PhRMA
RESEARCH • PROGRESS • HOPE

How Could the 2024 NHI Drug Pricing Reform Reduce Drug Lag and Loss?

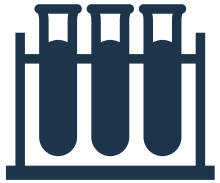
A first step taken – further solutions needed

April 3, 2024

Pharmaceutical Research and Manufacturers of America

The Biopharmaceutical Industry's Contribution to Japan

Improving health, reducing overall medical costs and driving economic growth



8,000+

Medicines in Development Worldwide
(1500+ in Japan)

81%

Cancer Patients Returning To Work Within a Year of Diagnosis

140,000+

Direct Biopharmaceutical Sector Jobs in Japan

74%

Potential First-In-Class Treatments

436 Million

COVID-19 Vaccine Doses Administered in Japan

¥250 Trillion

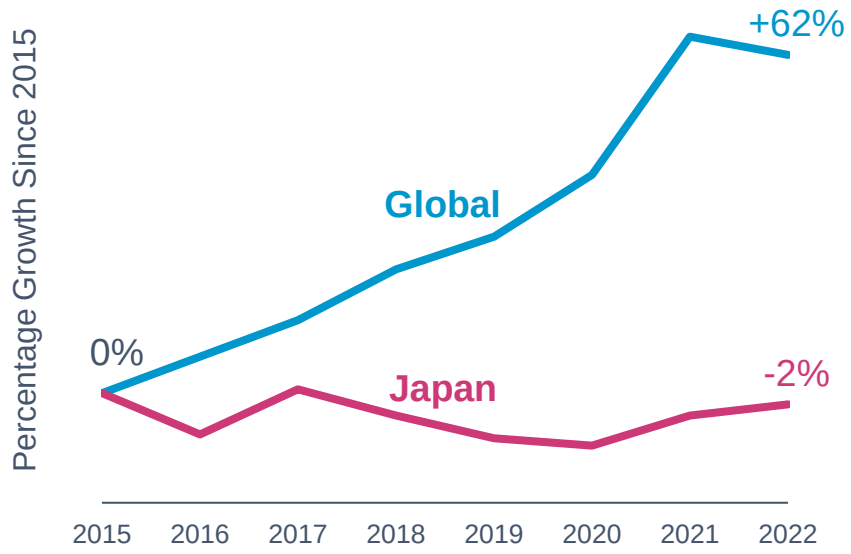
Global R&D Investment in the Last Decade
(¥14 Trillion in Japan)

PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of Citeline data, October 2023; 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 as of March 26, 2024, available at: https://japan.kantei.go.jp/ongoingtopics/vaccine.html; Ministry of Health, Labour and Welfare Statistics on Pharmaceutical and Medical Device Industry, Ministry of Internal Affairs and Communications Survey of Research and Development, 2023; Evaluate World Preview 2023: The Outlook to 2028, 2023.

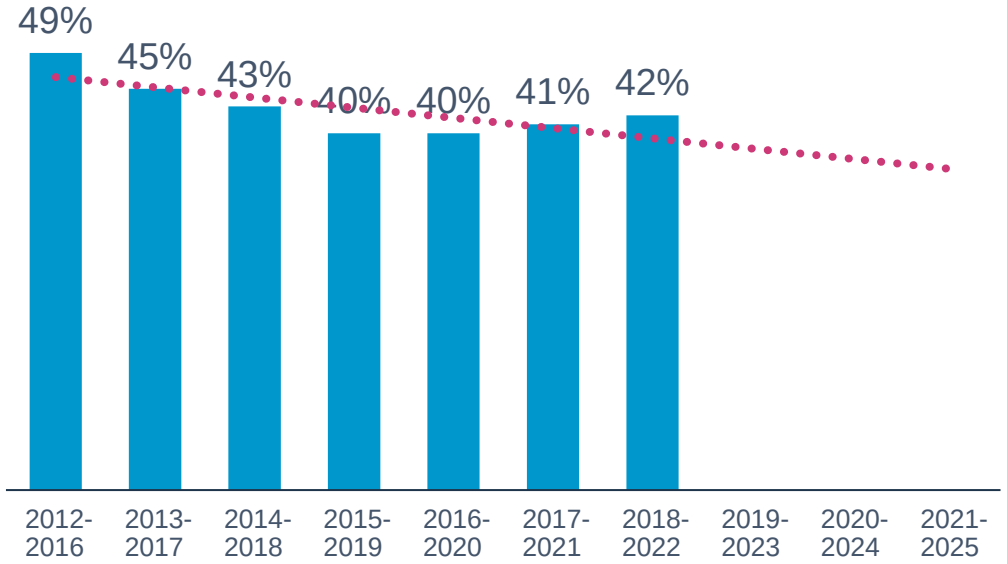
Repeated Price Cuts Widened the Japan's Biopharmaceutical Industry R&D Investment Gap, Causing Drug Lag and Loss

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



Japan is at a competitive disadvantage regarding global R&D investment

Percentage of Prior Five Years of Global New Medicines Available in Japan



Japan's drug lag and loss worsened after repeated price cuts since 2016

PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of IQVIA MIDAS and country regulatory data. March 2023. Japanese Ministry of Internal Affairs and Communications, Report on the Survey of Research and Development, 2023; Evaluate World Preview 2023: The Outlook to 2028, 2023.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2022.

