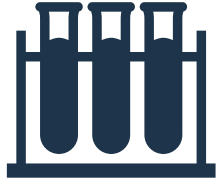


Achieving a Healthier and More Secure Future Through Biopharmaceutical Innovation

Simone Thomsen
Chair, PhRMA Japan-Based Executive Committee
President and Representative Director, Eli Lilly Japan K.K.

April 8, 2025

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



8,000+

Medicines in Clinical
Development Worldwide
(1000+ 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+


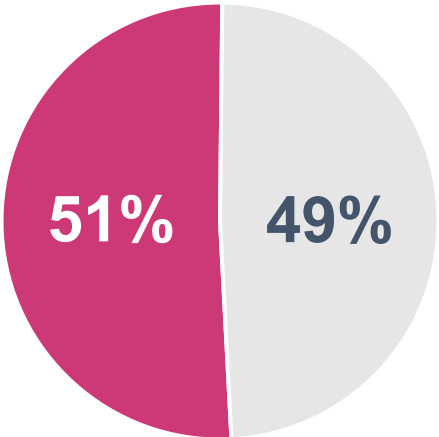

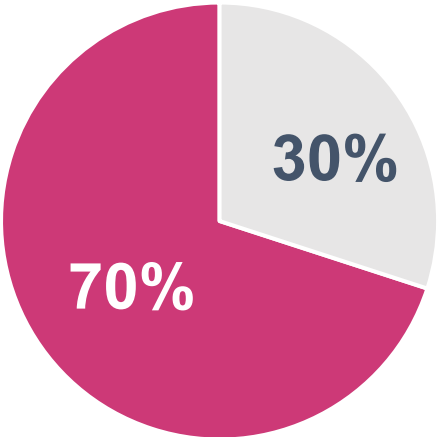

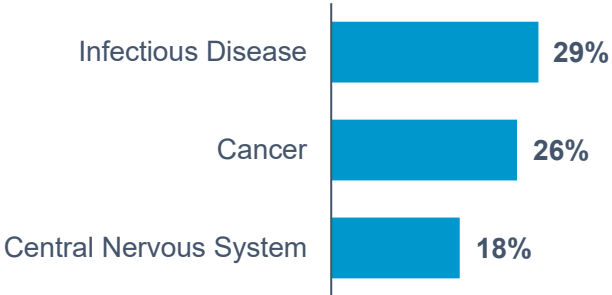
Direct Biopharmaceutical
Sector Jobs in Japan

¥250 Trillion

Global R&D Investment in
the Last Decade
(¥13 Trillion in Japan)

Problem 1: Japan's Drug Loss Projected To Worsen

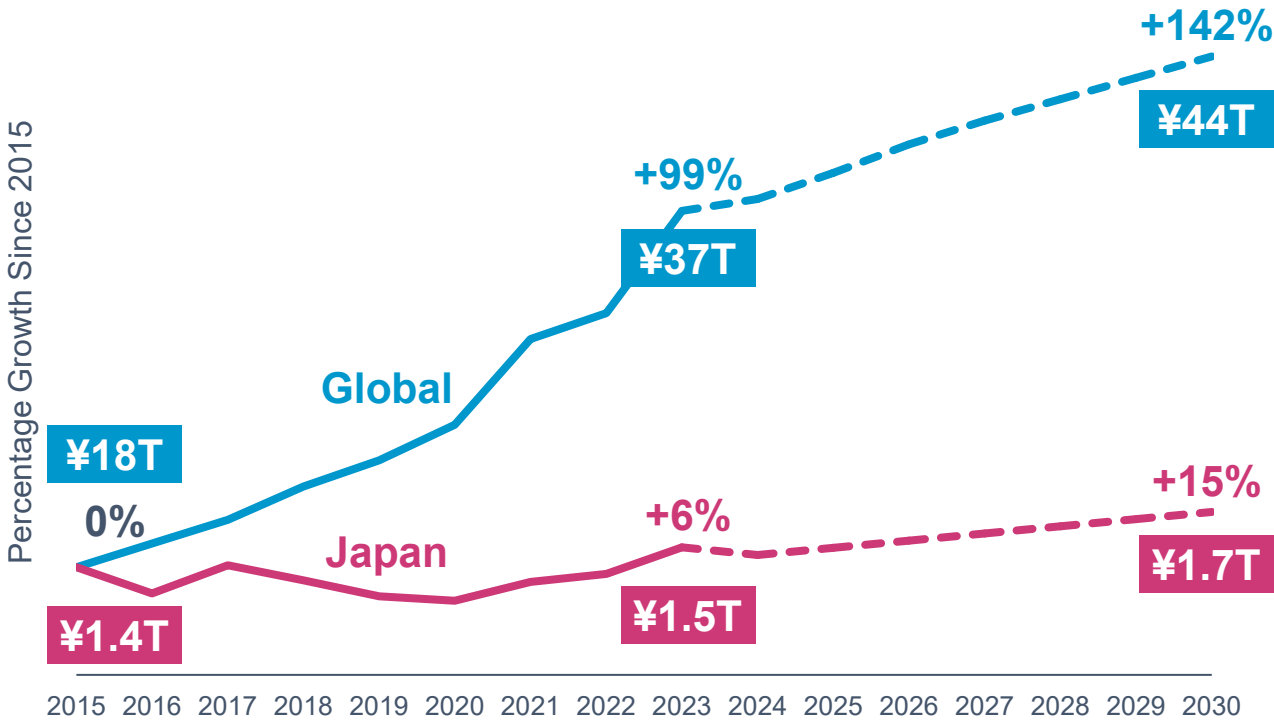
70% of new medicines in late-stage clinical development in the United States or Europe have not yet begun development in Japan

