



Ensuring Japan Is Not Left Behind: Maintaining Access to the Latest Treatments and Vaccines

Proposal for FY2024 NHI Drug Pricing Reform

March 9, 2023

Pharmaceutical Research and Manufacturers of America

Japan Wants Patients to Have Fast Access to the Latest Medicines...

Japanese patients are missing out on critical innovations

? Why is patient access to innovative medicines important?



Patients live longer, healthier and more productive lives with timely access to new medicines

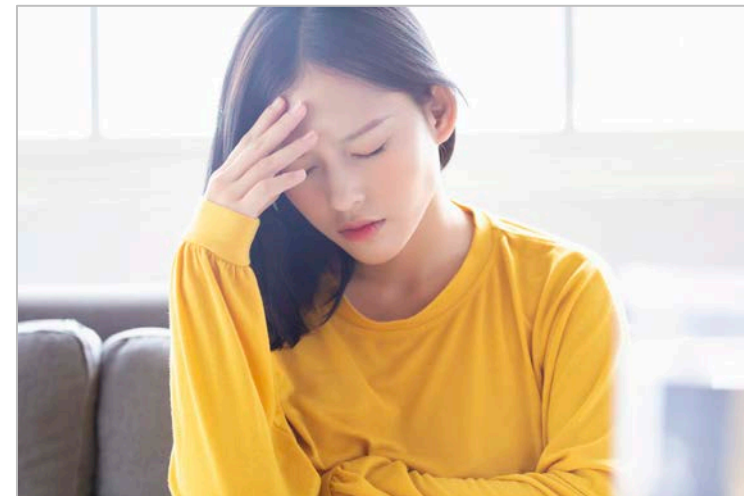
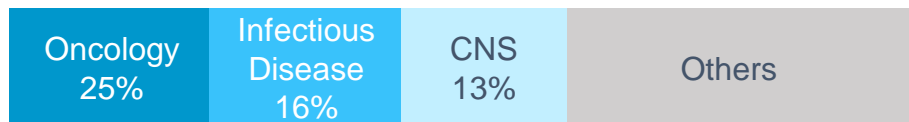
? Why is the reality today for Japanese patients?



The number of unapproved drugs in Japan is increasing and the drug lag is recurring



Unavailable drugs to treat critical conditions



Value of Medicines Communicated by MHLW Pharmaceutical Industry Vision

- Extend healthy life expectancy through advanced medical care
- Protect the people from health crises
- Support daily lives of patients and families
- Support economic activities such as consumption and labor participation

Japan's Biopharmaceutical Research Industry Does Not Thrive In the Current Policy Environment

Japan wants the industry to help fuel economic growth and prosperity

? What is the current situation for industry in Japan?



Biopharmaceutical R&D growth lags other leading countries

Change in Biopharmaceutical R&D from 2015 to 2021

-4% (vs. +59% globally)



Frequent drug price revisions and rule changes are reducing the attractiveness of the Japanese market

