EFPIA Day 2025 Press Event

Strategic Shift in the Era of Global Drug Pricing Policy Transformation

– Can Japan Safeguard Healthcare Access?—





21 October 2025

EFPIA Japan

Chair Takahiko Iwaya

EFPIA-Japan is promoting policy advocacy activities through collaboration with patient organizations.

Addressing Joint Statement

Discussion on issues and solutions in the healthcare system with patient representatives and industry, government, and academia.

Preparation of a joint statement addressing the "Drug Lag and Loss Issues, and Access to Clinical Trial Information."

Promoting PASE: Patient Advocacy Support

Implementation of a new initiative to promote the activation of patient group activities in Japan and support the reflection of patient voices in the healthcare system, aiming to enhance the medical environment surrounding patients.
(PASE: Patient Advocacy Support by EFPIA Japan)

Making Policy Proposal

Engaging in continuous discussions with patient representatives to deliver innovative new drugs to patients in Japan more quickly.

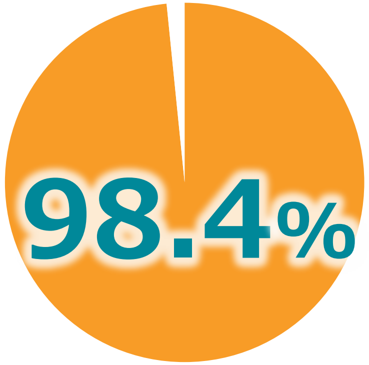
Mr.Takeshi Shukunobe, PPeCC, Inc.: "The significant change in quality of life brought about by medication is what innovation truly means. We are being asked how to reflect patient voices, such as those describing a medication as a 'life-changing drug,' in evaluations."

Mr.Yoshiyuki Majima, NPO PanCAN Japan:
“It is important to reflect the voices of patients in decision-making. Rather than viewing healthcare costs as a target for suppression, we should recognize investments in pharmaceuticals as growth strategy investments that contribute to enhanced productivity through continued employment and prevention of care needs.”

Pharmaceuticals are considered to support the social participation of people living with disease and contribute to improving their quality of life.

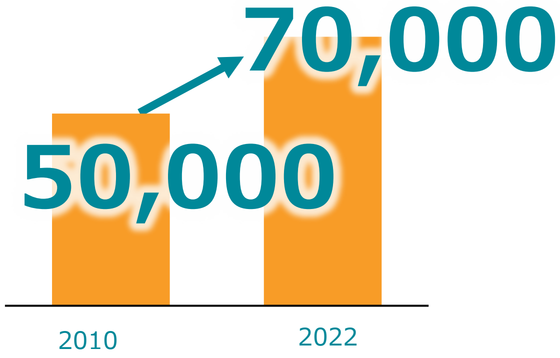
Continuing work while attending medical appointments

The percentage of employed cancer patients who wish to continue working in the early stages of diagnosis



Source: Journal of Industrial Health

Individuals receiving treatment for cancer while working (per 10,000 employed)



Source: Estimated from the MHLW's guidelines for supporting the balance between treatment and work in the workplace (Analysis of Labor Economy for the fiscal year 2011)

Social security as an investment for the future

A one-year extension of average lifespan increases the Gross Domestic Product

+4%

Source: Regional Economy 2019, Chapter 3, Section 1: Health and Economic Activities - Cabinet Office

As health improves, the number of individuals employed is likely to increase, and the productivity of workers will rise. This can lead to enhancements in both the quantity and quality of the labor force, potentially boosting the overall production of each region

Source: Regional Economy 2019, Chapter 3, Section 1: Health and Economic Activities - Cabinet Office

Expectations and concerns for the pharmaceutical industry due to changes and transformations in the macro environment.

