

Change in the Japanese pharmaceutical market: Cradle of innovation or grave of corporate profits?

Understanding structural shifts in the market can help pharma stakeholders innovate and, ultimately, deliver benefits for patients.

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An intense debate is under way as to whether the Japanese pharmaceutical market will continue to reward innovation or will respond to increasing healthcare expenditure by adopting overly restrictive pricing and access measures. In this short paper, we review some of the key changes we have observed in the market and reflect on the implications for pharma companies.

Structural changes, familiar themes

Currently, the Japanese biopharma market is confronting healthcare-expenditure challenges similar to those that most developed markets—especially the European market—faced eight to ten years ago. And it is reacting by implementing measures that are directionally aligned with what we have already seen globally:

- **Increased generics penetration.** Among the top 20 pharmaceutical products in 2013, generics or biosimilars were launched for nine of them between 2013 and 2017, with total sales of over ¥680 billion (\$6.7 billion¹) in 2013.² Generics' share by volume of the relevant replaceable market increased to 69.9 percent in fiscal year 2017, from 48.8 percent in fiscal year 2013.³ In the past, a branded product in Japan tended to benefit from a “long tail” with relatively slow generic erosion. In the past few years, some pharma companies experienced double-digit sales decline when generics were launched. Pharma companies in Japan can no longer rely on mature products to be continued sources of revenue as the country's rate of generics penetration is getting closer to that of most developed markets.
- **Pricing pressure.** To control healthcare costs, the government has been revising drug prices biennially, leading to price cuts of 5 to 7 percent every other year.⁴ The latest pricing reform in April 2018 has added pressure. For example, the scope of the price-maintenance premium—introduced in 2010 to delay biennial price cuts—has been narrowed to drugs deemed truly innovative, which number 560 in 2018 as opposed to 823 in 2016.⁵ From 2021, annual price revisions will begin for drugs with large *yakkasa* (dispenser margin).⁶ However, the 2018 *honebuto*, or Basic Policy on Economic and Fiscal Management and Reform, calls for price revisions of all products in 2019 when a consumption tax rise is planned, which will bring forward the de facto shift to annual revision. The discussion on cost-effectiveness assessment (CEA) continues.
- **Increasingly restricted access to physicians and limitations on sales-force activities.** Many hospitals have restrictions on visits from medical representatives (MRs), also known as sales reps. Such restrictions make physicians selective of which MRs they meet, and they spend less time seeing them in general. The Japanese Ministry of Health, Labour and Welfare (MHLW) started monitoring MR promotional activity in 2016, using physicians as undercover monitors. This activity uncovered many cases involving suspected violations in 2016 and 2017. As a result of monitoring and episodes of misconduct, MHLW plans to develop more stringent promotional guidelines by the end of 2018.⁷
- **Regionalization of healthcare.** The government has been working toward a community-based integrated-care system through which patients receive integrated care, from hospital inpatient and outpatient treatment to nursing care, home services, and support services in the community. As part of the process of establishing this system, by the end of fiscal year 2016, all 47 prefectures had estimated demand and predicted the number of hospital beds required by 2025. The regional healthcare plans developed are now being implemented.⁸

Short-term industry response: Accelerate the pace of global realignment of the go-to-market model

In response to this changing landscape, pharma companies are adapting their go-to-market models and reallocating (and reducing) the resources deployed in Japan. Multinational companies are importing capabilities and operating models they have developed in other global markets and are progressively realigning their Japanese affiliates to global standards with respect to capabilities and profit-and-loss profiles. This will take some time, as Japanese affiliates have historically been less modern and more profitable than their more developed global peers, especially those in Europe. Japanese companies, which have not developed similar capabilities in overseas markets, are struggling even more—having to develop new capabilities and overcome significant internal resistance to change. Among the most important changes we observe are the following:

- **Downsizing the sales force, with bolder action still needed.** Across Japan as a whole, the number of MRs peaked in fiscal year 2013 and is now decreasing.⁹ Over 2017 to 2018, the total sales force was down by 2.2 percent across the 59 companies surveyed by Jiho.¹⁰ This slow decline masks a significant reallocation among different players in the sector, with the net reduction in mature portfolio companies contrasting with hiring by innovative, specialty companies. However, while the trend is for a decline in sales-force size at most companies, sales-force productivity measures are still a mixed picture. This is due in part to the diversity of portfolios and in part to some companies moving more aggressively to global operating models, management, and productivity standards.
- **Accelerating in digital and analytics.** Pharma companies have started migrating toward digital engagement models of varying degrees

of sophistication, ranging from e-detailing to mobile platforms for physician and patient support. Leading pharma companies in Japan support their sales force with insights drawn from big data that integrate multiple internal and external sources. Such insights allow the companies to optimize physician targeting, improve message effectiveness, and drive productivity. Some companies have begun using analytics and artificial intelligence to support the sales organization—for instance, by recommending the approach and content of personalized information for physicians, suggesting which physician to visit, and deploying chatbots for multiple first-line communication opportunities.¹¹