Number of Drug Pricing Rule Changes Since 2015

50+

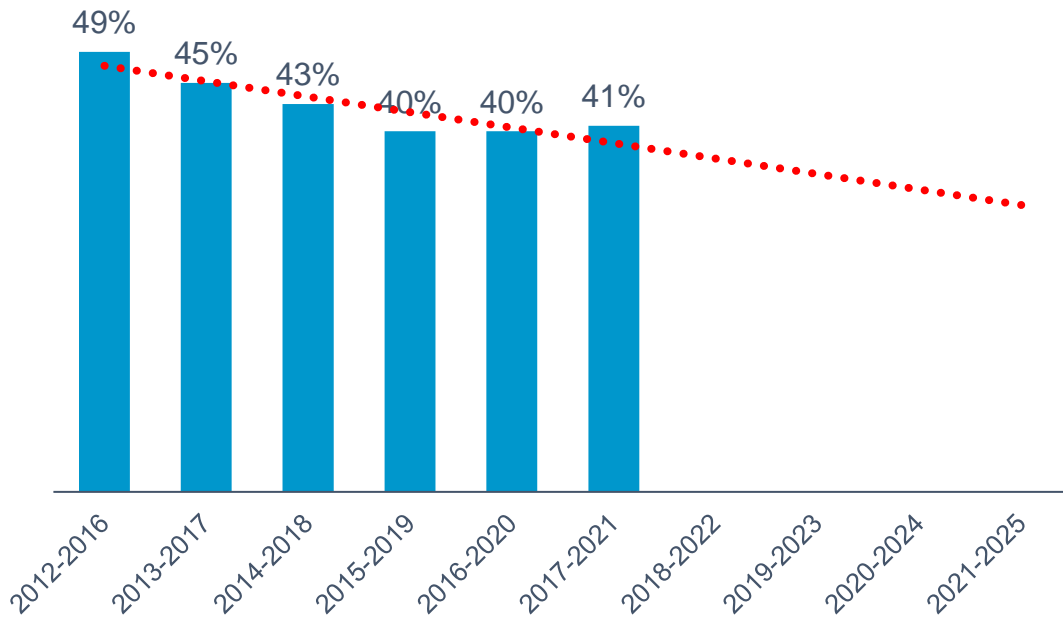


PM Kishida to House of Representatives Budget Committee on February 15

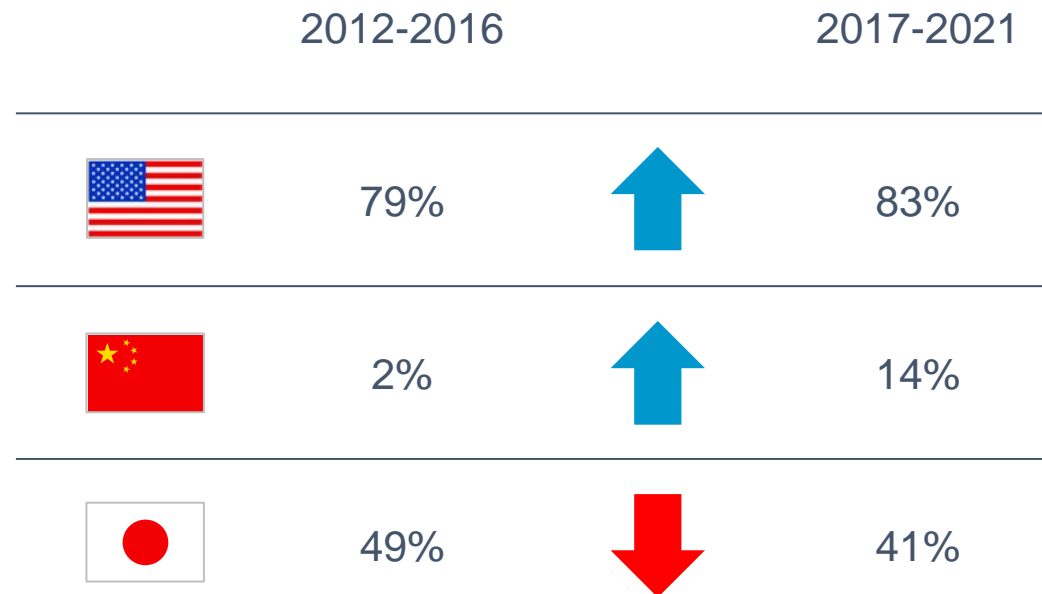
“The pharmaceutical industry plays an important role in contributing to the improvement of health and medical care for the people and at the same time is an important industry that will become the core of future economic growth.”