2024 Pricing Reform: Important First Step To Reverse Trend

Japan can return to pro-innovation policies by building on these first steps

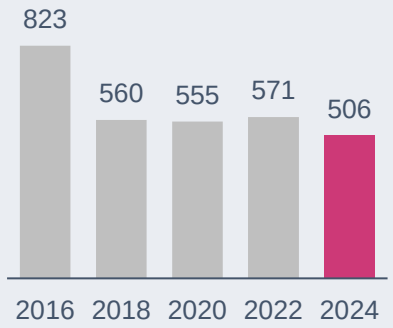
2024 Pricing Reform

- PMP company criteria abolished and product criteria expanded
- Expanded criteria for initial price premiums (early launch and pediatric)
- Exclusion of certain therapy areas from MER spillover

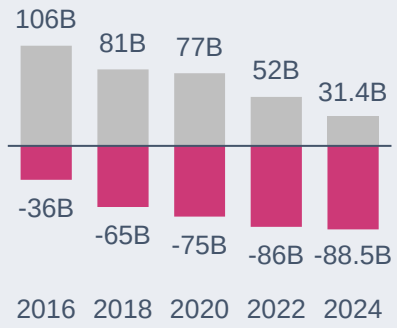
PhRMA
RESEARCH + PROGRESS + HOPE

Important First Step, But Impact Expected To Be Limited

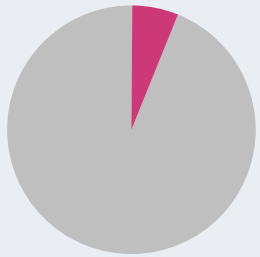
Overall, 50% of patented medicines will still receive annual price cuts



Number of PMP eligible products declined to 506 in 2024 from high of 823 in 2016



Total PMP premium fell to record low ¥31.4 billion while **deductions increased to record high ¥88.5 billion**



Only 6% of newly listed products are expected to be eligible for the **Early Launch Premium**

2

N

Only two of many product classes excluded from **Market Expansion Repricing spillover**

PhRMA
RESEARCH • PROGRESS • HOPE

Source: Japanese Ministry of Health, Labour and Welfare, Summary of NHI Drug Pricing Reform, 2016, 2018, 2020, 2022 and 2024; Central Social Insurance Medical Council materials, November 10, 2023, and March 22, 2024.

All Parts of the Biopharmaceutical Innovation Ecosystem Must Function Successfully to Reduce Drug Lag and Loss

Predictable and appropriate reward for innovative medicines allows reinvestment

Industry-academia collaboration in Japan and other countries

Timely patient access after approval

Simultaneous global drug development under harmonized regulations

PhRMA
RESEARCH • PROGRESS • HOPE

Japan Needs a Bold New National Biopharmaceutical Strategy

Strategy should identify all needed actions, goals and KPIs to promote a fully functional biopharmaceutical innovation ecosystem in Japan

Identify All Needed Actions

Top Three Examples

- Ensure NHI drug pricing system appropriately evaluates and rewards innovation
- Eliminate Japan-specific regulatory requirements and utilize RWD/RWE for approval process
- Accelerate industry-academia collaboration in biopharmaceutical R&D

Set Goals and KPIs for All Needed Actions

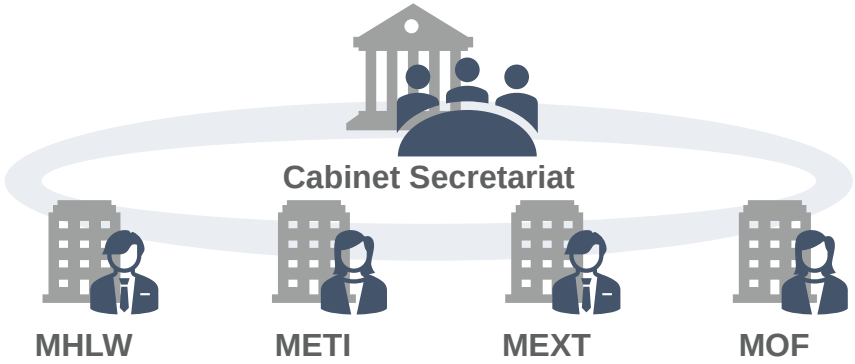
- X% of global new medicines are available
- X% increase in market growth, in line with levels of major international markets
- X% of patented products maintain price during the patent period
- X% in biopharmaceutical industry R&D investment
- # of increase in global clinical trials
- # of new molecular entities with proof of concept from industry-academia collaborations

PhRMA
RESEARCH • PROGRESS • HOPE

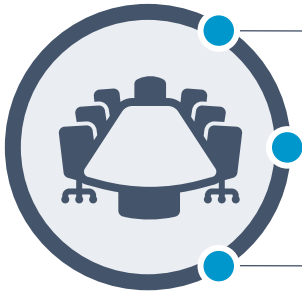
Proposal for Control Tower Function

A permanent conference body for routine, substantive engagement with industry should be established under a cross-ministerial control tower function

Permanent Cross-Ministerial Structure



Permanent Meeting Body for Input from Multinational Biopharmaceutical Companies



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

Proposed Roles of Control Tower Function

- Direct relevant ministries to formulate national strategy with goals and KPIs
- Actively monitor KPIs and take measures to ensure progress on goals
- Establish meeting body for regular input from multinational biopharmaceutical companies

PhRMA
RESEARCH + PROGRESS + HOPE

The Biopharmaceutical Industry Is Ready To Do Our Part

Working as partners for patients to develop a national strategy to reduce drug lag and loss

PhRMA
RESEARCH • PROGRESS • HOPE

PhRMA
RESEARCH • PROGRESS • HOPE