Current Drug Loss	Future Drug Loss	
<div>245 new medicines launched in the United States or Europe but not Japan between 2014 and the end of 2023</div> <div>124 (51%) of these new medicines have not begun development in Japan</div> <div></div>	<div>601 future new medicines are currently in Phase 3 clinical trials in the United States or Europe</div> <div>404 (70%) of these future new medicines have not begun development in Japan</div> <div></div>	<div>404 future new medicines not in development in Japan target major areas of unmet medical need</div> <div>Top 3 therapy areas of new medicines not in development in Japan</div> <div></div>

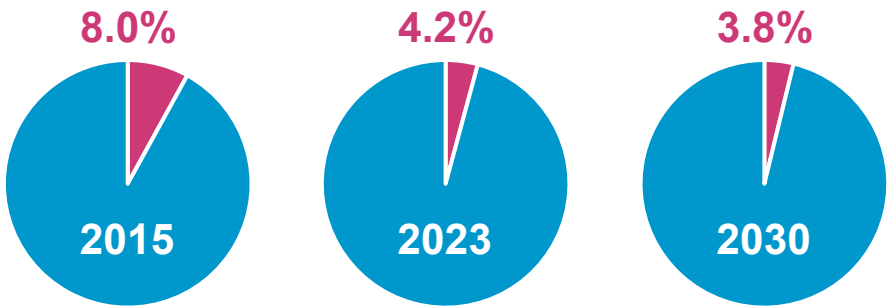
Problem 2: Japan's R&D Investment Gap Projected To Worsen

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



Japan Has Repeatedly Cut Prices of Innovative Medicines

The 2025 expanded off-year drug price revision reversed the positive direction of the 2024 drug pricing reform and undermined efforts to restore the innovation ecosystem

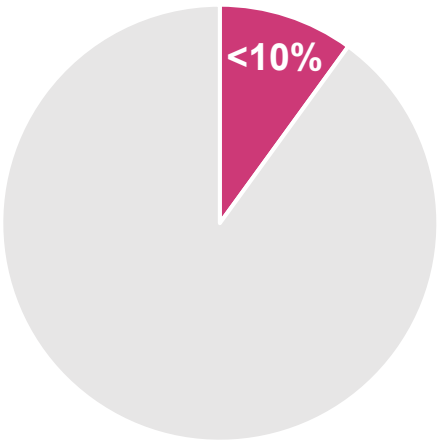


Japan Has Disproportionately Reduced Spending on Medicines

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

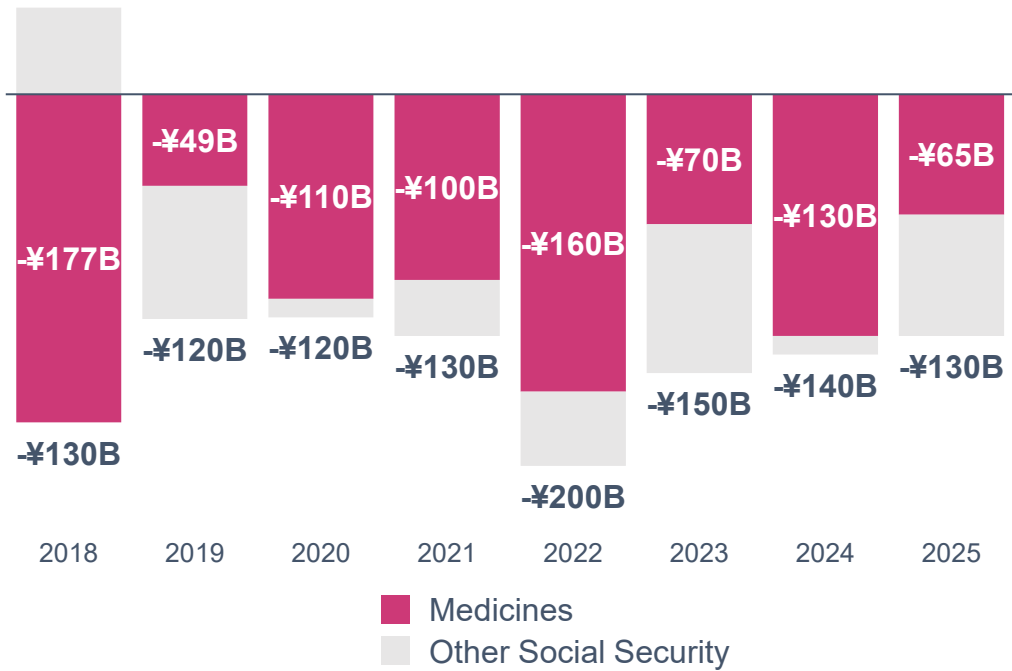
Share of Social Security Budget Spent on Medicines