Japan Now Shows Pronounced Signs of a Drug Lag

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

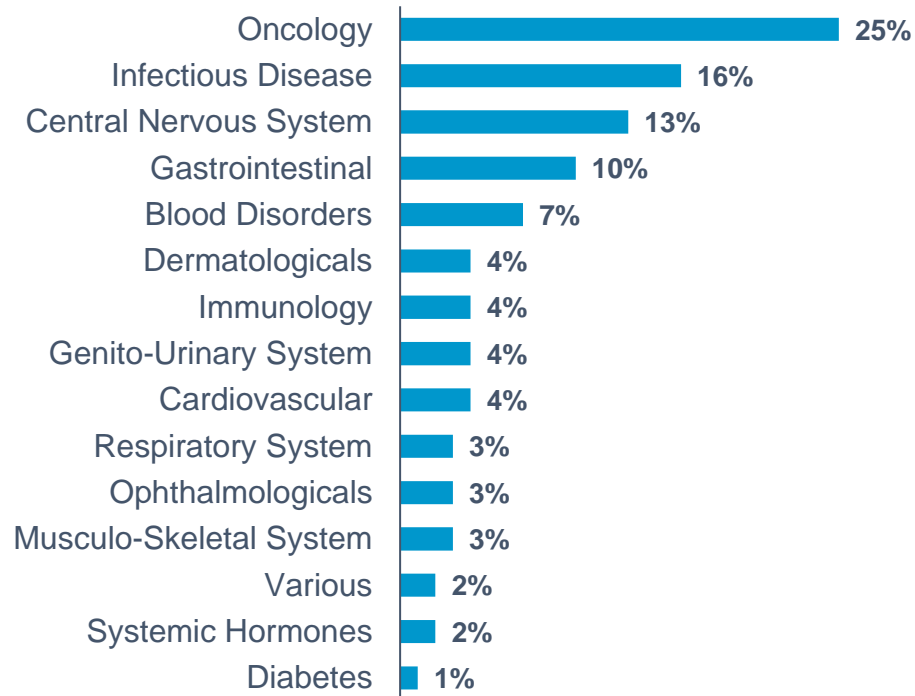


Changes in Availability of Global New Medicines in the U.S., China and Japan



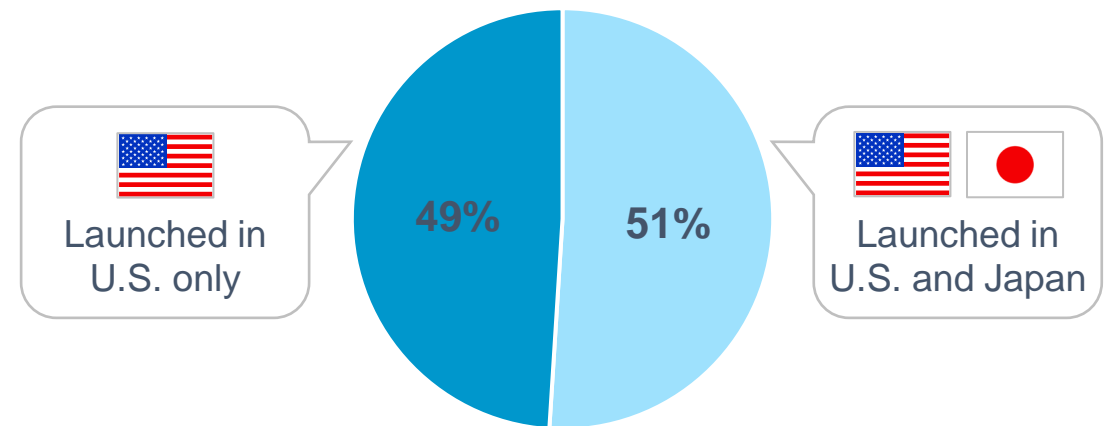
Many New Innovative Medicines To Treat Unmet Medical Needs Are Not Launching in Japan

Therapy Areas of New Medicines Launched Globally Between 2012 and 2021 But Not Available in Japan



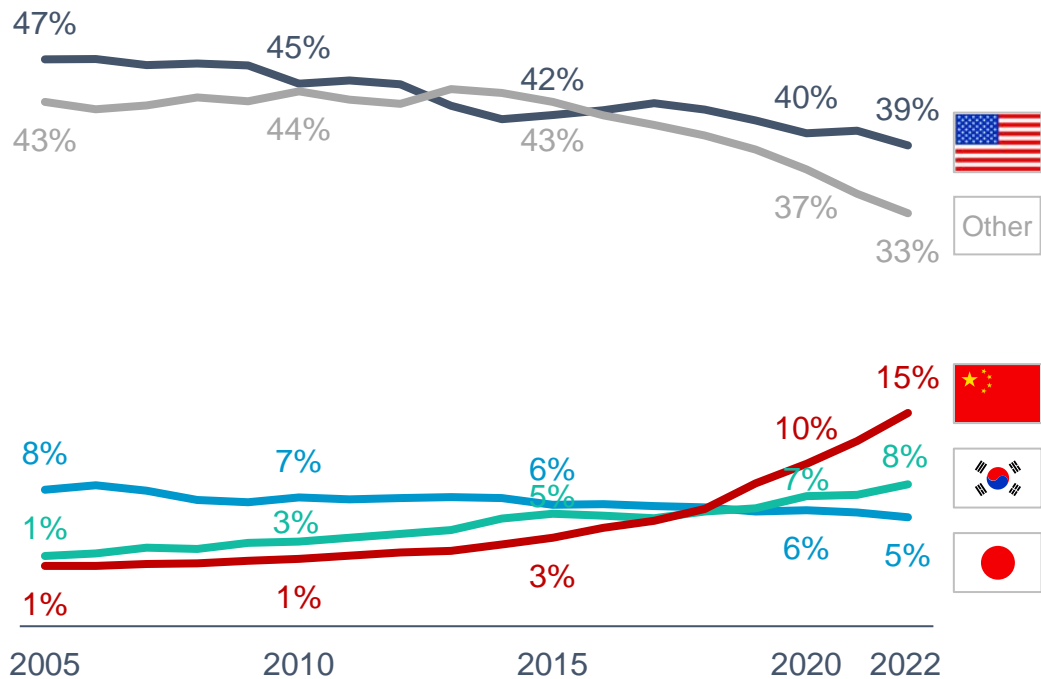
FDA Expedited Program Medicines Launched in the U.S. and Japan Between 2012 and 2021