<Expectations>

Indicating that the pharmaceutical industry is a core industry, a public-private dialogue has been initiated

The pharmaceutical industry is an important core industry and growth industry for our country

- The public-private council has been established to address drug lag/loss and strengthen the international competitiveness of the pharmaceutical industry
- Promoting a space for substantive action discussions through the public-private council working group

Economic and fiscal improvements under the new administration

Establishing health and medical security as a pillar of policy

- The new administration's "responsible proactive fiscal policy“
- Continues to position the pharmaceutical industry as a core industry, making "growth investment" necessary

<Concerns>

Alignment of the fiscal framework and systems is necessary

A review of the fiscal framework and drug pricing system that constrain industrial growth is needed

- Review of the traditional fiscal framework that aims to keep 'the growth of social security costs within the limits of aging growth’
- Review of the cost-effectiveness system, which functions as a price reduction system and is far removed from the original meaning of the term

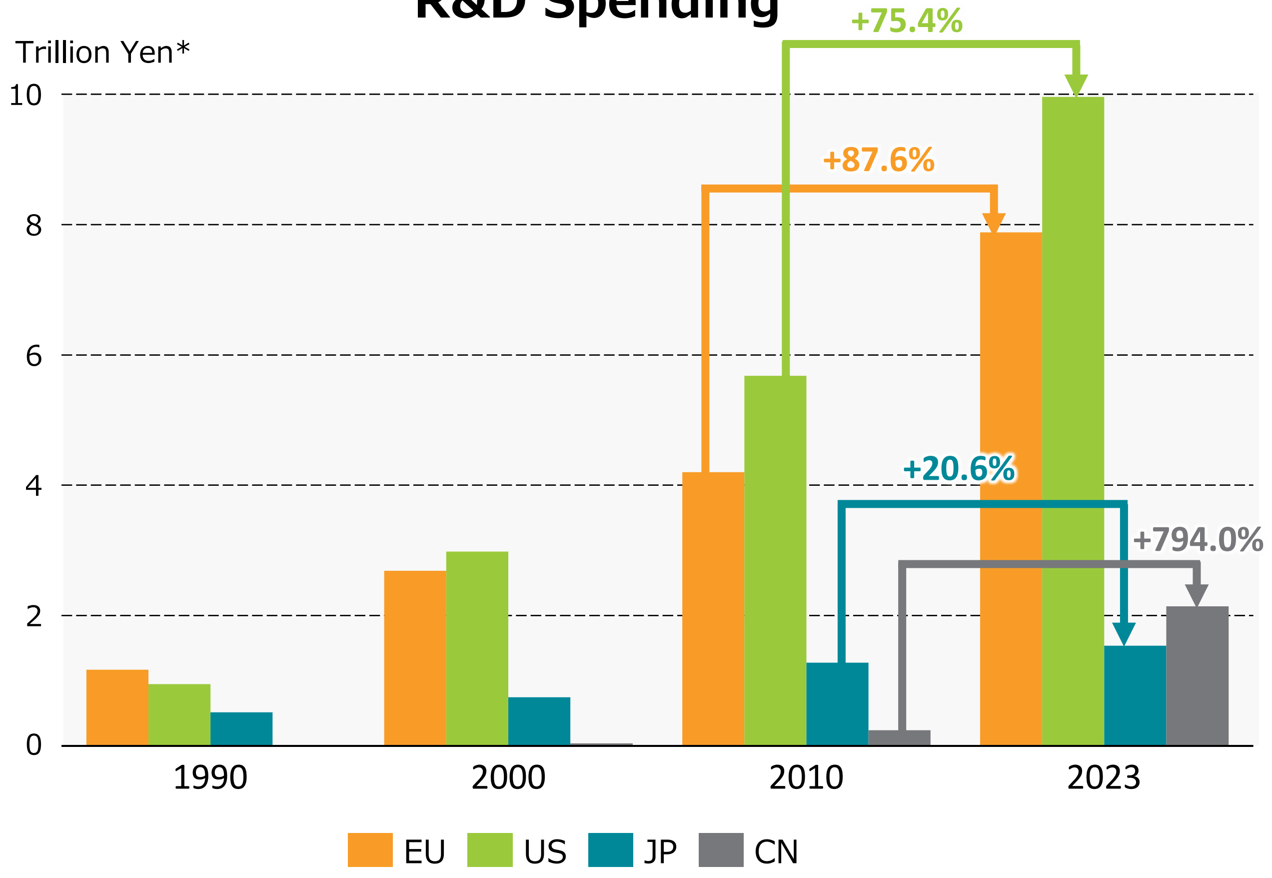
The impact of the U.S. Most-Favored-Nation drug pricing policy

