Japan Pharma Outlook 2027 Report Extract

Find out more about the full report
Introduction

Japan Pharma must navigate complex pressures and opportunities presented by an aging and declining Japanese population, as well as government measures designed to encourage innovation while controlling healthcare spending, to steer a path towards long-term global revenue growth.

Note: 2017* refers to the 2017 Japanese fiscal year, which is from 1 April 2017 to 31 March 2018.

Table 1: Pharmaceutical product sales for the 10 representative Japanese companies in PharmaVitae’s Japan Pharma peer set ($m), 2017–27*

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<tbody>
<tr>
<td>1</td>
<td>Takeda</td>
<td>15,594</td>
<td>16,824</td>
<td>17,286</td>
<td>1,692</td>
<td>1.0%</td>
<td>Takeda is set to remain the largest grossing pharmaceutical company in PharmaVitae’s Japan Pharma peer set. Before factoring in its planned acquisition of Shire, Takeda’s prescription pharmaceutical product revenue will account for approximately 25% of the peer set’s total pharmaceutical sales throughout the forecast period. Growth will be driven by continued uptake of Ninlaro in multiple myeloma, and Entyvio in inflammatory bowel disease.</td>
</tr>
<tr>
<td>2</td>
<td>Astellas</td>
<td>11,987</td>
<td>11,551</td>
<td>11,298</td>
<td>-689</td>
<td>-0.6%</td>
<td>PharmaVitae expects Astellas’s prescription pharmaceutical product revenue to sharply decline in the near term, with three out of four of the company’s largest products facing generic competition, which is set to cut approximately $2.3bn from Astellas’s top line over the forecast period. PharmaVitae predicts the company will return to growth in 2020*, driven by expansion of the peer set’s largest grossing product Xtandi in prostate cancer. However, PharmaVitae expects this growth to fail to offset earlier losses, and Astellas’s pharmaceutical product sales to decline at a CAGR of 0.6% out to 2027*.</td>
</tr>
<tr>
<td>3</td>
<td>Otsuka</td>
<td>7,143</td>
<td>9,262</td>
<td>9,703</td>
<td>2,560</td>
<td>3.1%</td>
<td>PharmaVitae predicts Otsuka will experience the largest monetary growth in prescription pharmaceutical product revenue over the forecast period within the peer set, driven by psychiatry drugs Rexulti and Abilify Maintena. PharmaVitae expects Otsuka to be buoyed by assets acquired in the US, and AVP-786 to become the company’s largest grossing product over the forecast period.</td>
</tr>
<tr>
<td>4</td>
<td>Daiichi Sankyo</td>
<td>7,749</td>
<td>7,255</td>
<td>6,706</td>
<td>-1,043</td>
<td>-1.4%</td>
<td>PharmaVitae expects Daiichi Sankyo to experience the largest percentage decline in prescription pharmaceutical product revenue over the forecast period within the peer set, as the company faces generic erosion of its key cardiovascular portfolio.</td>
</tr>
<tr>
<td>5</td>
<td>Eisai</td>
<td>4,418</td>
<td>5,162</td>
<td>6,698</td>
<td>2,280</td>
<td>4.2%</td>
<td>PharmaVitae forecasts Eisai to grow at a CAGR of 4.2% over the forecast period, driven by the success of its oncology and epilepsy products in offsetting the long-standing generic erosion of Aricept and Aciphex/Pariet, as well as more recent generic competition for its largest grossing oncology product Alaxi. Eisai’s long-term outlook hinges on the success of aducanumab in Alzheimer’s disease, which PharmaVitae forecasts to become the largest current pipeline asset in the peer set.</td>
</tr>
<tr>
<td>6</td>
<td>Sumitomo Dainippon</td>
<td>4,303</td>
<td>5,368</td>
<td>4,225</td>
<td>-78</td>
<td>0.2%</td>
<td>Sumitomo Dainippon is set to experience strong mid-term growth with the extended market exclusivity of its largest grossing product Latuda, and continued uptake of the company’s respiratory and oncology portfolios. However, the company will experience a sharp erosion of its prescription pharmaceutical product revenue in 2024* as generic competition launches against Latuda, eating away at previous revenue gains.</td>
</tr>
<tr>
<td>7</td>
<td>Shionogi</td>
<td>2,930</td>
<td>3,652</td>
<td>3,834</td>
<td>904</td>
<td>2.7%</td>
<td>Shionogi is set to experience modest growth as its portfolio of CNS and HIV products offsets generic erosion of its leading dyslipidemia drug Crestor.</td>
</tr>
<tr>
<td>8</td>
<td>Ono</td>
<td>2,414</td>
<td>3,361</td>
<td>3,833</td>
<td>1,419</td>
<td>4.7%</td>
<td>Ono is set to make significant progress over the forecast period, fueled by Opdivo’s success in oncology. PharmaVitae expects Ono to climb from its number 10 position in the peer set in 2017* to number 8 by 2027*.</td>
</tr>
<tr>
<td>9</td>
<td>Mitsubishi Tanabe</td>
<td>3,877</td>
<td>3,788</td>
<td>3,640</td>
<td>-237</td>
<td>-0.6%</td>
<td>Mitsubishi Tanabe’s outlook is negatively impacted by a key patent expiry for Glenря in 2019, and subsequent end to associated royalties from Novartis. Growth in the company’s metabolic disorders portfolio, and successful expansion into the US with Radicut, will fail to offset earlier losses, and PharmaVitae expects Mitsubishi Tanabe to decline at a -0.6% CAGR over the forecast period.</td>
</tr>
<tr>
<td>10</td>
<td>Kyowa Hakko Kirin</td>
<td>2,543</td>
<td>2,223</td>
<td>2,253</td>
<td>-290</td>
<td>-1.2%</td>
<td>PharmaVitae expects Kyowa Hakko Kirin to lose ground over the forecast period due to generic erosion of its hematology portfolio, and a difficult domestic market. Kyowa Hakko Kirin’s launch portfolio will add over $750m out to 2027*, but will fail to offset losses elsewhere.</td>
</tr>
</tbody>
</table>

