

Challenges Facing New Entrants into the Medical Device Market and Suggested Business Expansion Strategies

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With a market size of about 400 billion dollars as of 2014, the global medical device market has been growing rapidly, and this growth momentum is expected to continue. Spurred on by a market upswing, demand for innovative new technologies has been growing. Given this situation, even manufacturers specializing in other fields can find opportunities to enter this market. The medical device market where physicians make purchasing decisions is a lucrative market because of the high levels of added value offered by medical devices. Nevertheless, the key factors for success (KFS) in the market are not limited to those related to technological strengths.

Actually, many newly participating manufacturers have failed to expand their businesses after entry into this market. The causes of failure are often attributable to an inability to understand the importance of sales strategies in the medical device market. Being proud of their outstanding technological capabilities, some Japanese manufacturers tend to believe that “if we offer excellent products, they will sell without difficulty.”

In pursuit of “enhancing sales functions,” which is the most critical and most important factor for success, new entrants must meet five product/service requirements. These requirements are derived from factors that affect physicians' purchasing decisions. Successful manufacturers have been able to acquire and maintain highly effective sales functions by implementing measures designed to satisfy these requirements. It is difficult to expand business simply by offering superior products in the market.

To satisfy these product/service requirements, efforts to devise and implement necessary measures must start at the product development phase. In studying the measures, new entrants must actively consider the options of incorporating the management resources of other companies such as through undertaking mergers and acquisitions (M&A) and/or entering into partnerships. Another vital measure for business expansion is to transform a company's existing development management techniques to conform to the development environment of this market.

For more comprehensive discussions about the medical device business, please see the July 2014 issue of *Chiteki Shisan Souzou (Knowledge Creation and Integration)* featuring “Iryo-kiki biznesu ni yoru jigyo seicho wo gensou ni owarasenai tameni (Don't let projected business growth driven by the medical device business end up being a mere dream)” (only available in Japanese).

I Opportunities to Enter the Medical Device Market from Other Industries and Key Factors for Success

1 Entry opportunities can be found in the areas of new technologies that contribute to the creation of new value

The medical device market has been growing rapidly worldwide, and this growth momentum is expected to continue. In developed countries, fueled by aging populations, diagnostic and treatment devices for cancer, as well as devices and equipment in the area of orthopedics, have achieved high sales growth. In emerging markets, with the increase in the number of middle-income earners, lifestyle-related diseases are expected to increase, leading to increasing demand for devices and equipment in the area of cardiology.

Given the growing demand for medical care, every country is facing a pressing need to manage rapidly increasing medical costs. To address this issue, medical device manufacturers have been striving to develop innovative technologies and new services. In addition to working to develop new technologies on their own, major medical device manufacturers have been actively undertaking mergers and acquisitions (M&A) in attempts to acquire new technologies. In view of this situation, making use of their own technologies to develop new technologies that are needed by the growing medical device market will provide good opportunities for manufacturers intending to enter this market from other industries.

What is particularly important for new entrants to achieve success in this market is their ability to develop a strategy aimed at identifying and satisfying the needs of physicians. This is because physicians are often the ones who make purchasing decisions for medical

devices offering high added value and thus enabling a company to expect high profitability.

This paper discusses important issues that manufacturers specializing in other fields should consider in developing an entry strategy, especially for the medical device market where physicians make purchasing decisions.

2 Characteristics of the market where physicians make purchasing decisions

The products for which physicians make purchasing decisions include therapeutic devices and ancillary consumables as well as critical test, measurement and diagnostic equipment and their consumables, which significantly affect treatment outcome. These products are sold to each department of a hospital (Figures 1 and 2). In general, such medical devices offer high added value, thus enabling manufacturers to earn high profits. However, it is often the case that the world's largest manufacturers have already developed deep relationships with their customers (physicians). On the other hand, as for general-purpose consumables such as syringes, illustrated at the left of Figure 1, a hospital's purchasing department is often responsible for procurement and an agent delivers such products.

