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Securing Japan’s Future as a Leader in Biopharmaceutical Innovation

Pharmaceutical Research and Manufacturers of America

November 18, 2025

The Global Biopharmaceutical Industry Plays an Important Role in Improving Health, Security and Economic Growth in Japan

1,200+
Medicines in Clinical Development in Japan

74%
Potential First-In-Class Treatments

436 Million
COVID-19 Vaccine Doses Administered in Japan

81%
Cancer Patients Returning To Work Within a Year of Diagnosis

140,000+
Direct Biopharmaceutical Sector Jobs in Japan

¥14 Trillion
Japan R&D Investment in the Last Decade

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Source: PhRMA analysis of Citeline data, April 2025; Endo et al., Returning To Work After Sick Leave Due to Cancer: A 365-Day Cohort Study of Japanese Cancer Survivors, *Journal of Cancer Survivorship* 10(2):320-9, 2016; Prime Minister's Office of Japan, April 2024; Ministry of Health, Labour and Welfare Statistics on Pharmaceutical and Medical Device Industry, Ministry of Internal Affairs and Communications Survey of Research and Development, 2024; Evaluate Pharma© World Preview 2024: Pharma's Growth Boost, 2024.

Pfizer's Contribution to Japan

Pfizer has a 72-year legacy in Japan, delivering innovative medicines and vaccines nationwide and developing breakthrough treatments for Japan that change patient lives

Established in 1849
(175th anniversary in 2024)

Japan:
Established in 1953
(70th anniversary in 2023)

ファイザーは日本で70周年

Japan Approval

#1

Pfizer ranked first in the number of new drug approvals (NME/PLE) in Japan in the 5-year period from 2020 to 2024

Japan Participation

23

Select pipeline assets across Pfizer's 5 focus therapeutic areas are currently under development in Japan

Source: Pfizer analysis of PMDA new drug approvals (excluding biosimilars), available at: http://www.pmda.go.jp/review-services/drug-reviews/review-information/p-drugs/0010.html, November 2025; Pfizer analysis of select pipeline assets in Pfizer Quarterly Corporate Performance Report for Q2 2025, available at: https://investors.pfizer.com/Investors/Events--Presentations/event-details/2025/Pfizer-Quarterly-Corporate-Performance--Second-Quarter-2025-2025-yCTFL_7HmL/default.aspx, November 2025.
Note: NME = new molecular entities; PLE = product line extension; Pfizer's focus therapeutic areas are Inflammation and Immunology, Internal Medicine, Oncology, Rare Diseases, and Vaccines.

Japan Has Many of the Right Elements To Be a Global Leader in Biopharmaceutical Innovation

Strengths of Japan's Ecosystem

- Strong basic science capabilities, including academic institutions and Nobel Prizes
- World-class regulator (PMDA) that ensures safety, efficacy and quality
- Biopharmaceutical research companies
- Rapid access to medicines for all citizens through National Health Insurance

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…But Harmful Policies Are Holding Back the Promise of Japan's Innovative Biopharmaceutical Sector

Japan's Pricing Policies Threaten Progress

- Launch prices in Japan are lower and falling relative to other major markets
- Japan then cuts prices repeatedly during the patent period
- Current government proposals will worsen the situation

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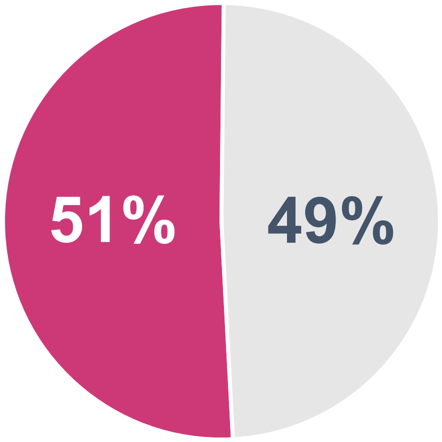
Japan's Drug Loss Is Projected To Worsen

70% of new medicines in late-stage clinical development in the United States or Europe have not yet begun development in Japan

Current Drug Loss

245 new medicines launched in the United States or Europe but not Japan between 2014 and the end of 2023