Grand total  | 62,958  | 68,446  | 69,476  | 6,518  | 1.0%        |

Source: Datamonitor Healthcare; PharmaVitae Analytics | Note: totals may not sum due to rounding; CAGR = compound annual growth rate; CNS = central nervous system system
About the full Report

Japan Pharma faces a challenging period as companies are negatively affected by ongoing generic erosion of former blockbuster products, and government policies intended to rein in increasing healthcare costs inadvertently cut domestic revenues. Nevertheless, its healthy launch portfolio and access to cash reserves for deal-making produce a positive outlook for PharmaVitae’s Japan Pharma peer set, and PharmaVitae forecasts the 10 representative Japanese pharmaceutical companies to add $6.5bn in sales out to 2027*, generating $69.5bn.

PharmaVitae explores and visualizes market dynamics in the Japan Pharma peer set out to 2027* through analysis and in-house sales forecasts for more than 320 products. By delving deeper into revenue trends, therapy area performance, and strategic drivers, PharmaVitae’s analysis is vital to understanding how Japan Pharma is set to navigate headwinds to steer towards long-term growth.

Key questions answered in the full report

Explore and visualize market dynamics in the PharmaVitae Japan Pharma peer set out to 2027* using 10-year in-house sales forecasts segmented by the following sections:

- **Industry Landscape** | What are the specific domestic challenges facing Japan Pharma?
- **Strategy Analysis** | What are the global revenue growth strategies being adopted by Japan Pharma?
- **Revenue Analysis** | Which are the top performing companies, products, and regions for Japan Pharma out to 2027*?
- **Therapy Area Analysis** | Which therapy areas will be the biggest drivers and resistors of topline growth out to 2027*?
- **Lifecycle Analysis** | How will drug launches offset market exclusivity losses to maintain a positive outlook?
- **Pipeline Analysis** | Which companies have the most valuable pipeline assets and launch portfolios?

**Strategy analysis**

- How is Japan Pharma using licensing deals to propel growth, and in what therapy areas are deals concentrated?
- How is Japan Pharma capitalizing on immuno-oncology using M&A and deal-making?
- How is Japan Pharma expanding its global footprint to maximize revenue?