Geopolitical risks associated with the U.S. Most-Favored-Nation drug pricing policy

- Due to the system that decreases drug prices during the patent period, such as through market expansion recalculation, Japan has become a target
- There is a risk that pharmaceutical companies may postpone the launch of new drugs in Japan, which has. impact on Japanese patients

The lower growth rate of pharmaceutical R&D spending in Japan, compared to the U.S, EU, and China
Declining Japan's market share in the global pharmaceutical market.

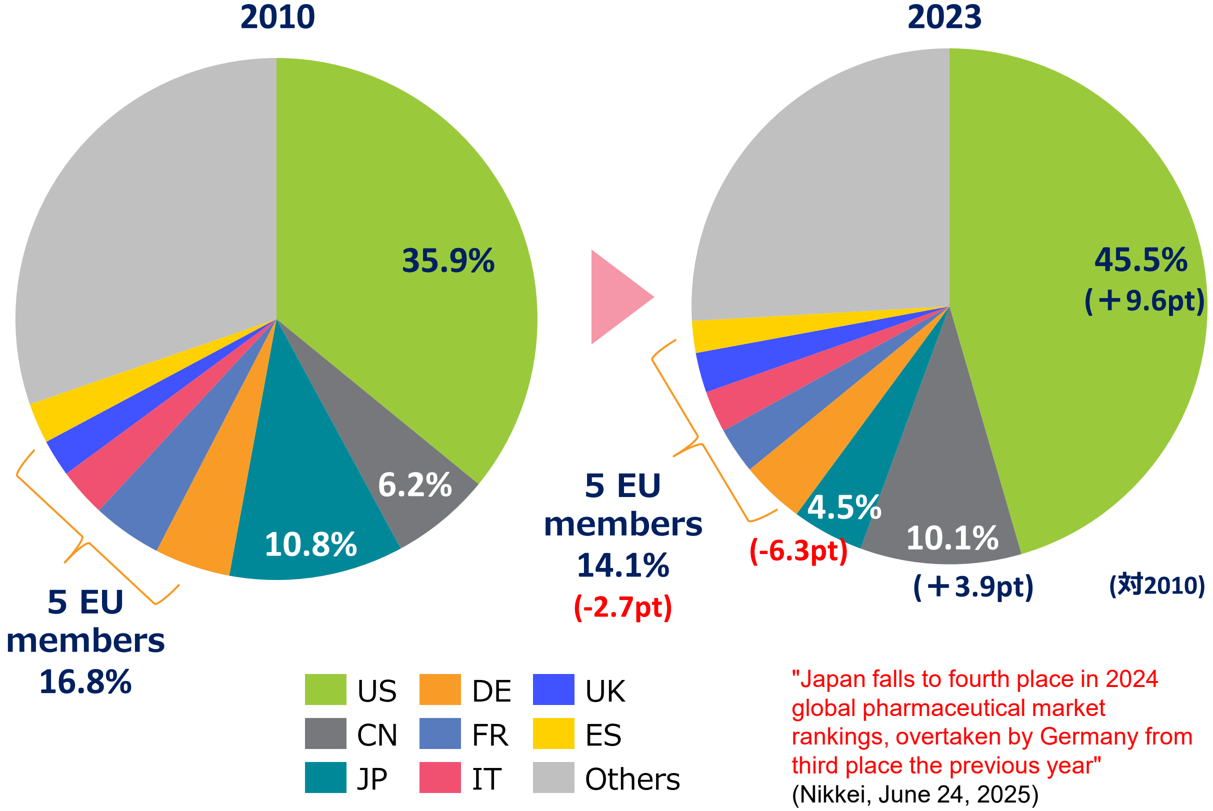
Trends in Pharmaceutical R&D Spending



* Note : Convert to yen using the average exchange rate for the year 2023 as a fixed rate.