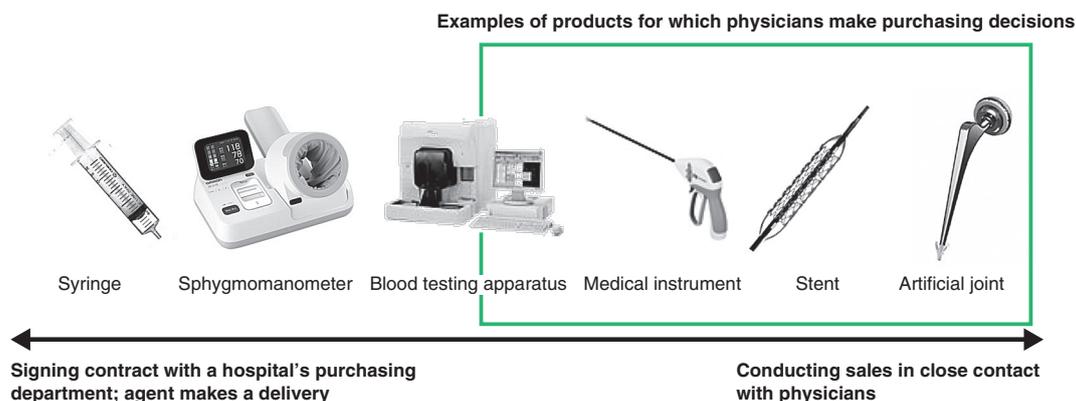
In light of this situation, it appears difficult for new entrants having no contact with physicians to participate in the market and then expand their business there.

3 Acquiring a customer base is the key factor for success in the medical device market and is a critical requirement for successful competition

The key factors for success (KFSs) for manufacturers operating in the medical device market are:

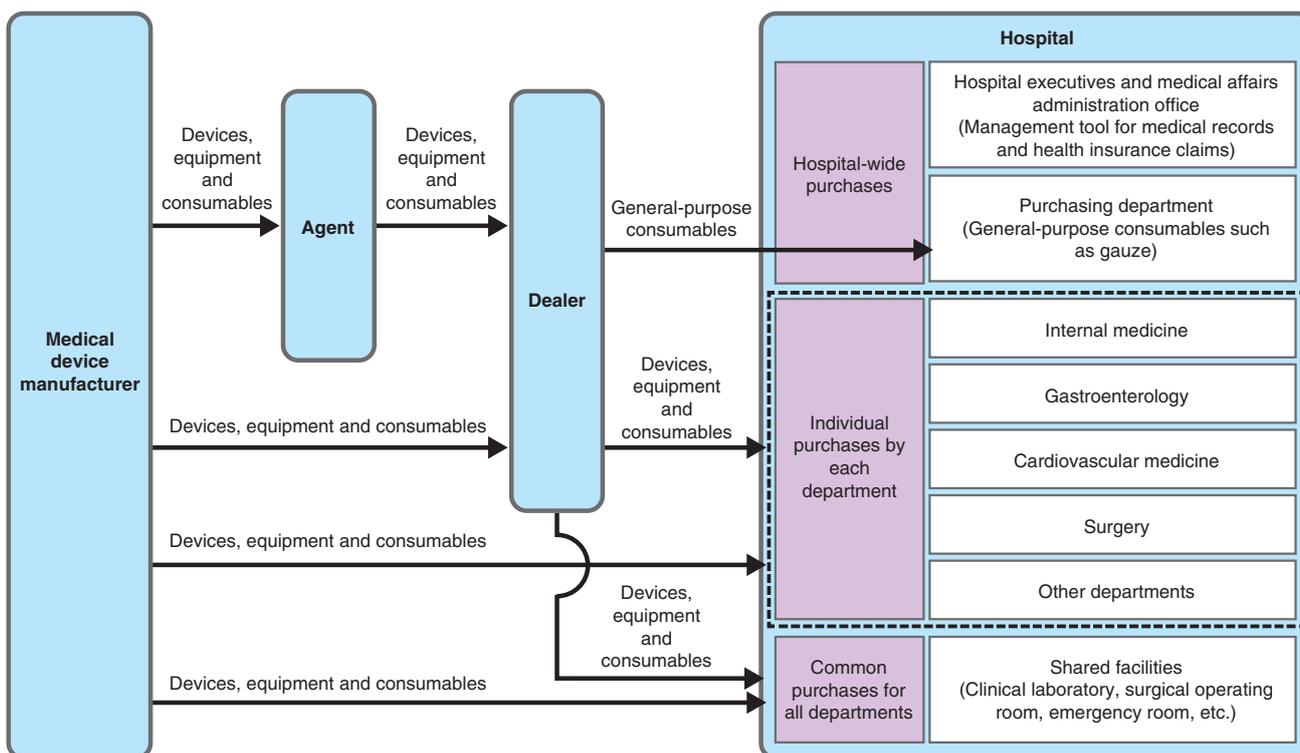
- (1) Sales functions that enable a company to build physician loyalty

