



CLOSE UP: Healthcare

Mixed Signals of Japan's Drug Pricing Policy

Key Takeaways

- **Balancing Costs and Innovation** – Japan faces ongoing tension between controlling healthcare spending and ensuring a competitive pharmaceutical market.
- **Positive Reforms in 2024** – The 2024 drug pricing system reform introduced new incentives and measures to promote pharmaceutical innovation.
- **Future Uncertainty** – The 2025 off-year drug price revision raised serious industry concerns. Anticipated challenges require strategic navigation as the Japanese government approaches discussions on the 2026 drug pricing system reform.

Japan is [the third largest pharmaceutical market in the world](#), following the United States and China. The regulatory and business environment for pharmaceuticals in Japan is shaped by two conflicting forces that put pressure on the government - the need to control the mounting social security and healthcare spending, and the need to maintain the attractiveness of the Japanese market and ensure the timely launch of innovative pharmaceuticals.

Impact of Drug Price Cuts on Innovation

Central to the Japanese government's efforts to optimize healthcare costs are revisions to medical fees and drug prices. However, repeated drug price cuts have created an unpredictable environment for pharmaceutical R&D in Japan, leading to the reemergence of drug lag and loss, and concerns about a further decline in the market.

In response, the Ministry of Health, Labor and Welfare (MHLW) is making efforts to signal that pharmaceutical innovation is properly valued in the Japanese market. In the 2024 drug pricing system reform, the MHLW introduced measures to expand eligibility for the usefulness premium upon initial listing to better evaluate innovative drugs, such as for rare diseases. Other measures included the introduction of a new price premium to incentivize the early introduction of new drugs to Japan, expansion of the eligibility criteria for the Price Maintenance Premium (PMP), and reform to the spillover repricing rule.

Japan's pharmaceutical industry faces a balancing act between fostering innovation and controlling healthcare costs amid an aging population and reemergence of drug lag and loss.





Furthermore, the [Gate Opening Summit for Innovative Drug Discovery](#) hosted by the Kishida administration in July 2024 and plans to establish a Public-Private Council in 2025 further signaled Japan's commitment to promote pharmaceutical innovation and address drug lag and loss.

Industry Concerns Over 2025 Off-Year Drug Price Revision

Despite the strides made in 2024, the implementation and scope of the 2025 off-year drug price revision have reignited significant concerns within the industry. The 2025 off-year drug price revision was implemented despite calls for its abolishment from the industry as well as members of both the ruling and opposition parties. The first-ever application of the PMP return in an off-year drug price revision raised particular concern, especially since it was implemented without sufficient consultation with the industry. Following such developments, the issue of drug pricing in Japan is now being escalated into a trade matter, with American industry associations submitting formal objections to the Japanese Embassy in the United States on the issue.

Outlook for 2026 Drug Pricing System Reform

Looking ahead to the 2026 drug pricing system reform, the Ishiba administration's limited focus on pharmaceutical policy has created a challenging environment. As discussions on the sustainability of the universal health insurance system intensify, driven by demographic shifts and propelled by changing political dynamics, political pressure to curb social security spending is expected to rise. Given such context, it is increasingly critical for the industry to strategically engage with political and government stakeholders to ensure their interests are effectively represented. Key developments to monitor include proposals from the Ministry of Finance's Fiscal System Council this spring, which may include measures that could negatively impact the pharmaceutical sector, such as expanding the cost-effectiveness analysis framework. The Basic Policy on Economic and Fiscal Management and Reform (*Honebuto*) 2025, which will be finalized this June, will play a pivotal role in shaping the direction of the 2026 reform. It will be crucial to ensure this document includes provisions that support innovation and provide long-term market stability and predictability for the pharmaceutical industry.

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