Half Have Not Launched in Japan

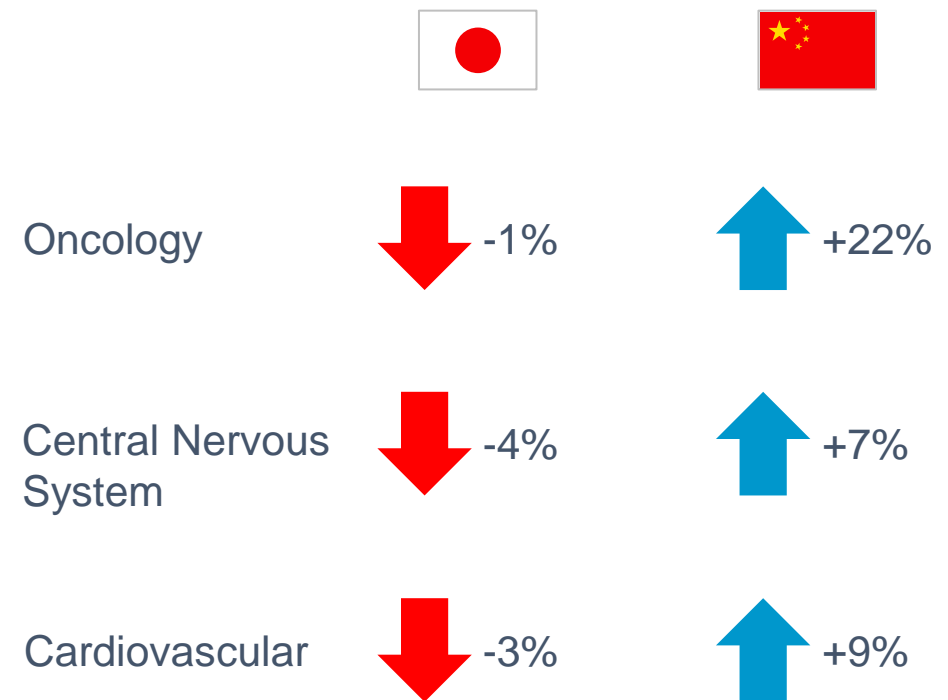


China Recently Surpassed Japan in Developing the Next Generation of New Medicines

Country Share of Early-Stage Pipeline Based on Development Location, 2005 to 2022

