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PHOTO: Fumiaki Sakamoto

For the future of pharmaceutical companies – Need for a sense of crisis

New drug R&D and globalization are keys to survival

The beginnings of a formulation of regional medical care vision for the future delivery system, the introduction of regional coordinating health care companies (RCHC), the establishment of Japan Agency for Medical Research and Development (AMED) ... 2015 will be remembered as a year for many changes in the medical delivery system and research and development environment, and as epoch-making year for pharmaceutical industry. Meanwhile, many Japanese companies have not succeeded in shifting profit centers from long-listed drugs to innovative new drugs. Globalization is another challenge. Japanese companies are entering a new era in which they cannot survive without new drug development, also without true globalization. Given these changes, how are companies to ride over these big waves? In this special issue, we have special guests, Mr. Toshihiko Takeda, the Deputy Director-General of Health Insurance Bureau, Ministry of Health, Labour and Welfare, and Dr. Toshio Miyata, Executive Director of Health and Global Policy Institute, to discuss various issues surrounding the pharmaceutical industry, including the impact of RCHC, challenges of new drug development, and the way to globalization.

(Translate:Toshihiko Takeda, the Deputy Director-General of Health Insurance Bureau, MHLW
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Miyata While pharmaceutical companies in Japan are in critical business environments, Japanese hospitals are also facing transitions related to restructuring. The Japanese government is working to transform the health and long-term care system through what is referred to as “Integrated Community Care System” (ICC system), which is an attempt to integrate health services with long-term care services for older persons through amendments to the Medical Service Law and Long-Term Care Insurance Law which passed last year.

Through last year’s amendment to the Medical Service Law, hospitals are now required to report their functions through a new system that was recently introduced. In addition, new amendments are currently being proposed to the Diet that would introduce a new special corporation scheme to coordinate regional health care services. Discussions on this proposed amendment are scheduled to take place soon.

Thus far, pharmaceutical companies have been trying to target acute care hospitals with nursing staff standards of 7 to 1 by sending Medical Representatives (MR) to these facilities, which account for approximately 363,000 beds. However, acute care facilities are facing reorganization. A newly introduced category of high-acute care beds are estimated to account for 180,000 beds, about half the current number of acute care beds. In this context, how should pharmaceutical companies should adapt?

Regional coordinating health care corporations in particular will have a drastic effect on pharmaceutical businesses. Mr. Takeda, how do you think this new regional coordinating corporation scheme will impact the pharmaceutical space?

Takeda Health care providers’ issues tend to be seen as unrelated to the issues of the pharmaceutical industry, but that is not the case.

First of all, it is very important to think about why this new corporation scheme was enacted. Now, the hospital industry is in a transition period. Along with global trends, medical care services in Japan are moving from hospital-based to home-based care.

Hospital-based care requires that every service be provided within the hospital. However, the transition to home-based outpatient-style care is making it impossible to support patients with services from hospitals alone. Without coordination with long-term care services or welfare services, it will be impossible for hospitals to survive in this aged society. As patients get older, hospitals should move increasingly toward coordinated care.

With the decreasing need for hospitalization, one of the biggest

challenges in medical practice is how hospitals will work with networking in the local community. Although the Japanese government is promoting an ICC system, medical services and long-term care services are being asked to change their business structure without government guidelines or policy.

As the hospital industry transitions, the regional coordinating health care corporation (RCHC) scheme can be regarded as a strategic and supportive tool for hospitals attempting to change. By establishing this corporation, it is expected that hospitals can concentrate or differentiate their medical function more easily. Furthermore, RCHC could function as a common infrastructure for human resource management or IT investment.

How will this affect pharmaceutical companies? There is no concrete answer to the question. Instead, each company should think of it by considering its own business environment.

I can only say that industry persons should be aware that the coming era will be one in which hospitals are no longer the absolute center of advanced medical care.