**Revenue analysis**

- Which will be the best performing companies out to 2027*?
- How will Japan Pharma perform across the US, Japan, five major EU markets (France, Germany, Italy, Spain, and the UK), and RoW?
Therapy area analysis
• What are the detailed competitive dynamics at play in the oncology and CNS markets?
• Which companies are building leadership in specific therapy areas?
• How are late-stage pipelines positioned, and what are the most coveted launch products?
• Which therapy areas will experience the largest growth and decline?

Lifecycle analysis
• What are Japan Pharma’s relative growth rankings?
• Which companies are reliant on pipeline launches to drive growth?
• Which companies will be most affected by future biosimilar and generic erosion out to 2027*?
• How much is expected to be wiped off Japan Pharma’s expiry portfolio?

Pipeline analysis
• What are the most coveted pipeline assets, and which companies have the most valuable launch portfolios?

Highlights
• Japan Pharma’s prescription pharmaceutical product revenue is forecast to grow to $69.5bn by 2027* at a CAGR of 1.0%.
• Largest company growth – Ono will experience the highest growth rate out to 2027*.
• Largest company decline – Daiichi Sankyo will experience the largest percentage decline out to 2027*.
• Regional analysis – Strong revenue growth in the US will offset the -0.2% CAGR decline in Japan.
• Most valuable therapy areas – Oncology and CNS will remain the two most valuable therapy areas for the peer set.
• Most valuable product – Astellas’s Xtandi (enzalutamide) will be the highest selling product within the peer set out to 2027* at $4.5bn.
• Most valuable pipeline product – Eisai’s aducanumab will become the highest selling pipeline product with $1.9bn in sales by 2027*.
• Most valuable pipeline – Astellas will have the most valuable pipeline with eight product launches adding $2.6bn to its topline revenue by 2027*.
• Strategy analysis – Japan Pharma is focusing on key therapy areas of high global unmet need and turning to collaborations to fuel growth.
Executive Summary

PharmaVitae’s Japan Pharma peer set is set to meet the significant challenges presented by the aging and declining Japanese population, as well as domestic pricing pressures, through ongoing global growth strategy adaptation. PharmaVitae forecasts the Japan Pharma peer set to add $6.5bn in annual prescription pharmaceutical product global revenue by 2027*, reaching $69.5bn in annual sales at a low CAGR of 1.0%. This growth will be driven by a healthy launch portfolio, which is set to add $11.4bn over the forecast period, and offset by heavy core and expiry portfolios, which are set to lose $4.8bn by 2027*.

Strategizing global growth in a fast-evolving industry landscape

Japan Pharma will increasingly rely on clinical product development and sales in the US and emerging markets as domestic pricing pressures strengthen, while domestic revenue growth will increasingly require Japan-based innovation and demonstration of cost-effectiveness for the public healthcare system.

Complex challenges and opportunities facing Japan Pharma

Supporting the aging Japanese population while encouraging innovation

Japan Pharma must overcome regular government pricing revisions designed to rein in healthcare spending, and exploit government incentives designed to boost innovation, to realize long-term global revenue growth. Japan Pharma is a rapidly changing industry with one of its main macroeconomic challenges being the aging and declining Japanese population, and associated pressures on the healthcare system. The Japanese population currently has a relatively “top-heavy” structure, and this pattern is set to intensify.
The extra healthcare and end-of-life care costs incurred by this population are adding to government spending, while there is a shrinking younger population and taxation base to support this. Thus, a major challenge for the Japanese government is to control costs while funding healthcare under the national health insurance (NHI) system.
Japanese government pressures – the stick approach

Figure 2: Government incentives – the stick approach

Government Policies to Control Healthcare Spending

<table>
<thead>
<tr>
<th>Regular Government Pricing Revisions</th>
<th>Government Facilitated Generics Growth</th>
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<tbody>
<tr>
<td>May occur annually from 2020 [JPN]</td>
<td>Generic volume domestic market share:</td>
</tr>
<tr>
<td>Set to increase the dichotomy between established and more innovative companies</td>
<td>• Rose from 26% to 66% over 2012-16 [JPN]</td>
</tr>
<tr>
<td></td>
<td>• Goal of 80% by 2020 [JPN]</td>
</tr>
</tbody>
</table>