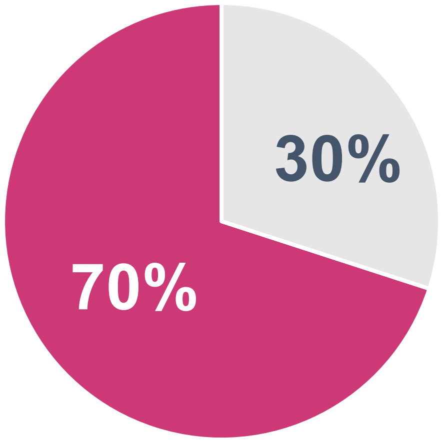
124 (51%) of these new medicines have not begun development in Japan



Future Drug Loss

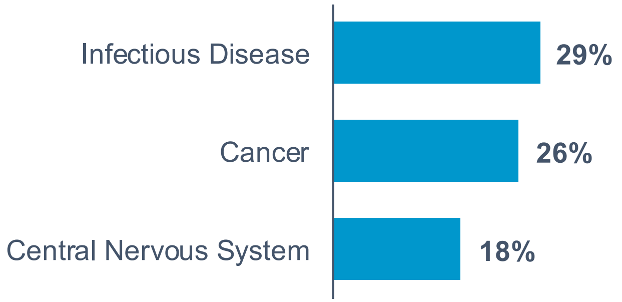
601 future new medicines are currently in Phase 3 clinical trials in the United States or Europe

404 (70%) of these future new medicines have not begun development in Japan



404 future new medicines not in development in Japan target major areas of unmet medical need

Top 3 therapy areas of new medicines not in development in Japan

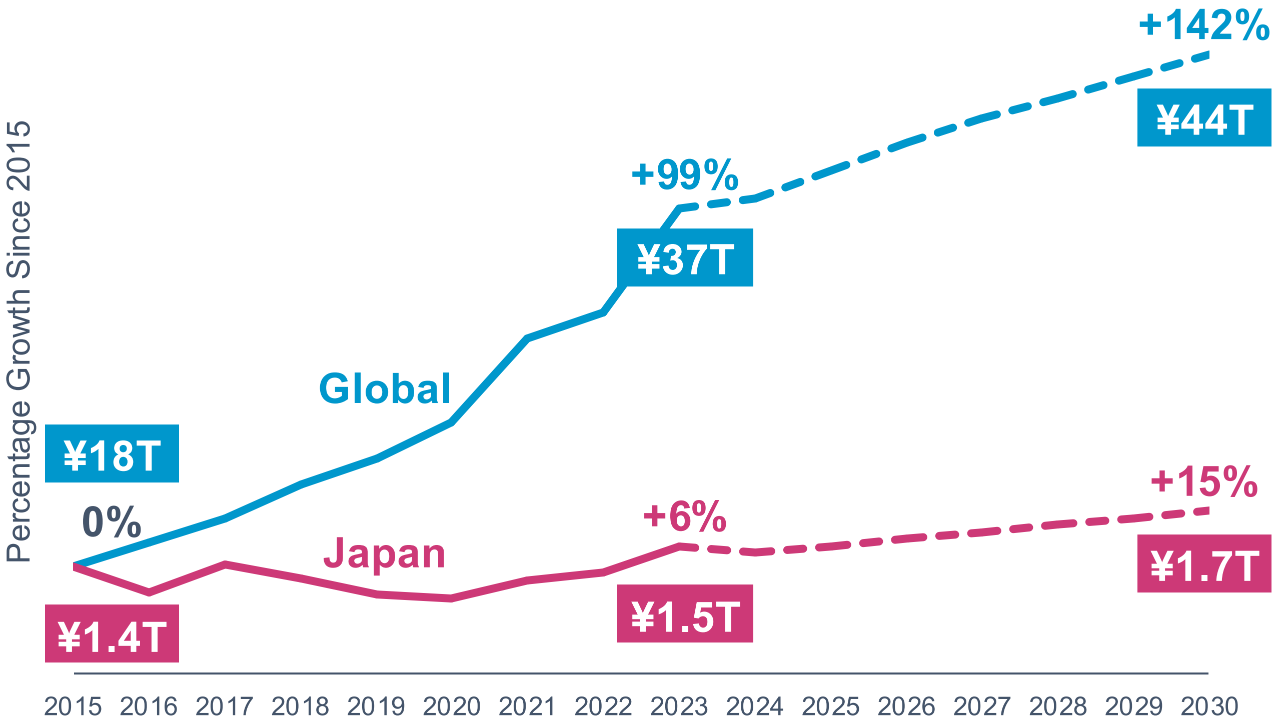


Source: PhRMA analysis of IQVIA MIDAS®, Global Data, NAVLIN and country regulatory authority data, November 2024.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023.