Source：Revision of EFPIA, The Pharmaceutical Industry in Figures,2025

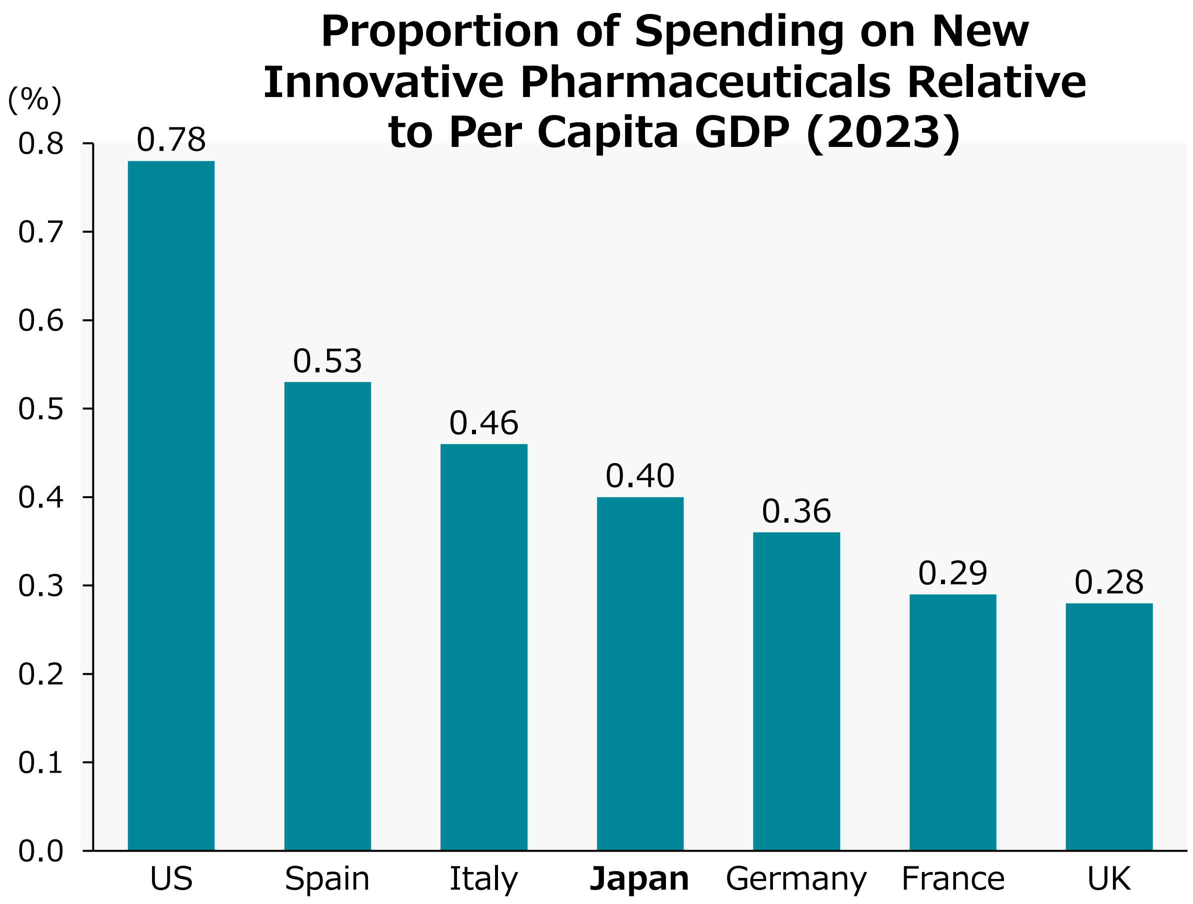
The share of each country in the global pharmaceutical market