Source: Datamonitor Healthcare; PharmaVitae Analytics

The Japanese government has implemented multiple measures to control healthcare spending in the face of an aging and declining population. These policies include long-held, regular pharmaceutical product reimbursement pricing revisions, which will continue to negatively impact the global revenue growth outlook for Japan Pharma. Furthermore, these premium pricing revisions, which currently occur every two years, could happen every year starting in 2020*, depending on a 2018–20* review. The premium pricing revisions are based on health technology assessment (HTA) criteria, which have recently been made much stricter. Additionally, the frequency of market expansion pricing revisions for products with sales exceeding JPY35bn (approximately $320m) annually will also increase to four times a year from 2018*. 
Setting a higher hurdle

Many in R&D-based Japan Pharma view the previous HTA requirements, and system of price maintenance premiums, as more supportive of successful innovation in drug discovery and development than the new system. The previous system was welcomed, and highly favored by industry. Nevertheless, it was likely too expensive for the government to maintain. Thus, the bar has been raised for new drugs to qualify as innovative, while a full HTA system is due to come into force by the end of 2018*, meaning that companies will have to also demonstrate cost-effectiveness for the healthcare system. Together, pricing revisions are set to increase the dichotomy between the haves and have-nots, or between mid-sized Japanese pharmaceutical companies that are more reliant on longer-listed branded products with generic competition, and potentially more innovative companies and generics firms that are benefiting from policies aimed at their respective spectrums.

Generics to flood the market

There has also been a significant growth in generics in Japan, which has been facilitated by Japan’s cost-conscious Ministry of Finance, and many policy changes over the past few years have encouraged the uptake of generics, including fee changes for prescribers and pharmacists, and changes to prescription forms to allow easier substitution. The domestic market share of generics by volume rose from 26% to 66% over 2012–16*, and is set to reach 80% by 2020*.
Japanese government incentives – the carrot approach

To counteract the specific pressures facing Japan Pharma, and to support the long-term global competitiveness of the industry, the Japanese government is set to offer incentives for companies to more vigorously pursue Japan-based innovation through a proposed company rankings system. This system will award tiered pricing premiums based on a company’s performance in conducting innovative drug development activities in Japan in preference to other regions.

While PharmaVitae has observed a decrease in Phase I–III clinical trial initiations by Top 20 Pharma (down 45%) and Japan Pharma (down 34%) over 2008–17, PharmaVitae has also noted a 40% rise in the proportion of Phase I–III clinical trial initiations with a site in Japan by Japan Pharma during this period. Nevertheless, PharmaVitae anticipates that less than half of all Japanese pharmaceutical companies will be eligible for the highest tier status in the planned new company rankings system.

*Based on Health Technology Assessment (HTA) criteria

Source: Datamonitor Healthcare; PharmaVitae Analytics
Figure 5: Phase I–III clinical trial starts by Top 20 Pharma according to the Scrip 100 League Table versus drug approvals in the US, EU, and Japan, 2008-17

![Graph showing clinical trial initiations and approvals from 2008 to 2017.](source)

Source: Citeline; Trialtrove; Scrip

Figure 6: Phase I–III clinical trial starts by Japan Pharma versus drug approvals in the US, EU, and Japan, 2008-17

![Graph showing clinical trial initiations and approvals from 2008 to 2017.](source)

Source: Citeline; Trialtrove
On the right track?
The policy environment for Japan Pharma is a complicated mix of positive and negative government factors, depending on portfolio and business strategy, and will continue to have a major and complex influence on the strategic direction and focus of the industry. The upshot of these measures is that the innovative industry must achieve higher levels of R&D productivity, and be prepared to demonstrate the value of its products to the healthcare system. Japanese pharmaceutical products will need to jump over higher government hurdles to be awarded attractive domestic prices. Whether simultaneously budget squeezing and incentivizing Japan Pharma to innovate will facilitate long-term revenue growth, or set the industry up for more challenges, is an open question.
Navigating the new domestic playing field

Japan Pharma will adopt three main strategies to steer through the maze of domestic challenges and opportunities facing the industry, namely rationalization, consolidation, and reinvention.