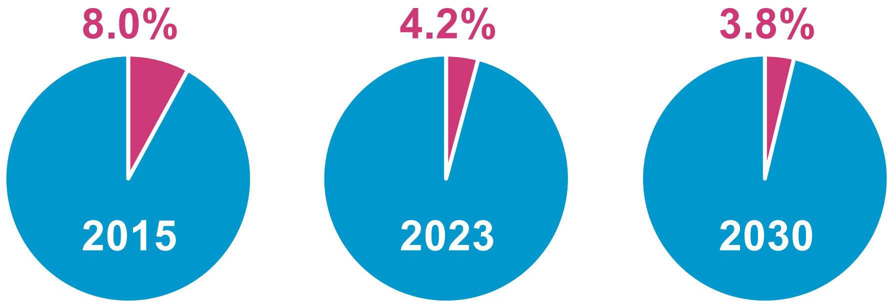
Japan’s R&D Investment Gap Is Projected To Worsen

Japan is now at a competitive disadvantage in attracting global biopharmaceutical industry R&D investment

Percentage Growth in Biopharmaceutical Industry R&D Investment in Japan vs. Global



Japan Share of Global Biopharmaceutical Industry R&D Investment



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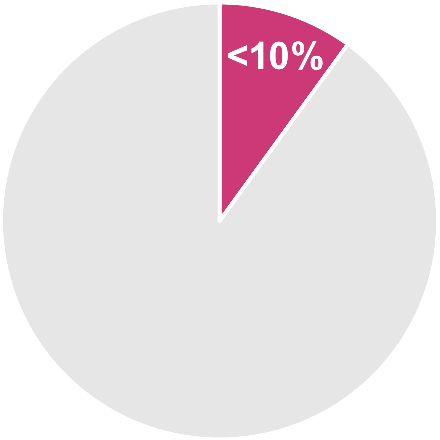
Source: PhRMA analysis of Ministry of Health, Labor and Welfare Statistics on Pharmaceutical and Medical Device Industry, Ministry of Internal Affairs and Communications Survey of Research and Development, 2024; Evaluate Pharma© World Preview 2024: Pharma’s Growth Boost, 2024.

Japan Has Disproportionately Reduced Spending on Medicines

The government has become overly dependent on drug price cuts to control the overall social security budget

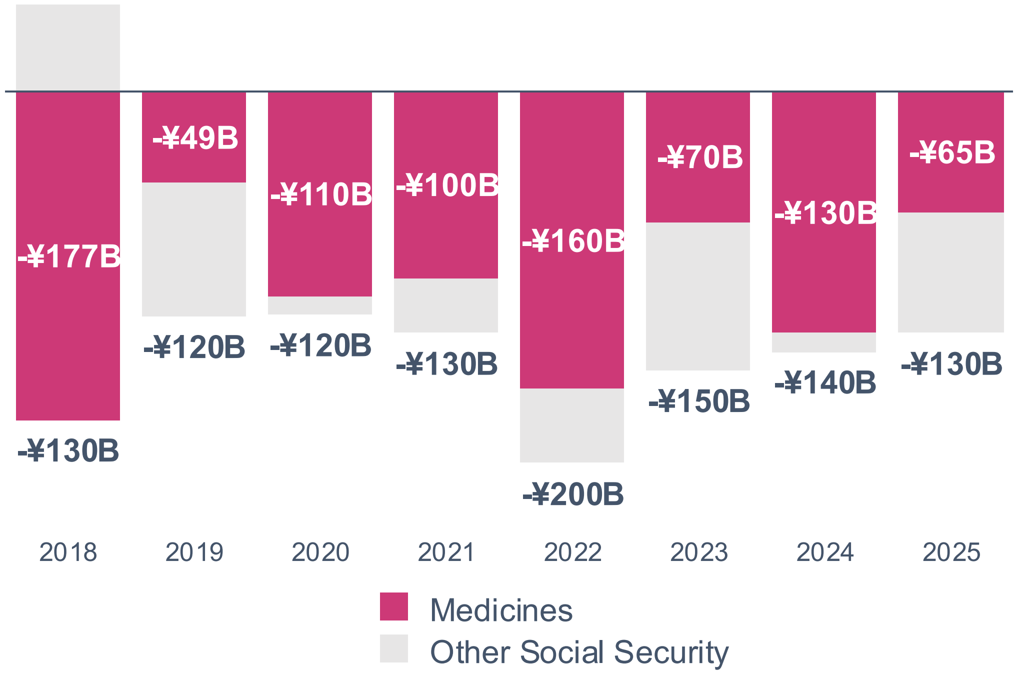
Share of Social Security Budget Spent on Medicines

