

Beyond Borders: New Growth and Direction for Japan's Pharmaceutical Industry

An Interview with BT Slingsby

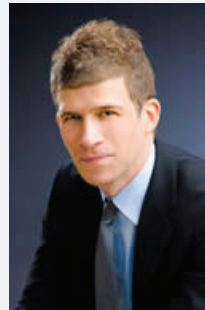
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Japan's pharmaceutical industry is in transition. Downward pressure on drug prices, expiring patents, and changing demographics have led industry leaders to develop new and creative approaches to expanding their markets globally. In this interview, NBR speaks with Dr. BT Slingsby (Eisai) about current trends in the Japanese pharmaceutical industry.

Q. Analyses of the global pharmaceutical industry have forecast continued growth in Latin American and Asian markets, with particularly robust growth in emerging market countries such as China and India. How are Japanese pharmaceutical companies responding?

An interesting trend in Japan pharma right now is that of pro-active globalization, in which Japanese companies are actively examining how they can open up and expand into other markets, particularly developing markets. Most major Japan pharma are in the United States and Europe. The question now is, how do they go beyond developed markets to the emerging markets, including frontier markets as well?

One reason for this change in thinking is the paradigm shift that is occurring in the economies of the world. In general, the European pharmaceutical markets, while significant in size, are not growing at their historical rates—some are even stagnant. The U.S. and Japan markets have already, and will likely continue to, experience similar reductions in growth rate, although not as severe as those of Europe. But beyond that, growth will be seen in the emerging markets, particularly the BRIC countries [Brazil, Russia, India, and China].¹ For



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founding of several for-profit and nonprofit entities in the United States and Japan and was active in healthcare research, with over 50 peer-reviewed articles published in journals including the *Lancet*, the *Journal of Public Health*, and the *Journal of General Internal Medicine*.

this reason, Japan pharma is becoming more global, not only by entering into new markets, but also by adopting more innovative strategies and making investments in subsidiaries previously set up in other Asian countries.

Q. From what you have said, the Japanese pharmaceutical industry, which has historically focused heavily on domestic R&D, appears to be in the midst of a transition. How do you see Japan's pharmaceutical industry evolving over the next ten years?

Looking to the future, I think that the greatest volume of pharmaceutical revenues is still going to be in the United States, Japan, and Europe. But in terms of growth rates, the highest percentage of growth is going to be found in the emerging markets. This difference is key. Emerging market growth is going to allow European, Japanese, and U.S. companies to continue to grow, and such growth is key to shareholders. Given that much of Japan pharma have yet to fully expand their businesses in many of the emerging markets, when compared to U.S. and European multinationals, one

¹ Key emerging markets in the pharmaceutical industry include: Brazil, China, India, Russia, Indonesia, Turkey, Mexico, and Argentina, among others.

could say that Japanese companies like Eisai have the greatest potential to grow via new investments and strategies. It's a matter of developing subsidiaries to support efficient and effective business in emerging markets. This is a key theme moving forward.

Additionally, to move forward means not only mergers and acquisitions anymore; it's about new business models—organic growth. New business models have to be integrated, they have to be innovative, they have to look at volume instead of profit margin, they have to address the unique needs of the healthcare system as a whole, and they have to look at how patients in each country access healthcare and medicines.

For instance, say you have a medication for dementia. In some emerging markets, dementia is written off as a symptom of old age when in fact it can be caused by a deficiency in Vitamin B12 or by hypothyroidism, hydrocephalus, or Alzheimer's disease, among other etiologies. So then, how do you increase awareness, diagnosis, and evidence-based treatment in that country? In India, we have several approaches to do so, ranging from healthcare professional training to community screening camps. In many cases, we do this in partnership with other organizations such as nonprofits through private-public partnerships (PPP). These PPPs allow each partner to share resources, cut costs, and reap the benefits of synergistic alliances.

Regardless of the approach, market development needs to be in line with addressing the unmet medical needs of the patients and their families in that country. By providing increased access and improved healthcare to patients, we can actually find market-based solutions to public health problems. This is a key phrase when expanding into emerging markets: "How do we find market-based solutions to public health problems?"

Q. Many see product development partnerships (PDPs) between governments, foundations, and pharmaceutical companies as a means to address a lack of commercial incentive to develop medicines for rare or neglected diseases, which often impact the developing world. Are PDPs a focus for the Japanese pharmaceutical industry in general?

PDPs are one model used to develop medicines for rare and neglected diseases that lack commercial incentive; however, they will likely not be a major model for drug development in pharma. The reason is that the return on investment is marginal.