Figure 8: Navigating the complex influence of domestic headwinds and government measures

<table>
<thead>
<tr>
<th>Rationalization</th>
<th>Consolidation</th>
<th>Reinvention</th>
</tr>
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<tbody>
<tr>
<td>Cost-saving measures, including job cuts</td>
<td>Greater economies of scale</td>
<td>Collaborations</td>
</tr>
<tr>
<td>Divestitures of non-core or longer-listed products</td>
<td>Sustain profitability</td>
<td>Sharpened focus on:</td>
</tr>
<tr>
<td></td>
<td>Boost R&amp;D productivity</td>
<td>• Oncology and central nervous system</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• US and emerging markets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• R&amp;D position in regenerative medicine</td>
</tr>
</tbody>
</table>

Source: Datamonitor Healthcare; PharmaVitae Analytics

Rationalization to continue
PharmaVitae's Japan Pharma peer set is embracing rationalization to overcome and capitalize on government measures. PharmaVitae expects this rationalization trend, which has involved cost savings such as job cuts and divestitures of non-core or longer-listed products, to continue as Japan Pharma's core and expiry portfolios further contract. PharmaVitae believes two other main strategies that will gain significant traction are consolidation and reinvention as more established companies face increasing domestic pricing pressures on longer-listed products, the Japanese market further shrinks, and Japan Pharma looks to the US and emerging markets for sustainable growth.

Consolidation on the cards
PharmaVitae believes Japan Pharma will at least partially revisit the consolidation approach seen in the 2000s as mid-sized companies seek greater economies of scale to become more competitive both domestically and globally. PharmaVitae anticipates that Japan Pharma will view consolidation as a means of absorbing compounding domestic pricing pressures, and better capitalizing on government innovation incentives, to sustain profitability and R&D productivity. PharmaVitae expects mid-sized companies with established positions in the US, where there are potentially fewer government pressures and shorter approval times, to seriously consider mergers in the near term to strengthen their US market penetration through existing commercialization rights. Companies such as Astellas and Daiichi Sankyo now have fully integrated operations in the US from previous deals and company acquisitions. Additionally, such mergers would potentially allow mid-sized companies to better master domestic challenges and opportunities, and help shore up their domestic market shares.

Reinvention – walking the tightrope
PharmaVitae anticipates a rise in collaborations, and ongoing reversal of the diversification of Japan Pharma seen in the 1990s, as Japanese companies focus their R&D resources on core therapy areas of high global unmet need, and prioritize the key therapy areas of oncology and CNS. PharmaVitae also expects Japan Pharma to continue to concentrate its efforts in regenerative medicine, where it holds a leading global R&D position, and potential first-to-market competitive edge. Additionally, PharmaVitae anticipates that Japan Pharma will continue to pursue organic growth in the US, while focusing inorganic expansion efforts in emerging markets, which present a significant long-term growth opportunity.
More M&A following Takeda/Shire?
PharmaVitae does not anticipate further major global M&A activity in the near term from Japan Pharma following Takeda’s recent agreement to acquire Shire. PharmaVitae views Shire as the best and last chance for Takeda to become one of the top 10 global players. Nevertheless, PharmaVitae believes that the Takeda/Shire merger agreement is neither an optimal portfolio or regional fit given Shire has recently divested its oncology assets, and is focused on the US, where Takeda already has a presence, rather than on emerging markets.

Gateway to North-East Asia
Japan Pharma presents an attractive partnering opportunity for emerging global companies to access the Japanese, South Korean, Taiwanese, and Chinese markets. The proximity, regulatory knowledge, and networking advantage offered by Japanese companies is potentially highly valuable to emerging companies offering licensing deals and commercialization rights in North-East Asia. Additionally, the government incentives in place for Japan Pharma to boost clinical trial activity in Japan will potentially make Japanese companies more willing development partners. Furthermore, the tripartite cooperation agreement between Japan, South Korea, and China means that clinical development collaborations with Japan Pharma may lead to faster approval times in South Korea and China for products out-licensed to Japanese companies.