Less than 10% of the budget is spent on medicines



Share of Social Security Budget Reductions from Medicines vs. Other Sectors

But 70% of budget reductions are from drug price cuts



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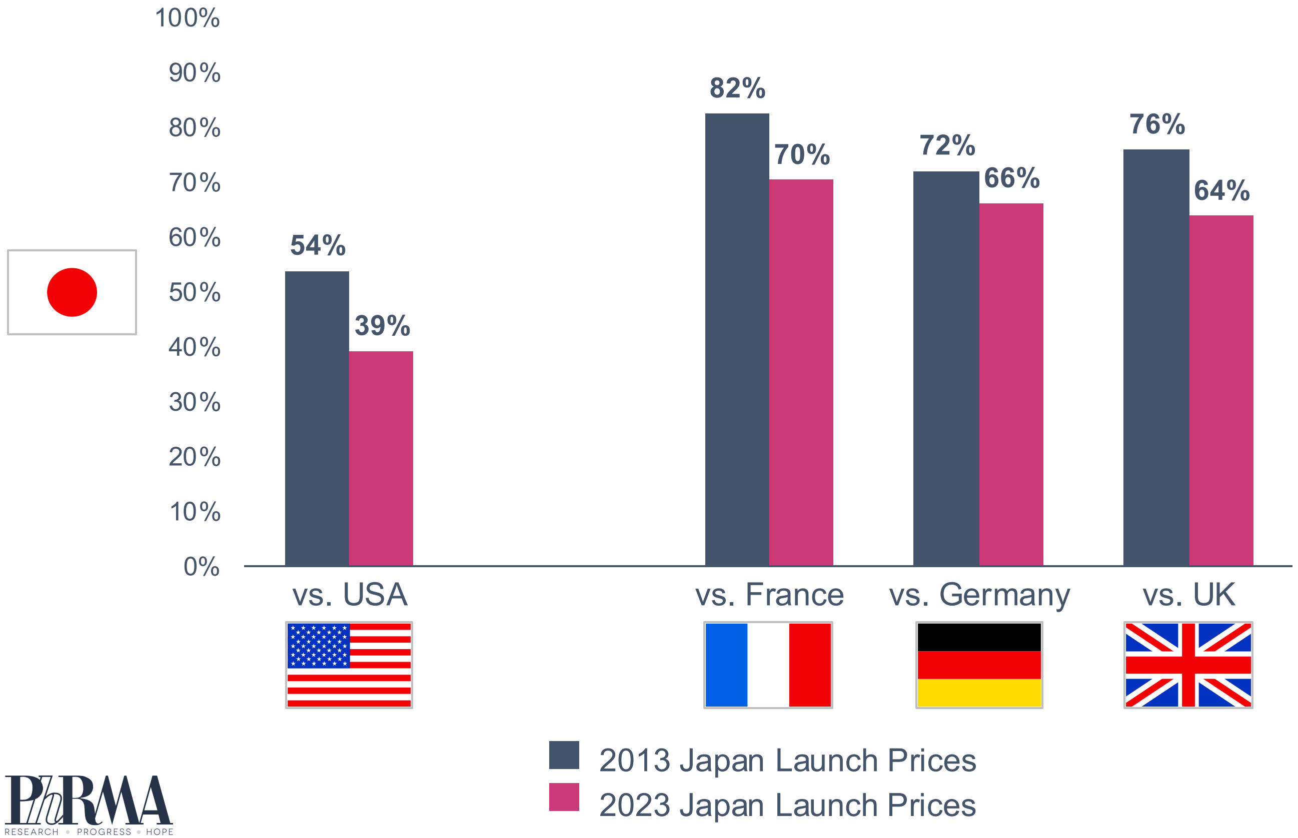
Source: PhRMA analysis of Ministry of Finance data, March 2025.
Note: The bar chart shows the national government contribution to health care spending, which is approximately 25% of total health care spending.