Figure 1. Examples of medical devices (products)



Sources of photos: Syringe: Terumo; sphygmomanometer: Omron; blood testing apparatus: Sysmex; medical instrument: Covidien; stent: Medtronic; artificial joint: Stryker.

Figure 2. Distribution channels for medical devices and consumables



- (2) Ability to develop and sell products employing technologies having high levels of novelty in conformity with the Pharmaceutical Affairs Law that applies to medical devices
- (3) Ability to develop killer products, ^{Note 1} which play a significant role in building physician loyalty

Only when a manufacturer has these functions and abilities, can it expect high profitability. What are particularly important among them are “sales functions that enable a company to build physician loyalty” mentioned in Item (1), above. Without knowing the importance of these functions, it is difficult for a company to expand business even if it is able to enter the market. In Chapter II, the cases of Japanese manufacturers that failed to enter the market are discussed, and typical causes of failure that new entrants are prone to encounter are analyzed.

II Causes of Failure of New Entrants from Other Industries

1 Failed case (1): Company A

(1) Despite having strength in technology, Company A failed in terms of sales

With a core revenue source derived from products related to electronic equipment, Company A is a well-known

leading manufacturer for its high level of technological capability within its relevant industry.

Because the declining trend of the electronic equipment industry has become apparent, Company A looked to the medical device business as a next-generation growth engine. In response to this management decision, a team was formed under the direct control of top management. By targeting peripheral businesses related to the rapidly growing medical device market, the company created multiple development themes by using its own technology as core technology. Jointly with its existing research and development centers, the newly formed team worked to develop and sell their products. In so doing, the company pursued the most straightforward business model of “developing its products by drawing on its high level of technological capability and promoting sales on its own.”

As might be expected of a company known for its high technological level, development proceeded smoothly for all themes, and it appeared that Company A would be able to launch new products having competitive advantages. However, when development approached the stage involving the procedures related to applying for approval required under the Pharmaceutical Affairs Law and when the company initiated studies of specific sales methods, a problem arose. The studies revealed that the company would be unable to achieve the anticipated level of sales for each theme, thus making business unprofitable. In order to develop sales channels aimed at physicians at its own expense, the level of sales that could be expected was small and there

was no prospect of recouping its investment. As a result, Company A decided to abandon some of the development themes.

Fortunately, some major competing manufacturers recognized high product functionality among some of the other development themes, and asked the company to enter into a joint development or sales partnership. By limiting the themes to these themes only, Company A decided to continue development with the aim of bringing new products to market by assuming original design manufacturing (ODM) or sales outsourcing.

Such being the case, for some themes, Company A gave up the idea of selling its products on its own, which is regarded as the business model generating the highest profit.

(2) Misjudgment of market structure and sales cost

If the case of Company A is viewed from the perspective of the three key factors for success, which were explained in Chapter I, a problem existed in terms of the sales functions from the early stage of product planning (Table 1). Even though all development themes were those pursued to develop killer products, each of the products was targeted at different clinical departments. In addition, the company was unable to anticipate the fierce competition it encountered in acquiring sales channels after the release of new products, incurring a higher sales cost. The actual cost of sales was more than four times higher than the estimated cost at the planning stage. The company's confidence in its high technological strength gave rise to optimism, that is, "if we develop superior products, such products will sell without difficulty."