Miyata Pharmaceutical companies have allocated many MRs to acute care hospitals to ensure healthy sales of their major products. With ICC advances, sales promotion targets are shifting to small or medium size hospitals and clinic physicians. Along with this shift, sales and marketing styles are transitioning to a style that more resembles “carpet bombing.”

On the other hand, hospitals will move to form alliances through the use of RCHC to integrate management strategy. I think it would be very important for pharmaceutical companies in Japan to review their promotion style now and try to address any needs they might be able to meet in local communities.

Takeda As for promotion activities of MRs, I think there are two points to be noticed in the new age of restructuring through ICC and introduction of RCHC.

First, you should notice that hospitals might form alliances to start collective buying with this RCHC scheme. Collective





buying is not simply buying in mass volume, but it includes collective negotiating that results when items for purchase, volumes, and prices are on the table at the same time. That would lead to central control of pharmaceutical product selection within RCHC. In this context, each company should consider the most appropriate marketing strategy.

Second, as medical care moves from a focus on inpatient to outpatient medicine, MRs also may shift from hospital doctors to clinic primary physicians. Yet, mass marketing is less favorable to clinic physicians compared to hospital doctors, based on my observation. In fact, there are younger physicians who seem to prefer medical specialists (MS) to drug wholesalers as they find them better to talk with because they are not company-biased.

So, what is it that pharmaceutical companies should do? I would say, do not rely on old sales managers with sales successes based on yesterday's health care system, and think differently when it comes to "new MRs."

Miyata As you pointed out, the RCHC scheme could possibly have a huge impact on the health industry.

In the U.S., business structures, such as holding companies, already exist with medical institutions. For example, Pittsburg University Hospital, once a part of the university, became an independent body as a special corporation with three branch hospitals within the corporation itself and a comprehensive alliance with clinics. The university was then able to focus on research. New medicine discovered and developed there became available and used widely within the medical institutions under one holding company. They can also attract patients from all over the world. In a sense, that corporation can be seen as global version of RCHC.

I expect that under that type of RCHC scheme, hospital mergers and acquisitions would take place with accelerated speed in Japan. National Center research hospitals (NCs), National Hospital Organization (NHO) hospitals, and other public-private hospitals will have to compete for survival. I would say, "The die is cast."

Takeda I am very worried because it seems that not all industry persons are facing this situation with a sense of crisis.

Miyata The changing environment of the pharmaceutical industry extends to research as characterized by the establishment of Japan Agency for Medical Research and Development (AMED). In Japan, discussions focus on the issue of Japanese companies not being able to utilize the many pharmaceutical seeds that are coming out of basic research activity in academia, mainly universities. Open innovation remains a big issue.

Under these circumstances, the question is: how can pharmaceutical companies survive? Mr. Takeda, you served as the Director for Economic Affairs Division (EAD) of Health Policy Bureau, which means you were in charge of pharmaceutical industry policy. What would be your advice from the standpoints of pharmaceutical industry policy and health care policy?

Takeda I am not in charge of those issues now, so it may not be appropriate for me to comment on the question directly. But, I would like to point out some of the critical problems as I see them.

In 2007, when I was Director of EAD, I made public a new version of a "Industrial Vision for Pharmaceutical Industry" in which I depicted the future of the industry.

Some of what I forecasted unfolded as I had expected and some did not. I regret to say that, in recent years, there seem to have been more negative developments than positive ones.

I attended the opening ceremony of The 29th General Assembly of the Japanese Association of Medical Sciences, which was held this past year from April 11 to April 13 in Kyoto. The Chairman of the association, Dr. Fumimaro Takaku, provided an anti-PD1 anti-tumor drug as an ideal example of the drug discovery situation in Japan. He shared concern about the current situation in which seeds for a promising drug developed by a Japanese researcher are developed by global companies instead of Japanese companies due to their limited development capacity. He clearly stated this, as I see it, bitter message to Japanese pharmaceutical companies, but I did not see any response from industry.