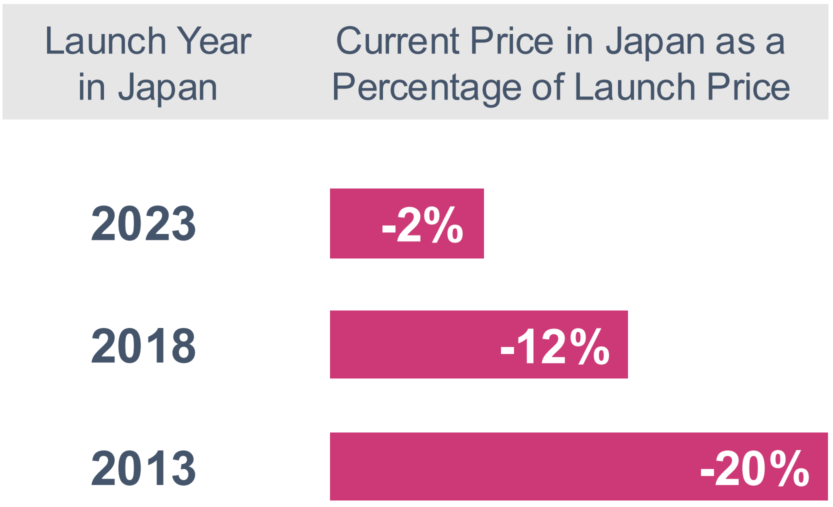
Japan’s Drug Pricing Has Worsened Significantly

Launch prices in Japan fell relative to all major markets over the past decade, and these price differentials are then exacerbated by repeated price cuts during the patent period

New Medicine Launch Prices in Japan as a Percentage of Other Country Launch Prices in 2013 vs. 2023



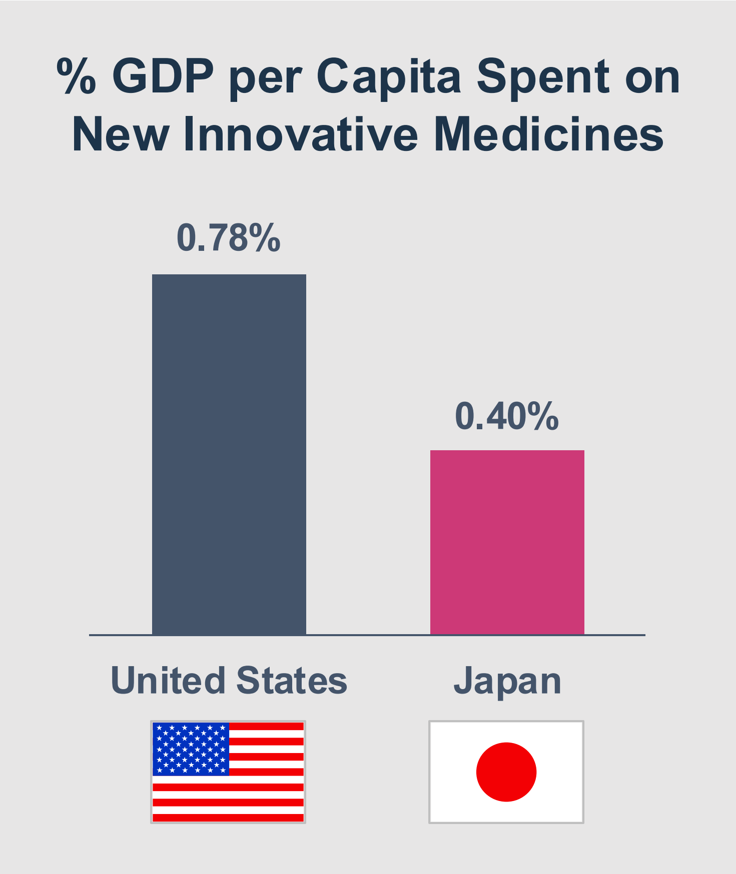
Average Price Erosion in Japan Since Product Launch



Source: PhRMA analysis of Global Data country prices for brand medicines, October 2025.
Note: Price erosion is calculated by comparing launch vs. current prices of brand medicines in Japan and then calculating the average price erosion for brand medicines that launched in Japan in the same year.