China awaits
PharmaVitae views recent developments in China as positive signals for the long-term growth potential of Japan Pharma. These events include the extension of patent lives from 20 to 25 years, and proposed reforms of China’s Food and Drug Administration designed to increase productivity and hasten regulatory review of globally developed drugs. Although there are ongoing, unfavorable patent and drug pricing issues for Japan Pharma in China, opportunities such as the tripartite cooperation agreement between Japan, South Korea, and China, which promises more sharing and recognition of late-stage clinical data and a jump start in the clinical development process on a case-by-case basis in preference of drugs for high unmet needs, are tipping the balance more in Japan Pharma’s favor.

Strength in regenerative medicine
Japan Pharma has a global early-stage clinical development competitive advantage in regenerative medicine, which is not fully reflected in forecasted sales, and was likely ignited by the 2012 Nobel prize awarded to Professor Shinya Yamanaka of Kyoto University, who discovered induced pluripotent stem cells (iPS cells). Japan Pharma’s impressive early progress in this exciting field will potentially be furthered by a relatively streamlined regulatory pathway for regenerative medicine created by the Ministry of Health, Labour and Welfare (MHLW). In April 2014, the government set up the Japan Agency for Medical Research and Development to help guide R&D, and to provide a clear regulatory framework and reimbursement policies for regenerative medicine in an initiative that was likely also inspired by the iPS cells discovery.
Industry Landscape

Japan Pharma’s changing industry landscape

Japan Pharma’s revenue growth will decelerate during 2017–27* as an aging and declining Japanese population and government pressures on drug prices temper the sector’s domestic pharmaceutical product sales. PharmaVitae forecasts prescription pharmaceutical product revenue for Japan Pharma to grow at a low CAGR of 1.0% over 2017–27*. In 2017*, sales in Japan made up 44.9% of the peer set’s revenue. However, this will fall to 37.9% by 2027* as sales in all ex-Japan regions covered by PharmaVitae grow and Japan Pharma increasingly relies on global development and commercialization for its long-term growth. Furthermore, government measures designed to rein in healthcare spending are set to increase the dichotomy between the haves and have-nots in Japan Pharma, or between mid-sized companies that are more reliant on longer-listed branded products with generic competition, and potentially more innovative companies and generics firms that are benefiting from policies aimed at their respective spectrums.

Domestic market pressures

Japan’s pharmaceutical market is slowing as it struggles to expand against an aging and declining population, as well as government pricing mechanisms intended to curb healthcare spending.

• Japanese government policies – In 2016*, healthcare costs reported by Japan’s Ministry of Finance reached JPY37.9tn, and are projected to rise to JPY54tn by 2025* (Ministry of Finance, 2017). The MHLW has imposed multiple measures to limit healthcare expenditure, including long-held regular pharmaceutical product reimbursement pricing revisions, and policies to encourage the use of generics. Collectively, these mechanisms have successfully driven down the cost of drugs, and encouraged the use of generics, creating an increasingly challenging business environment for Japan Pharma.
• Decelerating growth – PharmaVitae expects growth of the Japan Pharma peer set to slow to a 1.7% CAGR during 2017–22*, before falling back further to 0.3% growth in 2022–27* as mature products are impacted by the latest government pricing revisions. Furthermore, slower revenue growth and rising R&D expenses may hinder innovation and squeeze Japan Pharma’s development pipeline.

Aging population

Japan is facing an aging and declining population, and resultantly the Japanese government is taking significant measures to curb healthcare expenditure growth. According to the National Institute of Population and Social Security Research and census data, the Japanese population reached its peak in 2009, and officially entered decline in 2016, having fallen by approximately 1 million during 2010–15. Japan’s total population in 2017 is projected to be approximately 127.5 million (see figure below) (United Nations, 2017), but the pace of population decline is expected to accelerate steadily until 2045, by which time Japan is set to lose approximately 900,000 residents per year (IPSS, 2017). Japan’s population is estimated to fall to 108.8 million by 2050, and to 84.5 million by 2100 (United Nations, 2017).

Japan’s aging and declining population has been driven by:
• Falling birth rate – The country’s birth rate is the lowest of all the major markets (at 8.1 births per 1,000 population) (United Nations, Department of Economic and Social Affairs, 2017).
• High life expectancy – Japan has the highest average life expectancy worldwide (of 83.7 years) (WHO, 2017).