Focusing on the development themes aimed at a specific clinical department or a specific treatment method and working to provide a set of products to meet such specific needs by actively using technologies developed by other companies in addition to their own would have enabled the company to concentrate on creating a sales channel for only one single clinical department. Making investment to build a single sales channel at its own expense could have provided the company with the likelihood of developing a profitable medical device business.

Company A failed to notice the importance of sales strategy, and developed its strategy to enter the medical device market based only on the idea of "doing what we can with our own technologies." As a result, Company A failed before it was even able to put its own products on the market.

2 Failed case (2): Company B

(1) A few years after the launch of a product, Company B withdrew from the market

Similar to Company A, a primary source of Company B's revenue is the electronic equipment market. Company B is a major manufacturer well known for its particular electronic equipment having high market share.

While its core business was reasonably profitable, Company B was concerned about its "one-legged" approach—that of relying only on one specific business, and entered the medical device market. The company was successful in developing products centered on its

Table 1. Cases of failed market entry

Key factors for success in the medical device market where physicians make purchasing decisions	Company A		Company B	
	Actions	Success or failure	Actions	Success or failure
Sales functions to build physician loyalty	<ul style="list-style-type: none"> Failed to consider the need to invest in developing sales functions. As a result, for some products, Company A plans to undertake ODM for major competitors or to outsource sales functions. 	Failure	<ul style="list-style-type: none"> All sales functions were left in the hand of a partner; Company B had no contact with physicians (users). 	Failure
Ability to develop and sell products employing technologies having high levels of novelty in conformity with the Pharmaceutical Affairs Law	<ul style="list-style-type: none"> Some products are to be handled by a major competitor that developed the products jointly with Company A. 	Failure	<ul style="list-style-type: none"> Because the developed product was test equipment presenting low risk of medical accidents, it was relatively easy to acquire approval under the Pharmaceutical Affairs Law. 	Successful
Ability to develop killer products	<ul style="list-style-type: none"> Company A's engineers developed four products on their own. The four products developed were all superior. With their high functionality, they proved highly effective in improving physicians' treatment outcomes. 	Very successful	<ul style="list-style-type: none"> Company B developed a more compact device as compared to those of competitors. Because a compact device was new at that time, it was a breakthrough product. For clinic physicians who were the target customers, its simple operating procedures were also well received. 	Successful

Note: ODM = original design manufacturing.

own technology and putting them on the market. The marketing and sales functions were outsourced to a partner manufacturer having a sales channel with physicians. The company made a good start in selling their products. However, in a few years, sales ceased to grow and profitability kept declining. As a result, the company was unable to recover its huge investment, and decided to withdraw from the medical device business.

(2) Company B failed to notice changes in factors affecting purchasing decisions

The problem with Company B was that because the company believed that it could maintain competitiveness if it continued to offer high-quality products, it failed to notice changes in the needs of physicians. In other words, the company did not consider acquiring the support of physicians from aspects other than product functionality. Even though the price was high, the company's product was compact and offered high functionality. Because the product concept itself was novel, the product was highly competitive in terms of functions, enabling the company to generate high profits for a few years. However, a competitor launched a product similar to Company B's product, albeit somewhat inferior in terms of functionality, with an endorsement from a renowned physician leading the biggest faction in the area related to Company B's product. Since then, the interest of many physicians was directed towards the product of the late-coming competitor. Without an endorsement, Company B lost its competitive advantage. The reason for good sales enjoyed by Company B at the beginning of product launch was that there were no other alternative products. Because Company B left its sales activities in the hand of a partner, the company was unable to notice the actions of the competitor, and took no action until the decline in profitability became serious.

If Company B would have developed deep relationships with physicians (users), recognized the importance of endorsements and taken similar actions at an early stage after noticing the actions of its competitor, it might not have been deprived of its competitive strength.

In a manner similar to that of Company A, Company B also failed to notice the importance of sales strategy, and entered the market with the belief that "we can win if product functionality is high." As a result, Company B failed.