U.S. Most Favored Nation Policy Increases Urgency for Action

Japan has a window of opportunity to address these longstanding challenges and the concerns raised by the Trump Administration



Section 3. Addressing Foreign Nations Freeloading on American-Financed Innovation

"The Secretary of Commerce and the United States Trade Representative shall take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security and that has the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."

Source: Trump, Donald J. Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. Federal Register, vol. 90, no. 95, pp. 20749–20751. Executive Order 14297 at Sec. 3, May 15, 2025; Ernst & Young, "High-Income Country Spending on Innovative Medicines," June 2025.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023.

Industry Concerned About MFN Policy Impact in Japan

MFN policy could reshape global incentives and lead individual companies to change product development and launch strategies in Japan, according to a new survey

Foreign-headquartered biopharmaceutical companies play a critical role in Japan

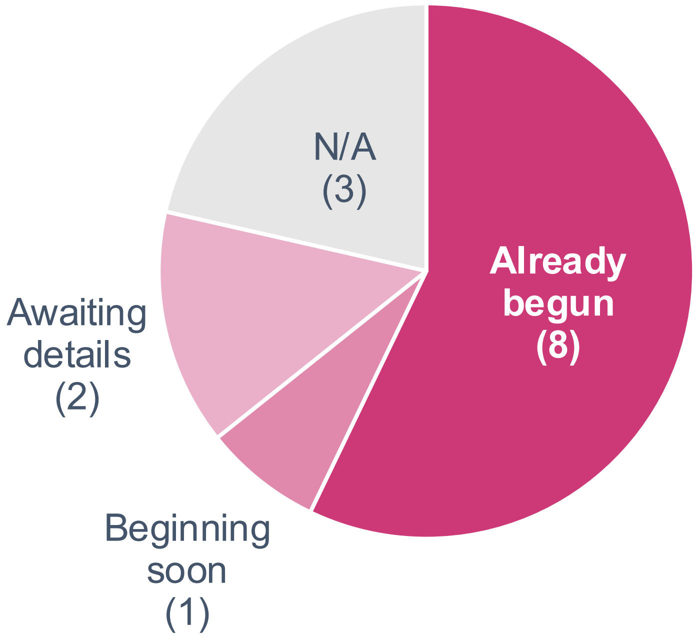
73%

New Medicines in Clinical Development in Japan

79%

New Medicines Launched in Japan from 2014-2023

Over half of surveyed companies reported beginning MFN impact discussions with their global headquarters



4 of 8 companies that began MFN impact discussions are required to review Japan prices

- Re-evaluating products with upcoming pricing negotiations
- Considering strategies and timelines for listing in Japan

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Source: PhRMA analysis of Citeline, IQVIA MIDAS®, Global Data, NAVLIN and country regulatory authority data, April 2025; PhRMA Japan member company survey regarding MPN policy impacts on Japan market, September 2025.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023.

A Restored Biopharmaceutical Innovation Ecosystem Will Bring Significant Benefits to Japan

Biopharmaceutical Innovation Ecosystem

Benefits to Japan

- Drug discovery and faster patient access to the latest medicines
- A more effective and sustainable health care system
- Increased investment, jobs and economic growth

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Our Recommendations To Secure Japan's Future Leadership

This year's drug pricing reforms should be guided by a forward-looking vision that actively reverses the policies causing drug loss and declining investment

1 Maintain Drug Prices During the Patent Period

- Exempt patented medicines from annual price cuts
- Stop expansion of cost-effectiveness assessment system
- Cap frequency and magnitude of price cuts from repricing rules

2 Improve Initial Price Setting and Recognition of Value

- Ensure appropriate recognition of innovation, including new modalities
- Reward additional product value demonstrated post-launch

3 Establish National Strategy Under Cabinet Secretariat

- Identify all necessary actions and KPIs to achieve a fully functional biopharmaceutical innovation ecosystem

Working Together To Reestablish Japan as a Leader in Drug Discovery

For the millions of patients in Japan and around the world who are counting on us to succeed

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