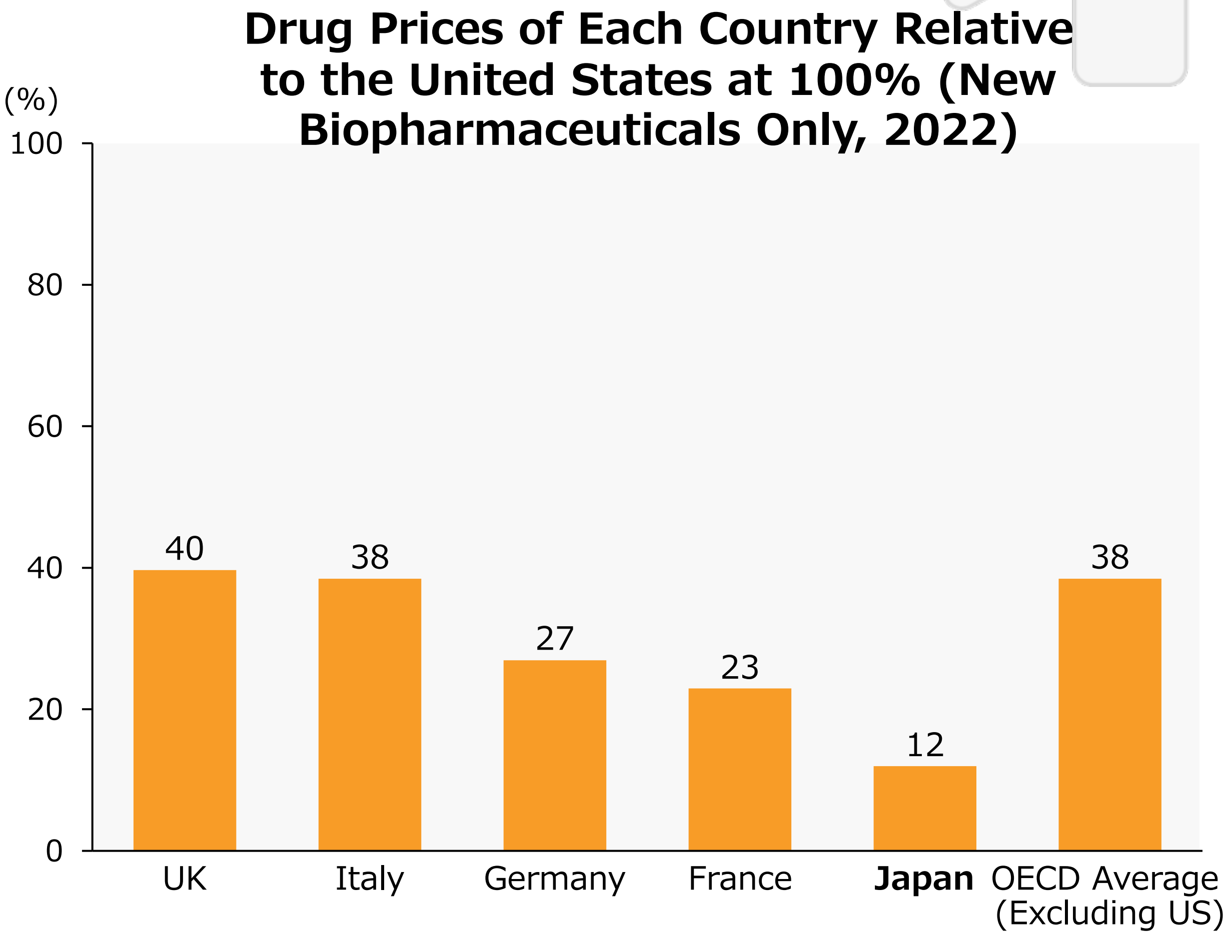
"Japan falls to fourth place in 2024 global pharmaceutical market rankings, overtaken by Germany from third place the previous year"
(Nikkei, June 24, 2025)

Source: Copyright © 2025 IQVIA. Created by the Institute for Pharmaceutical Industry Policy based on the IQVIA World Review, Data Period 2010 to 2023 (Reproduction without permission prohibited).
Reference: Japan Pharmaceutical Manufacturers Association, DATA BOOK 2025.

