, is concurrent with diminished market size. This situation is more obvious when you see the situation of FDA approval and PMDA approval on page 6. After all, an excess of imports over exports itself is not, in and of itself, a substantial problem. What is a current substantial problem for Japanese companies is a shortage of domestically developed high value-added products.
- Issues that Japanese companies face are listed in Fig. 7-2. I feel that it is especially important to refer to impacts of products on the global market. However, just pointing out the problems does nothing to change the situation. To execute change and penetrate the global market, there must be logic behind the setting of the business development function. And each company needs to understand the necessity for that logic. On the last page, I try to dig into the key points more precisely. (This section 7, along with the following section 8, are very much based on our regular discussions with Mr. Kenneth McDonnell and Mr. Jack Moorman of US-Japan MedTech Frontiers and I thank them very much.)

Figure 7-1 Current market situation of medical device industry

- In the global market, Chinese companies have grown and mega U.S. companies, which go ahead and commit to the ecosystem, are still major players.
- Japan's domestic market includes the following medical care/product issues: 1) in some cases the medical needs have grown but the market size has not, 2) in other cases the medical needs have grown but the accompanying growth in the market has been grabbed by foreign companies, and 3) in still other cases both the medical needs and the market size have grown and global expansion has been realized but these movements take a long time to develop.
- High value-added products from Japan are relatively limited.

Figure 7-2 Issues facing Japanese companies

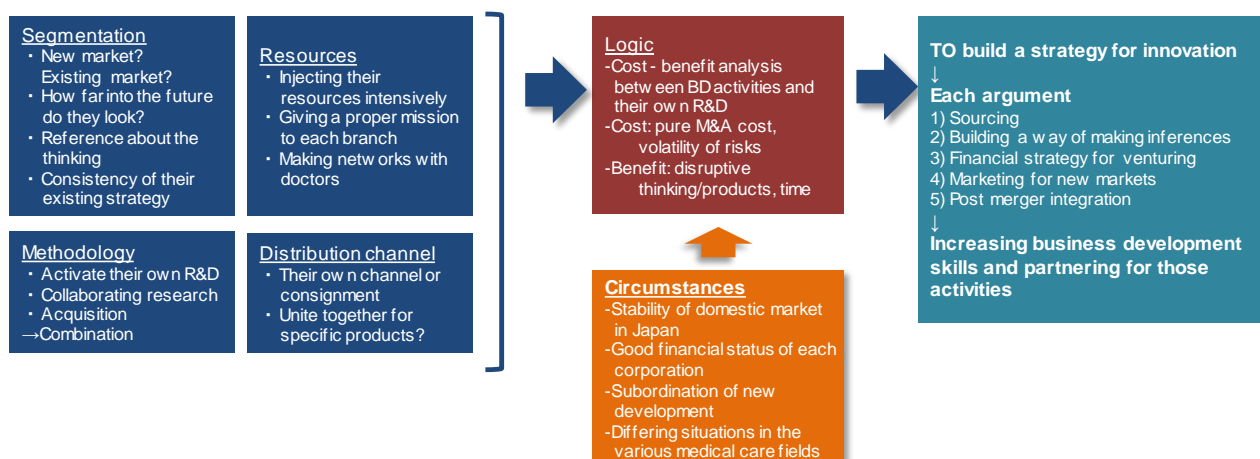
- Necessity for change is relatively low because the domestic market has sufficient volume.
 - Improvement-type development is major because of technology-driven thinking. The same situation exists in terms of collaborative research with universities.
 - Japanese companies are not good at identifying their strengths and weaknesses relative to the current business environment and choosing new business fields accordingly.
 - Weak connections with doctors, limits knowledge both of the latest trends and of related developments, including possible acquisition opportunities.
 - At the same time, resources (staff, money, etc.) are weak.
- ➡ Necessity of developing a logic behind the setting of the business development function in order to penetrate an expanding global market

8. Strategy for innovation by Japanese med-tech companies

- The overall problem is complex, but I suggest four general approaches.

- 1) Segmentation:** There are two ways to segment: 1) expand the existing market and 2) enter a brand new market. As for 1), the advantage is the existence of established distribution channels, but it has a pitfall of tending to be used primarily in the development of *kaizen*-type products. On the other hand, 2) is good in terms of venturing, but it has drawbacks in terms of both envisioning the future and knowing how to get into a new field. Also, as we saw on the previous page, in terms of both needs and development, booming areas have firmly established biases; thus, it's difficult to penetrate into already crowded fields. Unfortunately, Japanese companies often lag U.S. and European companies in many medical device fields. Targeting a niche field is better as a global strategy, but a major issue is how narrowly to define the niche. Also, it is very important to ensure that entry into new fields is consistent with the existing overall strategy.
 - 2) Methodology:** There are three methods: 1) act on one's own R&D, 2) do collaborative research, 3) acquire. Conventionally, 1) and 2) are the main ways. As for M&A, basically, in the early stage the entry is inexpensive but there are difficulties in terms of vision, and in the later stages the opposite is true. For Japanese makers the lack of M&A is particularly because of their difficulties in learning about product ideas, as hypotheticals are difficult topics for them to reference. Also, in terms of method 2), it is important that the aim is not just to develop technology but also to make products. It seems to be a weak point for Japanese makers. What is needed is to do combinations of methods 1), 2), and 3) strategically. There are opportunities for Japanese companies to penetrate the U.S. market, especially in the development stage, and the methodology aspect must be given due consideration.
 - 3) Resources:** It is important to focus on the innovation field; thus, companies should consider injecting their resources intensively for all kinds of business development, not just for their own R&D, and seek a balance between BD and R&D. Competency in BD activities such as M&A require some maturing through experience.
 - 4) Distribution channel:** Although it is another big issue, I do not touch on distribution channels, because of limited space in this paper. However, I want to just point out that Japanese companies may need to address this issue cooperatively, because individually their overseas distribution channels are in very short supply.
- For a firm to reach consensus on, and execute, its strategies, logic is a critical attribute. Each company needs to do cost - benefit analysis, weighing between BD activities and their own R&D. In this case, 'cost' is pure M&A cost, volatility of risks, and so on. 'Benefit' is disruptive thinking/products, time, and so on. The point is whether companies consider overseas M&A and collaborative research to be means to decrease cost and increase benefit. In order to attain the requisite logic, companies, especially Japanese companies, need to develop their mid-level management know-how.
 - Each company needs to build a consistent strategy to address each of these issues and develop high value-added products. For each issue, the company needs to logically consider 1) the way of collecting information, 2) the way of drawing inferences from such information, 3) financial strategy, 4) marketing, and 5) PMI. In these respects, it is important for Japanese companies in the med-tech field both to increase their individual business development skills and to find ways to work collaboratively. My colleagues and I are trying to think of ways to support our client companies in their various situations.

Figure 8 Important subjects and strategy for innovation



Sources. Various data.

All inquiries should be directed to the Economic & Industrial Research Department,
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