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



Increased Focus on U.S.-Japan Biopharmaceutical Trade

Repeated price cuts to innovative medicines and lack of transparency have increased attention on policies that undervalue U.S. exports and increase the U.S. trade deficit



2025 National Trade Estimate Report on
**FOREIGN TRADE
BARRIERS**

of the President of the United States
on the Trade Agreements Program

UNITED STATES TRADE REPRESENTATIVE

The U.S. had a \$68 billion trade deficit with Japan in 2024. Pharmaceuticals are the second largest U.S. export to Japan.

“Japan made changes to its [Price Maintenance Premium] rules that significantly reduced the number of innovative products ... that received the full benefit of the PMP.”

“The United States continues to urge Japan to solicit and consider the input of all stakeholders, including U.S. stakeholders, when developing any measures related to reimbursement policies....”

Foreign-Headquartered Biopharmaceutical Companies Are Major Contributors to Japan's Health and Future

Medicines Pipeline



Foreign companies are responsible for **73% of new medicines in clinical development in Japan**

Clinical Trials



Foreign companies are responsible for **78% of clinical trials in Japan**

Medicines Launched



Foreign companies are responsible for **79% of innovative medicines launched in Japan**

Priorities to End the Crisis in Bringing Innovation to Japan

Drug pricing reforms, supportive policy frameworks and public-private partnership are needed to restore Japan's leadership in life sciences and stop the recurrence of drug loss



Drug Pricing Reforms To Promote Innovation and Patient Access



Maintain Drug Prices During Patent Period

- Abolish off-year drug price revision
- Stop expansion of cost-effectiveness assessment system
- Improve market-expansion repricing (e.g., regenerative medicines)

Supportive Government Policy Frameworks



Formulate National Biopharmaceutical Strategy

- Develop and monitor KPIs under a cross-ministerial control tower function



Reform Current Fiscal Framework

- Recognize health system savings and economic growth from innovative medicines

Achieved Through Public-Private Partnership

Pro-Innovation Drug Pricing Reforms Are Urgently Needed

The 2026 NHI drug pricing reform must stop the policies that are accelerating Japan's drug loss and declining investment

Top Challenges with Current System



Half of patented medicines are subjected to annual price cuts



Proposed expansion of cost-effectiveness assessment system will worsen drug loss



Market-expansion repricing rules are outdated for innovative modalities

Policy Reform Recommendations

Maintain Drug Prices During Patent Period



Abolish the off-year drug price revision



Stop expansion of cost-effectiveness assessment system



Improve market-expansion repricing rules (e.g., regenerative medicines)

New Government Policy Frameworks Are Urgently Needed

Japan needs a comprehensive national strategy and a new fiscal framework to restore the biopharmaceutical sector and ensure the latest innovations reach Japan's patients

National Biopharmaceutical Strategy

Honebuto, 2023

"In order to promote investment globally in new modalities, a comprehensive strategy will be created under the control tower function of the government."

Council on Improving Drug Discovery Capabilities, 2024

"...we need a national strategy that supports biopharmaceuticals and promotes early development and clinical trials."

Areas of Focus



- Promoting a transparent and pro-innovation drug pricing system
- Strengthening the environment for R&D and biotech start-ups
- Improving Japan's regulatory environment

Fiscal Framework Reform

Decisions about the drug budget should reflect the economic benefits of innovative medicines



Sho Aoki Is an ALS Patient Advocating for Eliminating Japan's Drug Lag and Loss



- In 2022, Sho Aoki was diagnosed with ALS at age 33 and given a prognosis of 2 to 5 years.
- By April 2023, a new ALS treatment approved in the United States remained unapproved in Japan.
- ALS progresses rapidly, so he decided to import the drug personally due to the urgency of his situation.
- He started a fundraising campaign to cover the annual drug cost of 30 million yen. He received his first dose in September 2023.
- Drug lag is critical for rapidly progressing diseases like ALS and can be fatal.
- He questions Japan's review and approval speed, feeling that it lacks urgency.

Video Message from Sho Aoki



Working Together To Ensure No Patient Is Left Behind

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