In 2015, 33% of Japan’s population was aged 60 years or older; by 2050, this will rise to 42.4%, while the proportion aged over 85 years is expected to more than double over the same period (United Nations, Department of Economic and Social Affairs, 2017).
Increasing prevalence of chronic disease

The prevalence of noncommunicable diseases is growing in Japan as better treatments become available and patients survive longer. Noncommunicable diseases are diseases of long duration, and generally slow progression, such as cardiovascular disease, cancer, chronic respiratory diseases, and diabetes. This presents both an opportunity and a challenge for Japan. On one side, the increase in chronic, age-related diseases, where there is unmet medical need, presents an opportunity for significant advances in the development of new therapies. However, as the size of the Japanese healthcare market grows, it places considerable financial strain on the domestic public healthcare system.

Pricing background

For Japan Pharma, favorable pricing outcomes hinge on products receiving a price premium, which can be awarded for added benefit over comparators, or innovation. Pricing and reimbursement decisions, which are made by the Central Social Insurance Medical Council (Chuikyo) within the MHLW, are closely connected with most medicines being reimbursed contingent on successful pricing negotiations. The medicine is then listed on the NHI reimbursement list.

For newly launched medicines, there are two pricing options:

- **Novel medicines** are priced using a cost-based method where drug development and manufacturing, importation, sales, administrative costs, and profits are considered. For medicines that show significant innovation, the allowed operating profit can be increased by 50–100% compared to the average operating profit of 18.3% in 2013 (Simon-Kucher, 2014). The price is then adjusted if a significant discrepancy exists between the calculated price and the drug’s foreign price.

- **For medicines for which there are similar drugs available in Japan**, the cost of the daily dose of the comparator is used to establish a base price (similar efficacy pricing method), to which further premiums are added depending on the additional benefit that the new drug offers compared to the similar drug (see table below). In addition, medicines that are awarded premiums for innovation, utility, or Sakigake designation (equivalent to a US Food and Drug Administration breakthrough therapy designation), and that are approved in Japan before any other market, are granted an additional 10% premium (Simon-Kucher, 2014).
Table 1: Pricing premiums given to medicines that can demonstrate benefit over comparators

<table>
<thead>
<tr>
<th>Type of premium</th>
<th>Premium (%)</th>
<th>Basic rules</th>
</tr>
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<tbody>
<tr>
<td>Novelty premium</td>
<td>70–120</td>
<td>Meeting all three conditions: clinically useful new mechanism of action, high efficacy/safety, improvement of disease treatment method</td>
</tr>
<tr>
<td>Utility premium (i)</td>
<td>35–60</td>
<td>Meeting two conditions of novelty premium: clinically useful new mechanism of action, high efficacy/safety, improvement of disease treatment method</td>
</tr>
<tr>
<td>Utility premium (ii)</td>
<td>5–30</td>
<td>Meeting one condition of above (tier i) or a formulation improvement shows a high medical usefulness</td>
</tr>
<tr>
<td>Marketability premium (i)</td>
<td>10–20</td>
<td>Orphan drug, etc</td>
</tr>
<tr>
<td>Marketability premium (ii)</td>
<td>5</td>
<td>Efficacy and effectiveness shows superiority over comparison drug</td>
</tr>
<tr>
<td>Pediatric use premium</td>
<td>5–20</td>
<td>Dosage and usage expressly includes those pertaining to children, etc</td>
</tr>
<tr>
<td>Sakigake designation premium</td>
<td>10–20</td>
<td>Newly entered drugs that have Sakigake designation, including drugs where pharmaceutical approval was obtained in Japan ahead of other countries, etc</td>
</tr>
</tbody>
</table>

Price revisions

In Japan, there is a system of biannual price revisions for ethical drugs (branded and patent protected drugs), which is designed to both lower treatment costs and encourage innovation (see figure below).

Figure 2: The revision of branded drug prices promotes replacement by generics and encourages innovation

- **Biannual price revisions** – Currently, the official NHI prices for ethical drugs are revised once every two years, based on surveys and calculations conducted by the MHLW. In these revisions, the prices of drugs are cut according to prevailing market prices using the similar efficacy pricing method, unless protected with a price premium.
- **Consecutive revisions** – The effect of price revisions has intensified recently with Japanese companies in their third year of consecutive price revisions owing to an irregular revision in 2017* to adjust for a 2% hike in consumption tax. The Japanese government is planning another consumption tax increase in October 2019, and price revisions are set to occur annually starting in 2020* (see “Drastic drug pricing reform” below for more detail).
• **Innovation premiums** – Products granted an NHI innovation premium are highly valuable for a company because they effectively escape the impact of the price reductions, and can be reimbursed at a higher price.