3 What new entrants lack

The cases of Companies A and B described above are not exceptional. Japanese manufacturers having no experience in the medical device business and trying to enter this market tend to think little of the importance of sales functions because of their confidence in their high technological strengths. They are strongly inclined to make the best use of their own technologies to compete

in the market, and are apt to focus their competitive strategies only on the area of product functionality. While technological strengths are, no doubt, vital in the medical device business and constitute one of the key factors for success, such strengths can show results only when combined with enhanced sales functions. Without enhanced sales functions, it is not possible to ensure business expansion.

In Chapter III, by focusing on strengthening sales functions, the authors discuss the factors affecting purchasing decisions that are specific to physicians, which new entrants from other industries must know, and introduce business models adopted by manufacturers that were successful in market entry.

III Factors Affecting Physicians' Purchasing Decisions and Business Models Adopted by Successful Manufacturers

1 Specific factors affecting physicians' purchasing decisions

The basic needs of physicians include adopting new medical technologies that are gaining in popularity to improve treatment outcomes, treating patients in the most appropriate manner and in the shortest possible time and equipping themselves with the latest technology within the limited time available to them for choosing the most effective medical devices.

Most physicians try to spend as much time as they can for treating patients and increasing their knowledge about diagnosis and treatment. Therefore, in most cases, they cannot afford to spend time examining new therapeutic and diagnostic devices, learning by trial and error how best to utilize new technologies or instructing their junior colleagues.

As a major principle governing the behaviors of physicians, they have "awareness of unseen horizontal relationships." Rather than the hospital at which they work, they identify themselves strongly with a specific medical society, master-apprentice relationship or the top-ranked hospital in hierarchical permutation for a group of hospitals. By identifying themselves with one of these organizations, they are likely to make purchasing decisions in accordance with the policy of such an organization.

Three specific factors affect physicians' purchasing decisions.

- (i) Contributing greatly to the improvement of one's own treatment outcomes
- (ii) Having high product/company visibility

- (iii) Contributing to the improvement of work efficiency (saving time required for selecting a series of devices, learning by trial and error, instructing junior colleagues and other activities related to medical care)

There are five requirements for medical devices to meet these needs.

- ① A product must be a killer product contributing to the improvement of treatment outcomes.
- ② The product must be endorsed by a medical society and/or key opinion leaders (KOLs). ^{Note 2}
- ③ Peripheral devices and instruments that are used for treatment together with the killer product can be obtained as a set.
- ④ The product enables easy use of an optimal treatment method.
- ⑤ A training environment where physicians can learn new therapeutic technology by experience in the shortest possible time is available.

Added value that meets the needs of physicians is not limited to the outstanding performance of a product. Supporting physicians' work also constitutes value that a manufacturer must provide. Suppose Product A has superior functions and Product B has somewhat inferior functions as compared with Product A but offers added values and services such as those listed in Items ②,③,④ and ⑤ above. Very few physicians would choose Product A.

2 Manufacturers that pursued the enhancement of sales functions achieved success

Medical device manufacturers that have been successful in the market have made efforts not only to develop superior products but also to enhance sales functions in consideration of specific factors affecting physicians' purchasing decisions, as explained in Section 1, above.

For example, DePuy Synthes, which is part of the Johnson & Johnson group of companies and is one of the global leaders in this market, specializes in orthopedic products and offers a comprehensive portfolio of artificial joints. The company has been expanding its product lineup for each joint part (each surgical treatment) such as hip, knee and shoulder replacement. At the same time, the company also sells educational programs to provide surgeons with a wide array of surgical techniques suitable for each joint part. In order for surgeons to become familiar with surgical techniques using these artificial joints, thereby increasing the visibility of its product as an easier-to-use item, the company offers educational seminars for surgeons and provides training courses to impart the latest technologies and procedures at its own training facilities. In light of the three factors

affecting physicians' purchasing decisions, which were explained in Section 1, above, selling educational programs and providing training courses would contribute to "(iii) the improvement of work efficiency." Among emerging markets, the company targets India, in which educational institutes were established to help provide surgeons and healthcare professionals with the latest technology. In addition, the company sends skilled healthcare professionals to locations where therapeutic needs are not met to expand the areas where such professionals can actually use their skills, thereby promoting the sales of its products.

