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

A first step taken – further solutions needed

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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)

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


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.

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

- Japan: -2% growth since 2015
- Global: +62% growth since 2015

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

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

- 2012-2016: 49%
- 2013-2017: 45%
- 2014-2018: 43%
- 2015-2019: 40%
- 2016-2020: 40%
- 2017-2021: 41%
- 2018-2022: 42%

Japan’s drug lag and loss worsened after repeated price cuts since 2016
2024 Pricing Reform: Important First Step To Reverse Trend

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

- **2010** Price Maintenance Premium (PMP) Pilot
- **2016** Huge Seller Repricing
- **2018** Fundamental Pricing Reform
- **2019** Cost Effectiveness Evaluation
- **2021** Off-Year Price Revision
- **2022** New Pricing Process for Large Budget Impact Drugs
- **2023** Off-Year Price Revision
- **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
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

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

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

- Reinvestment in New Medicines
- Research & Development
- Regulatory Review & Approval
- Delivering New Medicines
- Timely patient access after approval
- Unmet Medical Needs
- Improvement of People’s Health and Economic Growth
- Industry-academia collaboration in Japan and other countries
- Predictable and appropriate reward for innovative medicines allows reinvestment
- Simultaneous global drug development under harmonized regulations

Unmet Medical Needs

Improvement of People’s Health and Economic Growth

Timely patient access after approval

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Reinvestment in New Medicines
## 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

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<th>Top Three Examples</th>
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<tr>
<td>Ensure NHI drug pricing system appropriately evaluates and rewards innovation</td>
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<tr>
<td>Eliminate Japan-specific regulatory requirements and utilize RWD/RWE for approval process</td>
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<tr>
<td>Accelerate industry-academia collaboration in biopharmaceutical R&amp;D</td>
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### 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
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

- Cabinet Secretariat
- MHLW
- METI
- MEXT
- MOF

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

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