As pharmaceuticals are shared globally, the United States significantly burdens the development of innovation, and increased spending by countries including Japan is desired.



Source: PhRMA Public Document
“Re: Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation”, 27th June 2025



Source: Modified from RAND CORPORATION “International Prescription Drug Price Comparisons Data2022“

U.S. Most-Favored-Nation policy is prompting to consider the drug pricing policies and investment approaches for sustainable drug development.

The U.S. Most-Favored-Nation Pricing Policy

U.S. Presidential Executive Order: Providing Most-Favored-Nation Pricing for Prescription Drugs to American Patients (May 12, 2025)

- **Introduction of Most-Favored-Nation (MFN) pricing in the U.S.**
  - Ensure American citizens can purchase medications at the same minimum prices as those in other advanced countries.
- **Countering 'free-riding' by countries other than the U.S.**
  - The Secretary of Commerce and the Trade Representative will take measures against foreign price suppression policies that undermine U.S. national security.

Source: U.S. The WHITE HOUSE website

Concerns Arising from the Implementation of the U.S. Most-Favored-Nation Pricing Policy

Japanese prices are referenced in the U.S.

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Deteriorating Profitability of Pharmaceutical Companies **in the U.S. Market**

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To maintain drug prices in the U.S., **consider avoiding the launch of new drugs in the Japanese market or withdrawing from it.**

Expansion of Drug lag·Loss

Source: Japan Research Institute, Michinori Naruse, "The Impact of U.S. Trump Drug Pricing Policy on Our Country."

The pharmaceutical industry must be positioned as a key industry for Japan, and public and private sectors must jointly explore reforms to address drug lag/loss.

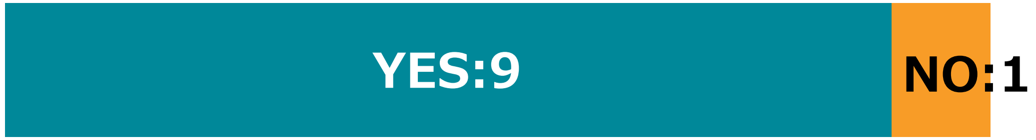
Questionnaire of EFPIA Japan Board Companies Regarding the U.S. Most-Favored-Nation Drug Pricing Policy

N=10

Q1 : Does your company (HQ) consider this to impact global pricing strategy?

Q3 : Have there already been any product impacted in other countries due to this?

Q2 : Does your company (HQ) consider this to impact global R&D strategy?



Q4 : Have there already been any product impacted in Japan due to this?

Source: EFPIA Japan Board Member Company Survey: "Impact of the U.S. Most-Favored-Nation Drug Pricing Policy" EFPIA Japan Board Member Survey: "Impact of the U.S. Most-Favored-Nation Drug Pricing Policy" Oct.2025

Amid the international changes in drug pricing policies, Japan requires a strategic policy shift to achieve 'sustainable access'

Investment in innovative pharmaceuticals is not just a cost; it enhances the quality of life and labor productivity for each individual, positively impacts the economy, and contributes to fiscal stability.
It is **a crucial investment in society**.

EFPIA Japan's Proposals for the 2026 Reform of the Drug Pricing System

There are no countries among major Western countries that have a rule to forcefully reduce the prices of new drugs under patent every year.

- Exclude new drugs under patent from drug price revisions
- Review the rules for 'market expansion recalculation'
- Not to expand 'cost-effectiveness evaluation'

The evaluation of the value of innovative pharmaceuticals requires reforms that take into account not only domestic circumstances and finances but also international drug pricing levels and geopolitical perspectives.

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European Federation of Pharmaceutical Industries and Associations

Thank you