Stryker, another orthopedic giant, has been successful in broadening its product lineup that can be sold via the same sales channel through the acquisition of medical device and instrument manufacturers. By providing a primary product and peripheral equipment (a group of devices and instruments) as a set, the company aimed to expand the market share within the same sales channel. Furthermore, the company has implemented various measures to increase visibility of its products, which included holding luncheon seminars at international conferences and having products endorsed by key opinion leaders through encouraging them to write papers and make presentations at medical society conferences.

As such, major medical device manufacturers have been taking a variety of measures in consideration of the factors affecting physicians' purchasing decisions (Table 2). In view of these efforts, no matter how high the functionality of a product offered by manufacturers entering this market from other industries, it is not easy for them to expand business independently.

In Chapter IV, the authors describe the steps toward enhancing sales functions, which is necessary for new entrants from other industries to achieve business expansion, and suggest the measures that should be taken.

IV Suggested Business Expansion Strategies for New Entrants from Other Industries

1 Processes toward enhancing sales functions with an eye on business expansion

To enhance sales functions in the medical device market, as shown in Table 2, the products/services offered by manufacturers must meet the five indicated requirements in consideration of the factors affecting physicians' purchasing decisions. What is vital in considering the measures to meet such requirements is to examine the measures from the perspective of "measures to be taken must definitely be effective in expanding business." The measures that would be effective in expanding business

Table 2. “Product/service requirements” in consideration of the three factors affecting purchasing decisions and examples of measures taken by major medical device manufacturers

Factors affecting physicians' purchasing decisions	Product/service requirements	Measures taken by major medical device manufacturers
(i) Contributing to the improvement of treatment outcomes	① A product must be a killer product contributing to the improvement of treatment outcomes.	<ul style="list-style-type: none"> • Having close contact with KOLs and understanding their needs. • Acquiring new technologies and products through M&A or by entering into partnerships.
(ii) High product/company visibility	② The product must be endorsed by a medical society and/or KOLs.	<ul style="list-style-type: none"> • Holding luncheon seminars to promote products. • Having the product endorsed by KOLs through encouraging them to write papers and make presentations at medical society conferences.
(iii) Contributing to the improvement of work efficiency	③ Peripheral devices and instruments that are used for treatment together with the killer product can be obtained as a set. ④ The product enables easy use of an optimal treatment method. ⑤ A training environment where physicians can learn new therapeutic technology by experience in the shortest possible time is available.	<ul style="list-style-type: none"> • Selling the product together with instruments, devices and consumables as a set. • Acquiring or entering into a partnership with a company that offers related equipment. • Issuing scientific journals • Establishing an accreditation system for physicians and holding educational seminars to help physicians acquire the latest technology. • Setting up the company's own training facilities.

Notes: KOL = key opinion leader, M&A = mergers and acquisitions.

are explained in the following paragraphs by dividing the processes toward business expansion into five steps.

Figure 3 shows five steps in the processes toward business expansion. In particular, Japanese manufacturers are prone to fail to act properly to meet “product/service requirements ② to ⑤” that should be satisfied at Steps 4 and 5 in the “market launch and business expansion phase.” In addition, they tend to misidentify the time to initiate measures to satisfy these requirements.

For example, the measures that are particularly effective at Step 4 are to appeal to KOLs who can exert influence by leveraging physicians’ “awareness of unseen horizontal relationships,” which was explained in Chapter III. By having KOLs endorse a company’s products and developing an impression that “KOLs are recommending the company’s products,” the company will be able to boost the possibility of expanding its market share. To be successful in taking this measure, it is desirable to adopt an approach of getting KOLs involved in the company’s efforts from the “product development phase” (which is Product/service requirement ②). Most KOLs are unlikely to be motivated to recommend products in which their own ideas are not represented. Therefore, even if the company contacts KOLs after the completion of product development, it is most likely to be difficult to have them endorse its products.