Then on April 13, I attended the third meeting of The Public-Private Policy Dialog for innovative pharmaceutical and medical devices. I thought this meeting should include members from AMED and other research bodies. Serious and essential discussions on issues, such as what research areas should be emphasized and how resource should be allocated, should take place among those members.

Recently I hear some people say that the Dialogue is the opportunity for the industry to make a petition to government, but I feel deeply sorry to hear this. Also, I feel industry people exude an atmosphere of, as in the good old days, being able to keep the industry afloat without drastic changes, but this is not

true. With increased awareness and tension, the public sector and industry sector should work together to think about what to do now.

AMED started its activity and the Pharmaceuticals and Medical Devices Agency (PMDA) has shortened the drug approval process to the global level. It may sound a little harsh, but it is inevitable for the industry to be asked, “Who didn’t finish their homework?”

Miyata At the General Assembly, I attended many sessions and heard various stakeholders’ presentations and comments. It seemed to me that there is no consensus of the current situation and future.

It is critically important to share common principals. The Dialogue was not originally started to petition, but it was started to build consensus on principles or objects for policy development.

Takeda When I started this Dialogue in 2007, I gathered critical stakeholders in pharmaceutical R&D. The members included not only top executives from industry and government, but also top management in academia, universities and NCs, those who play an important role in R&D by actually carrying out clinical development.

Through this dialogue, I think it is very important to share common recognition among government, industry and academia. Industry looks globally, while government basically looks domestically. Aligning those different views to a common goal is an important function of this dialogue.

Having said that, I am concerned whether Japanese pharmaceutical companies are thinking globally or not. Since globalization is a top priority issue for research-based pharmaceutical companies, top executives of the companies have a significant responsibility. The degree to which the top of a company is eager to globalize his company has critical influence on company strategy. But not all of major Japanese companies are doing so.

It may not be appropriate to name a single company, but Takeda Pharmaceuticals has made the right decision to welcome international personnel as a CEO candidate, and it seems to me that the company has been serious about globalization. But some in industry are said to be hoping to avoid the trend for fear that they might have foreign CEO and be forced to use English. It seems to me, the fact that these issues arise in conversation reflects the under-globalized reality of Japanese industry. I might say that companies that choose not to learn from others are not qualified for globalization.

Miyata Mr. Takeda, you mentioned RCHC could accelerate introduction of collective buying, which contributes to the use of generic drugs. Then, those Japanese pharmaceutical companies that rely on off-patent brand-name drugs, or “long-listed drugs,” will be forced to change their business strategy.



Top executives of companies should lead the company toward globalization with a sense of crisis, or they might not be able to survive. I would like to encourage top Japanese companies, including Takeda pharmaceuticals.

Takeda I think Dr. Miyata has a good understanding of the industry. And I think that is because you are not only looking the industry but also looking at medical society as a whole, and looking to other countries as well. I have some anxiety about how much further these discussions would be held and spread within industry.

The key concept of the Industrial Vision is to aim toward two goals at the same time. One goal is the promotion of generic drugs, and the other is the evaluation of innovative new drugs.

The Industrial Vision says,

“One patent per product means that, when original products go off-patent, market share is lost through the transfer to generics. Accordingly, companies cannot continue to grow without continuous production of new drugs.”

Policy change has strong impact on private company strategy, so I thought the policy time frame for generic promotion and innovation acceleration are on the same timeline. But research-based pharmaceutical companies can’t survive unless major pharmaceutical sales come from patented new drugs.

Almost 9 years have passed since the vision came out in 2007 and, as I envisioned, generic drug usage ratio has advanced, and the so called “drug lag” is coming to end.

But at the same time, Japanese companies are becoming more reliant on off-patent, long-listed drugs. One reason for this is that blockbuster drug patents have expired globally, so company management strategy alone is not entirely at fault.

But, through recent social security system reforms, medical society and medical institutions are facing the government’s blue print for health care restructuring by 2025. I worry that the pharmaceutical industry, with a myriad of challenges to cope with may have lost its way. More serious efforts are needed, that is my opinion.