• **“Huge seller” price cuts** – The MHLW also has measures in place to cut the original prices of launch drugs that have shown overreaching growth. Those drugs that exceed initial sales projections are subject to additional price cuts. This will be particularly important for pan-indication drugs such as Opdivo (nivolumab; Bristol-Myers Squibb/Ono Pharmaceutical), which derive a premium price for initial approval in an orphan indication before expanding into other indications with larger patient populations. As an example, Japanese government officials recently reduced the reimbursement rate for Xtandi (enzalutamide; Pfizer/Astellas) by 25% to JPY2,354 per tablet, and for Opdivo by 23.8% to JPY278,000 per 100mg, after sales exceeded projections.

**Generic initiatives**

The Japanese government has also taken significant strides to promote the use of generics, and to decrease the prices of longer-listed products that are off-patent.

• **Z2 rule** – The MHLW has implemented the “Z2 rule,” under which targeted mature originator drugs will be subjected to price cuts that are linked to the uptake of generic versions. As such, longer-listed drugs will face price revisions that are repeated every two years until generics account for 60% of market share by volume. The government has also initiated multiple educational and administrative initiatives to lessen branded drug loyalty among physicians in Japan, and collectively these mechanisms have successfully driven down the cost of longer-listed products, and promoted the market share by volume of generics in Japan.

• **Significant generic penetration owing to government policies** – During 2012–16*, the market share by volume of generics in Japan increased from 25.8% to 65.5%. Currently, the MHLW is easily on track to meet its target of at least 80% market share by volume for generics by April 2020 (MHLW, 2017).

**Drastic drug pricing reform**

The MHLW recently overhauled its drug reimbursement policy in a move that encourages, but also potentially threatens, innovation by Japan Pharma as it places greater risk on the profitability of newly launched branded products. The multiple changes have been implemented from 2018* despite strong opposition from pharmaceutical trade groups in Japan, the US, and Europe, who cite fewer incentives for companies to develop drugs in Japan.

• **Annual price revisions** – Under the recent reforms, price revisions may begin to occur annually from 2020*, intensifying pressure on drug makers and product reimbursement in Japan.

• **Price maintenance premiums overhaul** – The new criteria for innovation premiums have set a higher standard and have led to a reduced number of drugs meeting the criteria and being awarded price maintenance premiums. The new rules also add a three-year eligibility cutoff period for second- and later-in-class drugs. After making the changes in 2018*, the MHLW announced that the number of products eligible for innovation premiums fell by approximately 32%. Additional proposals include a new premium coefficient tiering system of companies, which awards tiered premiums according to a company’s performance in promoting drug development specifically in Japan in preference to other regions.

**Cost-effectiveness assessment scheme**

In 2018*, the MHLW is also set to introduce a new cost-effectiveness assessment (CEA) scheme to revise prices for drugs deemed “kyogaku” (best-selling).

• **Pilot program of best-selling drugs** – A pilot program was designed to assess pricing for seven best-selling drugs with broad labels, including Sovaldi (sofosbuvir; Gilead) and Opdivo, and to establish their cost-effectiveness. The assessments were based on the product’s incremental cost-effectiveness ratio, or cost per quality-adjusted life year gained, similar to a model already implemented in the UK. The prices of most products in the CEA program were subsequently revised downwards. For example, Opdivo’s price was reduced by 23.8% for 2018* through the program.

• **Full implementation of CEA** – The CEA program is expected to be fully rolled out in 2018* for all ethical products (Cabinet Office - Council of Economic and Fiscal Policy, 2017). This will transform the business model of Japan Pharma, further rewarding innovative new drug development that demonstrates a real cost-effectiveness benefit, while further reducing the prices of longer-listed drugs.
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Strategy Analysis | Revenue Analysis | Therapy Area Analysis | Life-cycle Analysis | Pipeline Analysis

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