At Step 5, at which “sales channel share expansion” is pursued, the most important action is to create a system whereby the company can offer a series of medical devices that are used together with the relevant product for the same therapeutic method (which is Product/service requirement ③). In order to have such a system ready for business expansion, it must be noted that time is necessary to identify devices and instruments that are suitable as those that are used with the company’s product and to examine the methods to procure such ancillary

devices. In most cases, procurement options include self-development, sales partnerships with other companies, acquisition of technology/business owned by other companies and joint development with other companies. Considering the time required to create a system enabling the offering of a series of products including the time necessary for gathering and analyzing information, negotiating for development, acquisition or partnership, as well as the time necessary for integration after acquisition, efforts to this end should begin at an early stage.

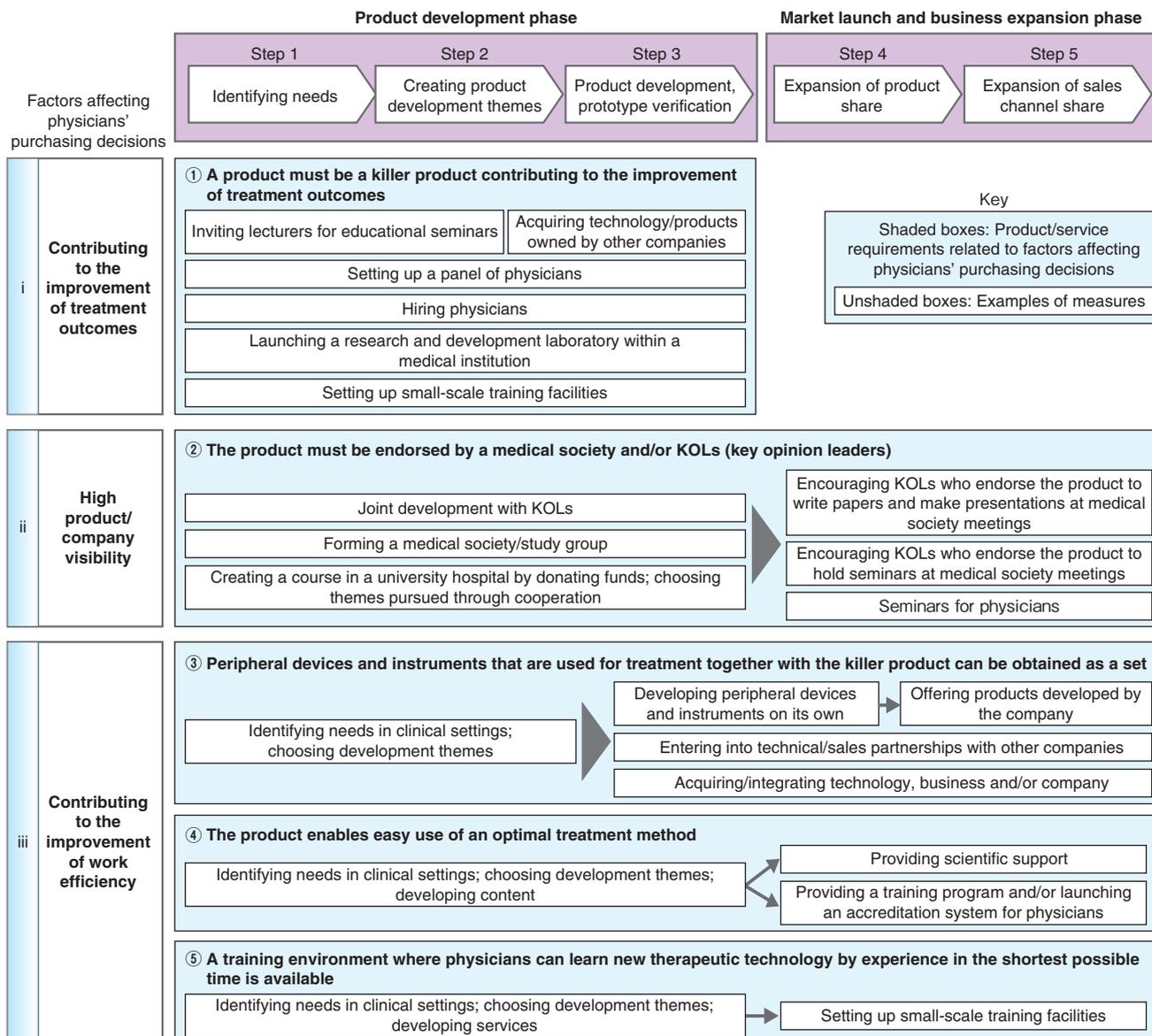
The same measures as those required for Product/service requirement ③ must be taken for Product/service requirements ④ and ⑤. Fortunately, the measures used to identify the needs for the development of killer products (which is Product/service requirement ①) are often taken in association with the collection of information required for Product/service requirements ③, ④ and ⑤. During the processes of exploring needs and undertaking development, it would be possible to work out the measures for ③, ④ and ⑤.