- **Shifting to medical affairs.** Pharma companies have invested in developing the medical-affairs role in Japan, although this is still emerging as a valued career option and the role is not always well understood. Efforts have been supported in some cases by importing best practices and existing tools and in other cases by developing locally tailored solutions. Most companies have increased the number of medical-science liaisons (MSLs) they employ as a consequence of physicians' greater openness to this approach and a perceived need for more medical- and scientific-focused discussion. Among 16 companies recently surveyed by McKinsey, almost half of the employed MSLs were former MRs, which indicates both a talent bottleneck that is limiting the medical function in achieving its full potential impact and a priority on employment continuity versus talent renewal.¹²
- **Reorganizing in response to regionalization.** Many companies have changed their number of branches and sales offices. Several have allocated dedicated staff to understand local needs and develop and formulate strategies for each region or district, while a number have empowered

branch and sales-office managers to address each region and district's needs rather than following a single nationwide strategy. Based on a recent survey that asked physicians which companies are contributing most to regional healthcare, eight out of the top ten companies are Japanese,¹³ indicating greater involvement on this front and perhaps a competitive advantage on home soil that multinational companies should address.

- **Building market-access capabilities.** Pharma companies are slowly building market-access capabilities. Although the current focus remains on traditional price negotiation, companies have developed basic capabilities, such as budget-impact modeling, and are progressively developing the health economics and outcomes research capabilities required to address the upcoming health-technology assessment (HTA) model. Approximately ten products have undergone the ongoing CEA pilot. The companies involved—mostly multinational companies—are learning from this process and will probably have an advantage in dealing with the new access framework if they can build capabilities at scale.
- **Going global.** Japanese companies, not only the large ones but also the midsize ones, are increasing their share of overseas sales. The share of overseas sales of the top 14 Japanese public branded pharma companies increased to 49 percent in fiscal year 2017, from 39 percent in fiscal year 2012.¹⁴ Under pressure to grow overseas, companies are reallocating resources, and some are progressively reducing investment in the local market and accelerating the evolution of the go-to-market model in Japan.

Medium- to long-term outlook: Normalization and sustainability

Japan has been a leading and profitable market recognized for its rapid adoption and favorable pricing of innovative products. Has that changed?

What model will Japan develop to continue to provide the best care to its patients in a more sustainable way?

The introduction of the changes described in the previous section has been accelerated by a few trigger events—namely a few “big spenders” forcing the application of top-down price cuts and episodes of misconduct accelerating the introduction of restrictive regulations. This acceleration of reform during 2016 to 2018, along with the continued deteriorating outlook for healthcare expenditure, has led to growing concern relating to the structural attractiveness of Japan's pharma market.

Several observations and policies point to a normalization of the Japanese healthcare system in the direction of rationalization and specialization of the provision of care, cost control in the mature-products segment, and recognition of value. Among the most visible are the following:

- **Provider reform will facilitate value demonstration and cost allocation.** The community-based integrated-care system that the government is targeting and the healthcare plans that prefectures have developed call for specialization and roles to be differentiated by type of medical institution to ensure inpatient and outpatient treatment and nursing and home care for patients. Some prefectures specifically mention creating pathways for regional coordination in their healthcare plans.¹⁵ This will make it easier to manage patients through the treatment pathway and to coordinate the care network in a more formal and transparent way. As such, the system will be better able to monitor the cost effectiveness of therapeutic options and recommend the best option. This, in turn, will open the door to the demonstration of value, outcomes, and, ultimately, cost control, which can benefit innovators in the delivery of outcomes and deep penetration of generics where appropriate.

- *The introduction of HTA will stabilize the pricing framework.* The CEA pilot started with seven marketed drugs. The price of two drugs was lowered in April 2018, and five other drugs will be assessed in 2018.¹⁶ As the government is discussing full introduction and expansion to new products and technologies, two new drugs launched over the past two years will also be assessed in 2018 (although price will not be assessed).¹⁷ In the short term, this creates uncertainty and worries that the pendulum might be swinging too much on the side of cost control. This also shows, however, that the administration is rolling out the new system with caution to avoid big mistakes and has a desire to learn in the process. At steady state, the model should provide greater stability and predictability.
- *Big spenders and budget pressure are forcing the dialogue on more creative pay-for-performance arrangements.* Japan lags most developed markets in performance- or outcome-based pricing arrangements due to the healthcare system, an approach to pricing and budget planning that favors simplicity and predictability over sophistication and flexibility, and a lack of real urgency to reduce drug spend until very recently. It is hard to predict how this will evolve, but under price pressure, some innovative pharma companies with high-priced drugs have been engaging the national payer to test new performance-based arrangements. If the initial hurdle is overcome, this form of pricing could become more widespread and protect innovators and differentiated products from the risk of low prices and drastic price cuts.
- *Broader adoption of optimal usage guidelines will occur.* Optimal-usage guidelines specifying patient criteria and requirements of physicians and medical institutions were first introduced in 2017. As of June 2018, there are guidelines for seven biologic drugs.¹⁸ Initially perceived as surprising and restrictive, they represent a normalization of the Japanese market in which physicians still experience a degree of freedom and lack of controls greater than most other developed markets. In the future, pharma companies will place greater emphasis on using clinical or real-world evidence to partner in shaping guidelines, and product promotion will follow the implied paradigm.
- *The emphasis on innovation will continue.* Government policy and pricing reform enacted in 2018 aspire to reward innovation. For example, the criteria for price-maintenance premium revised in 2018 have been narrowed to innovative drugs; the range of premium under the cost-based method for new drugs with no comparator was raised to up to 120 percent of calculated price, from up to 100 percent of operating profit. On the other hand, to drive the shift away from a market dependent on long-listed products (products whose generics are launched), additional price cuts were introduced in April 2018 to reduce the price of long-listed products progressively after ten years from generics launch to 1.0 to 1.5 times the generics price. Long-listed products with a generics-replacement rate of 80 percent or higher would eventually get the same price as generics, and originator manufacturers have the option to withdraw their long-listed product from the market. Also, the government is promoting R&D in priority areas such as regenerative medicine and genomic medicine.
- *Go-to-market models are slowly converging toward a more modern and profitable standard.* A discrepancy is emerging between leading multinational companies, which are shifting to a specialty system and are introducing digital and analytics solutions, and local companies, which are still in some cases providing a traditional, high-touch commercial experience to physicians. This is an anomaly