Don't get me wrong—PDPs are an efficient and effective way for the private and public sectors to work together for the development of medicines for rare and neglected diseases that lack commercial incentive. It is a sustainable model. And in some cases, it can be profitable. For instance, if a company develops a new medicine for a rare disease while sharing investment and risks in a PDP model, and then expands the indication² for that new medicine to a more common disease, the company can then both make a unique contribution to the patients and families of that rare disease, and at the same time benefit from some return on investment with the additional indication. In the United States, some bio-venture companies use PDPs and funding support from public entities such as the U.S. NIH to advance their drug development programs. However, this is not a major business model for big pharma. In fact, the exit strategy for many of these bioventures is to sell to, or license out, the technology at a clinical stage to big pharma.

Regarding your second question of whether PDPs are a focus for the Japanese pharma industry, in the space of global health and drug development for neglected diseases, many U.S. and European pharma companies have partnerships with nonprofits like DNDi (Drugs for Neglected Diseases Initiative, based in Geneva) and MMV (Medicines for Malaria Ventures, also based in Geneva). In contrast, only a few Japanese companies—Eisai and Otsuka to name two—have similar partnerships. Compared to our counterparts in the United States and Europe, Japan pharma as a whole has yet to become a key stakeholder in the development of medicines for neglected diseases via PDPs.

To partner with PDPs and contribute to the research and development of new medicines and vaccines for the developing world is a vital investment for any global pharmaceutical company. These partnerships should be looked at as long-term investments into future markets and new innovations. Future markets meaning that new healthcare technologies for the neglected and rare diseases will allow the very poor in the developing world to become healthier and either join or remain in the workforce. This not only better the health of patients in the developing world, but also the health of their societies and economies. This progress results in the growth of the middle income population and thus the growth of future markets. Many global pharma companies including our company, Eisai, recognize that commitments to advance the development of new healthcare technologies vis-a-vis PDPs are not only a responsibility but a returnable long-term investment.

² In medicine, an indication is a valid reason to use a certain test, medication, procedure, or surgery.

Q. Sustainability—in both public and global health—is of paramount concern today. What role does pharma play in the dynamics of healthcare systems and sustainability? From your perspective, what are the tensions and possible solutions?

The sustainability of healthcare in general is a major concern right now—one that goes beyond pharma. Essentially, healthcare systems as they stand right now are not sustainable. If you look in Europe, there are instances where governments are delisting drugs. In Greece, for example, some patients who have been on certain medications for years because of a chronic disorder are now having trouble getting their medication. One reason for this is that the government no longer can (or will) pay the same price for medicines. As a result, some companies pull out of the market for that drug, as it falls below a profitable price—it is not sustainable. Companies may want to keep supplying certain products and wish they could do so at lower prices, but that isn't always possible; and governments may want to buy the drugs, but if the system isn't sustainable, difficult, unfortunate choices must be made.

Japan has one of the best, if not *the* best, coverage on a per capita basis for healthcare. But again, the healthcare system is currently experiencing enormous funding constraints. It's almost ironic looking at the United States and Japan together. Japan has full national coverage, but uses less of its GDP than the United States does. Yet both models are not sustainable. Among the current models of healthcare and healthcare coverage worldwide, can we find a truly sustainable system? And looking down the road, what is the role of pharma in creating a sustainable approach to healthcare?

These are complex questions that again go beyond pharma. For pharma, government, and academia collectively, a major question is how can we continue to promote innovation and develop new technologies? Today, it takes years and anywhere from several hundred million to a couple billion U.S. dollars to develop a new medicine. There are few sectors in the world that require over ten years in R&D to develop one product, with that product costing on average a billion dollars to do so. For government, academia, and industry to work better together in the development of healthcare technology is key. Given that the majority of R&D spending comes from industry, we also need to find ways to better promote and reward industry for new innovations. These can be both disruptive and sustainable types of innovation. Examples of the former would be anti-infective with a novel mechanism of action that is effective against multiple resistant strains, an oncology drug

that can significantly lengthen the life expectancy of a patient, or a new vaccine that can prevent a cancer significantly. Likewise, examples of the latter would be new formulations that reduce the adverse event profile of a drug or that allow a vaccine to be manufactured at a fraction of its original cost or that allow a medication to no longer require cold chain conditions. Both disruptive and sustainable innovations need to be promoted and recognized, given the different needs of patients worldwide.

For our society, and industry at large, we need to find solutions to both the problem of sustainable healthcare financing so that patients and their families can better access healthcare long-term, and the problem of better promoting innovation, so that our standards and quality of healthcare continue to improve with novel technologies and therapies. 