In this way, based on the assumption that in order to achieve business expansion, multiple product/service requirements must be met, proper measures for each requirement must be taken in a timely manner. Among the measures indicated in Figure 3, new participants from other industries should enter this market by combining measures that require a relatively small amount of investment. Doing so would be the best strategy to avoid investment loss due to error in decision making, which is attributable to the lack of knowledge particular to the medical device industry.

2 Acquiring the resources of other companies is unavoidable

It must be noted that even though it may not be necessary now, acquiring the resources of other companies will

Figure 3. Business expansion processes and examples of measures to be taken by new entrants from other industries in consideration of factors affecting physicians' purchasing decisions



become unavoidable someday in the future. In order to be able to offer peripheral devices and instruments that are necessary to meet Product/service requirement ③, incorporating the resources of other companies such as through M&A often becomes an appropriate and realistic solution. Many major medical device manufacturers have been actively undertaking M&A and/or entering into partnerships. This is because they are fully aware that acquiring the resources of other companies, rather than developing them on their own, is more efficient as a measure to obtain peripheral device and instrument technologies or such devices and instruments themselves for use with the key product as a set. Through M&A and/or partnerships, a new entrant can quickly capture technology that contributes to product development and can promptly gain access to physicians' sales channels including service functions.

3 A review of techniques used for development management is also important

As discussed thus far in this paper, while Japanese manufacturers have outstanding technological strengths, what are essential for them to enter this market, besides such strengths, include the needs to implement measures aimed at enhancing sales functions and to maintain the innovative product line by continuously launching new products. To this end, efforts must be made to ensure good use of internal resources such as personnel and technologies for businesses other than medical device business as well as to flexibly bring in external technologies and products. However, there are many cases in which because the development management techniques applied for existing businesses were used “as

is” for the medical device business, delays were caused in making investment decisions and errors in judgment were made in investment allocations. Such failures led to an inability to launch products at the right time, resulting in loss of competitiveness.

For example, medical devices often entail a long period to obtain approval required under Japan’s Pharmaceutical Affairs Law. Therefore, the “time to market” for new products is usually longer than anticipated. Furthermore, depending on the results of examination for approval, a developed product cannot necessarily be put on the market. Because such cases frequently occur, the introduction of medical devices presents a high risk. Another characteristic related to the development of medical devices is that the company often encounters the need to objectively compare its own technologies with technologies of other companies and select more appropriate technologies. As such, if the company fails to change its development management techniques to those that conform to the specific characteristics of medical devices, the company would be unable to maintain a lineup of competitive products. For the company to remain competitive, it is vital for the person responsible for making decisions for development investments, who is, in most cases, a member of the board of directors responsible for medical device business, to correctly understand the characteristics of the development environment of the medical device market. These efforts should also be considered as important measures to ensure business expansion for new entrants from other industries.

In order to benefit from the high profitability generally offered by the medical device market, a business model must be transformed to one that is different from traditional business models with an eye on the importance of sales functions and appropriate techniques for development management.

Notes:

- 1 Killer products refer to products and services that have overwhelming attractiveness such as those contributing to the improvement of treatment outcome.
- 2 Key opinion leaders refer to physicians who have a profound influence on the purchasing decisions of other physicians by endorsing a certain medical device and/or recommending the use of such product.

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