of the transition state, and companies will progressively converge to a modern, lower-cost model that will bring Japan back in line with global markets. Profitability will decline compared with historical values, but we believe Japan will remain among the global markets with the best size, stability, and profitability profile.

- *The consumer class is independent and empowered.* Physicians are highly empowered and independent in Japan and will remain so for at least a generation. Measures to control and drive physician choices when it comes to therapeutic decisions (for example, budget control, prior authorizations, procurement constraints, and so on) are de facto nonexistent. Physicians are also oriented toward patient satisfaction in part because of a service culture as well as the lack of a formal primary-care system. Last, patients are informed and expect high-quality products. This combination creates a fundamental, underlying force that will put a brake on aggressive cost-control measures and ensure a significant market for innovative products.
- *Consolidation in the long-listed segment will further contribute to rationalization of spend.* Consolidation of portfolios in the mature segment is already taking place. While many midsize companies with mature portfolios will take some time to consolidate because of their mostly private and family-ownership structure, they will inevitably modernize or consolidate. This will remove them as a commercial presence in the field and leave room for innovators with better value for patients or for generic products with lower cost.

Conclusions: Ignore the hype and innovate

The Japanese pharmaceutical market is undergoing probably its most sweeping structural reform in decades. Some forces—pricing pressure, generics penetration, and restriction of physician access—

point to an erosion of its attractiveness. The fundamentals—demographics and epidemiology, the declining cost of the promotional model, and a focus on innovation and differentiation—remain strong. And looking to the future, the emphasis on value and outcomes will continue to secure a place for innovative and differentiated products in Japan.

The more alarmist voices being heard in the ongoing debate are not reflective of the underlying fundamentals. That said, normalization toward more global standards for promotional practices and greater focus on value and outcomes can be beneficial to the sector.

The sector could also benefit from greater clarity on the future regulatory, pricing, and access frameworks and certainty over the execution of the provider reform. Businesses and innovators that understand this picture will be the ones best prepared to deliver the benefits that the new policies aim to provide for patients in Japan. ■

¹ Using 2013 average currency-exchange rate, with which \$1 equals ¥101.517.

² TESTA Marketing; team analysis.

³ Japan Generic Medicines Association.

⁴ *Chuijkyo* (Central Social Insurance Medical Council) Drug Pricing Subcommittee, August 24, 2016, mhlw.go.jp.

⁵ MHLW, March 5, 2018, and March 4, 2016, mhlw.go.jp.

⁶ *Chuijkyo* Drug Pricing Subcommittee, January 17, 2018, mhlw.go.jp.

⁷ *Nikkan Yakugyo*, April 12, 2018.

⁸ Health Policy Notification 0331, Number 57, March 31, 2017; revised Health Policy Notification 0731, Number 4, July 31, 2017.

⁹ MR Education & Accreditation Center of Japan, mre.or.jp.

¹⁰ *Nikkan Yakugyo*, April 25, 2018.

¹¹ For more details on digital and analytics in pharma in Japan, see Raymond Chan, Yusuke Nishikawa, Jan van Overbeeke, and Michele Raviscioni, "The digital imperative for pharma companies in Japan," March 2018, McKinsey.com.

¹² For more details on medical affairs in Japan, see Minyoung Kim, Tomoko Nagatani, Ayano Uda, and Jan van Overbeeke, "Elevating the impact of medical affairs in Japan," October 2017, McKinsey.com.

¹³ANTERIO, June 27, 2018.

¹⁴SPEEDA by UZABASE.

¹⁵MHLW, mhlw.go.jp.

¹⁶Chuijyo Joint Subcommittee, March 7, 2018, mhlw.go.jp.

¹⁷Chuijyo Joint Subcommittee, June 13, 2018, mhlw.go.jp.

¹⁸Pharmaceuticals and Medical Devices Agency, pmda.go.jp.

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