

7. Addendum 2: Point of view with regard to corporate scale and reorganization

(1) Background to the industrial reorganization expected in the pharmaceutical industry:

From the latter half of the 1990s into the early 2000s, beginning with the industrial reorganization by the global companies, Japan also witnessed frequent mergers and consolidations amongst its pharmaceutical companies. The late 2000s saw numerous corporate takeovers of Western venture companies by Japanese companies. Behind these events lay the intent of the various companies to streamline and rationalize their management structures in view of the impending expiry of patents on their main products (primarily low-molecular-weight compounds.) There was also a new development in the industry with the rise of biopharmaceuticals, which required the bolstering of product pipelines for this new area of business. It is also conceivable that the sustained appreciation of the yen gave a boost to the spate of corporate buyouts. As a reflection of these developments, the proportion of products originating from drug discovery ventures has increased over time in recent years (Ministry of Health, Labour and Welfare's *Vision for the Pharmaceutical Industry 2013*). Pharmaceutical development is beginning to shift to a new style, as can be seen from the fact that a self-contained, single-company model has decreased while open innovations have increased.

Now, at the time of writing in 2015, many of the low-molecular-weight compounds that used to be an important source of revenue for R&D-based pharmaceutical companies have become long-listed drugs, and their market share is being significantly decreased due to the impact of the Japanese government's drastic policy promoting the use of generic drugs. Furthermore, the patents on early stage biopharmaceuticals are finally beginning to expire and, in the future, biosimilar products will be launched in rapid succession and will replace the original pioneer drugs in the marketplace.

Amid this drastic change in the market environment, R&D-based pharmaceutical companies are facing the need to make the choice of either continuing with a drug discovery business model or changing course and shifting into other business areas. Even if companies decide to continue with a drug discovery business model, it is expected that many of the new drugs developed in the future will be required to have advantages, such as far greater clinical benefits than existing drugs and indications in areas where satisfaction with treatment is still low. Competition is intensifying over the limited drug discovery seeds, and a rapid increase in development costs is expected.

(2) Issues to be addressed moving forward

As indicated in the previous paragraph, the change in product characteristics and soaring development costs represent a major threat to R&D-based pharmaceutical companies.

The demands placed on pharmaceuticals are continually becoming more advanced, and there is a need for innovative products that are superior to existing drugs in terms of efficacy and safety. Creating these kinds of products requires considerable expense. Even now, the creation of innovative drugs is said to require development costs in the region of several hundred billion yen. It is expected to soar even higher in the future.

To take the abovementioned risk of development and shoulder a large amount of development costs, it is essential to bolster capital strength and increase management efficiency. One of the possible approaches to this may be to discuss the expansion of the scale of businesses through M&A, etc., as touched upon in the Comprehensive Strategy to Strengthen the Pharmaceutical Industry. Here, M&A is not necessarily limited to mergers between companies within the same industry. It is expected that pharmaceutical companies will also merge with those from different industries.

On the other hand, it may also be considered that expanding the scale of a business is not everything, and that what is really important in new drug development is the quantity and quality of a company's development pipelines. Partnerships in certain therapeutic fields often seen in medium-sized Japanese pharmaceutical companies (such as the delegation of overseas development to global companies), for example, are also an option. This is because there is demand for companies that will take the role of uncovering and nurturing the drug discovery seeds originating not only from within their own organizations, but also from other routes, such as through academia and new business ventures. Among some medium-sized pharmaceutical companies, there is also a trend towards specializing in specialty areas, which can also be considered as one means of securing development pipelines.

As shown above, R&D-based pharmaceutical companies have many different possibilities for making management decisions. Regardless of which choices a company makes or whether a company expands into other areas of business, the company should seek the best answer and make decisions accordingly, giving consideration to the interests of stakeholders.