

## Big in Japan? As drug costs surge, diabetes and cancer win healthy premiums



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The impact on nations' medicine bills from the industry's strong run of expensive, novel products launches is well documented – a new [report](#) from *EvaluatePharma* reveals that in Japan, the world's second-biggest drug market, these new arrivals have already had a big impact.

In the five years to 2014 new drugs with a combined peak sales potential of \$34bn were given a green light by the country's regulators, double the value of the previous five-year period. Mirroring trends seen elsewhere, this was driven by both an increase in the rate of approvals and climbing prices. However, with the county willing to pay significant premiums for innovation – Opdivo achieved a record 60% boost to its reimbursement price, for example – it is clear that this market should remain a key target for ambitious drug companies.

**Top 10 Japan reimbursed drugs in 2014: ranked on company forecast peak sales**

Product	Company	Peak sales (\$m)	No of patients	Cost per patient per year
Suglat	Astellas Pharma	515	800,000	\$644
Farxiga	Bristol-Myers Squibb	491	760,000	\$646
Canaglu	Mitsubishi Tanabe Pharma	428	720,000	\$595
Zalutia	Eli Lilly	417	970,000	\$430
Effient	Daiichi Sankyo	393	540,000	\$728
Zytiga	Johnson & Johnson	344	7,500	\$45,921
Deberza	Kowa Company	334	530,000	\$630
Giotrif	Boehringer Ingelheim	226	6,900	\$32,816
Lusefi	Taisho Pharmaceutical Holdings	226	360,000	\$628
Daklinza	Bristol-Myers Squibb	207	17,000	\$12,156

*Source: EvaluatePharma Japan Sales, Volume, Pricing 2015*

Leading the charge of expensive new product launches in Japan have been novel diabetes drugs. The SGLT2 inhibitors Suglat and Farxiga, sold by Astellas and AstraZeneca, were the country's most potentially valuable products to reach the market last year, the report shows.

As part of the process of achieving a reimbursement price from the government – the main payer in Japan – companies must submit peak sales forecasts and patient number estimates, information that is released publically. *EvaluatePharma* has collated this data to yield an analysis of the country's reimbursement and approval record over the last few years; the full report can be downloaded [here](#).

Japan has a large treated diabetic population, which has been granted access to many of the new mechanisms of action to emerge in the past few years. Interestingly, cancer, which has been heavily responsible for climbing drug bills in the west, comes midway down the table in terms of sales potential of new approvals. This finding likely highlights the differences in disease rate occurrences between Japan and other developed nations.

<b>Forecast peak sales and count of new NHI reimbursed drugs - Japan</b>				
	<b>Peak sales (\$m)</b>		<b>Drug Count</b>	
<b>Therapy area</b>	<b>2005-09</b>	<b>2010-14</b>	<b>2005-09</b>	<b>2010-14</b>
Endocrine	1.0	6.1	7	27
Central Nervous System	1.9	5.3	25	52
Musculoskeletal	2.2	4.7	11	22
Cardiovascular	3.5	4.3	16	17
Blood	1.2	3.6	9	19
Oncology & Immunomodulators	1.2	3.2	29	40
Respiratory	1.5	1.7	16	17
Systemic Anti-infectives	1.7	1.7	30	27
Gastro-Intestinal	0.3	1.2	7	9
Sensory Organs	0.7	1.1	12	13
Genito-Urinary	1.1	0.8	14	7
Various	0.4	0.2	15	12
Dermatology	0.1	0.1	3	2
<b>Total</b>	<b>16.9</b>	<b>34.0</b>	<b>194</b>	<b>264</b>

*Source: EvaluatePharma Japan Sales, Volume, Pricing 2015*

The data also reveal that diabetes drugs managed to win much higher reimbursement prices from the government than the next most valuable therapy area, CNS. In the last five years 52 new drugs with peak sales potential of \$5.3bn were approved to treat conditions like depression and schizophrenia, almost double the number of novel endocrine products, which were deemed to be worth more.

This is not surprising considering the arrival of novel diabetes mechanisms and the lack of real innovation in the CNS psychiatric space. It is also explained further by looking at the two pricing methods used in the country, for setting the level at which new compounds will be reimbursed.

Drugs with comparable products are priced in direct comparison and are awarded a premium if they are judged to offer improvements, for example in terms of usefulness or treatment regimens.

Truly innovative products with no comparator are priced according to the sum of the key costs related to drug production, such as raw materials and labour, and any premium is based on a percentage adjustment to standard average operating profits for major Japanese manufacturers.

Further adjustments, some of which are based on the average prices paid elsewhere in the world, can also be made. Again, all these calculations are available publically and have been collated by *EvaluatePharma*.

Their analysis reveals that the price watchdog awarded two of the highest recorded adjustments for novelty, efficacy and safety in 2014.

Ono Pharmaceutical's checkpoint inhibitor Opdivo achieved a 60% boost on the standard operating profit rate. And Otsuka was awarded a 40% hike on Delytyba, its new tuberculosis drug.

The highest premium awarded for a similar drug last year was also 40%, to Bristol-Myers Squibb for its hepatitis C drug Daklinza; Johnson & Johnson's Olysio was used as the comparator. The fact that Daklinza has not managed to achieve FDA marketing approval in the US yet illustrates how Japan remains a key market for the major drug makers - notwithstanding the painful depreciation of the yen in the last couple of years.

These sorts of premiums will already be having an impact on Japan's drugs bill. Despite the country's biennial price cuts these expensive new arrivals will exert mounting pressure on budgets in years to come (*Biennial drug price cuts show no sign of holding back the Japanese market, March 11, 2015*). And, like elsewhere in the world, they will no doubt prompt similar debates around affordability and patient access.

**Top 5 largest adjustments for novelty, efficacy and safety 2006-14**

<b>Brand name</b>	<b>Company</b>	<b>Standard avg operating profit (%)</b>	<b>Adjustment</b>	<b>Final operating profit rate (%)</b>
Opdivo I.V. 20mg	Ono Pharmaceutical	16.9	60.0	27.0
Opdivo I.V. 100mg	Ono Pharmaceutical	16.9	60.0	27.0
Halaven Intravenous Injection 1mg	Eisai	19.2	40.0	26.9
Deltyba Tablet 50mg	Otsuka Pharmaceutical	16.9	40.0	23.7
Recomodulin Intravenous Infusion 12800	Asahi Kasei Pharma	19.2	30.0	25.0
Pirespa Tablet 200mg	Shionogi	19.2	30.0	25.0
Samsca Tablet 15mg	Otsuka Pharmaceutical	19.2	30.0	25.0

*Source: EvaluatePharma Japan Sales, Volume, Pricing 2015*

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