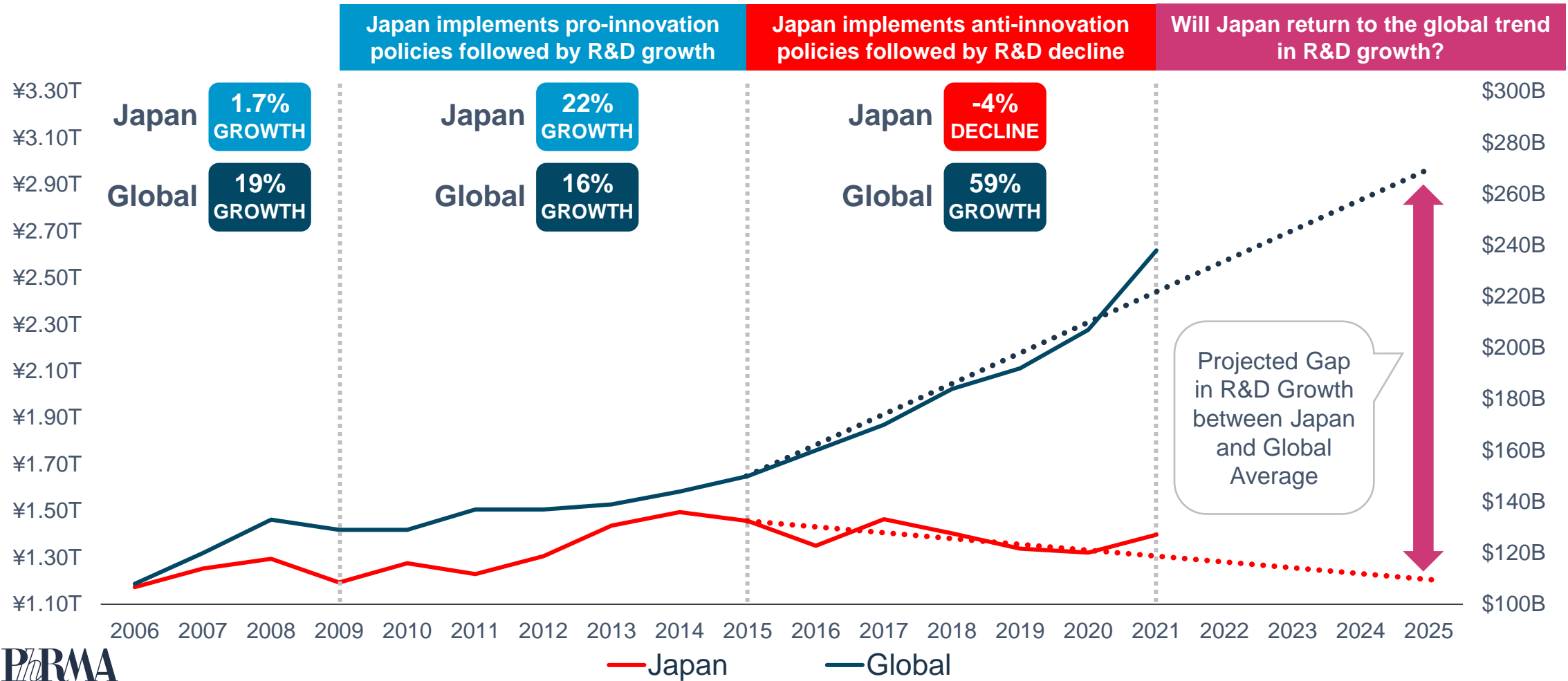


Japan vs. China Change in Country Share of Early-Stage Pipeline by Therapy Area



Major Reforms to the Drug Pricing Systems Are Needed

Without pro-innovation reforms, Japan will continue to lose its competitiveness and the gap between Japan and Global R&D investment will continue to widen



Enhancing Japan's Biopharmaceutical Innovation Ecosystem to Improve Health and Economic Growth

R&D investment requires clear incentives that are commensurate with success



Enhancing Japan's Biopharmaceutical Innovation Ecosystem to Improve Health and Economic Growth

Current pricing policies prevent reinvestment and disrupt this virtuous cycle



Priorities for FY2024 NHI Drug Pricing Reform

Policy reforms are needed to restore healthy growth to the Japanese market and to prevent the drug lag from worsening

Price Maintenance During Patent Period

Initial Price Setting

Review Actual Market Price-Based Revisions



Improve Market Expansion Repricing Rules



Improve Initial Price-Setting Rules



Review Actual Market Price-Based Revisions

Issues with Current System



Under the current system, excessive and unevenly distributed yakka-sa can occur



Price revision to correct the yakka-sa is unique to Japan and one reason why prices fall during the patent period



Due to the PMP reduction and annual price revisions, the impact of market price-based revision is expanding



Fundamental reform of the system is needed to continue incentivizing investment in Japan

Necessary Reforms



Transition to a system that does not cause excessive and unevenly distributed yakka-sa



Develop a suitable system after evaluating approaches used in other markets (e.g., fixed margins, reimbursement by actual acquisition cost or claw back of yakka-sa) and transition to the new system as soon as possible



As a transitional measure until a new system can be introduced, improve the PMP product and company criteria to ensure products can maintain prices during the patent period

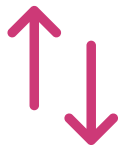


Improve Market Expansion Repricing Rules

Issues with Current System



Repricing is applied to similar products which is unreasonable and unpredictable



The price reduction is determined by the how much the market expands without considering the value of new indications



As the number of multi-indication products (e.g., oncology and immunology) grows, does the risk of repeated repricing

Necessary Reforms



Abolish the market expansion spillover rule



Introduce a rule to moderate the price reduction when an innovative indication is added



Set an upper limit to the percentage price reduction or the number of times a product can be repriced

Improve Initial Price-Setting Rules

Issues with Current System



Under the cost-calculation method, premiums for the most innovative products cannot be obtained when cost disclosure is not possible

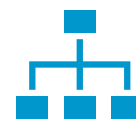


Regardless of the pricing method used, most new products eligible for price premiums receive relatively small or no premiums at all



Upward foreign price adjustment (FPA) is applied only at launch, which disincentivates the early launch of new medicines in Japan

Necessary Reforms



Expand scope of comparators allowed under the comparator pricing method to decrease reliance on the cost-calculation method



The requirements for the usefulness premium should be expanded to allow the evaluation of product value that is difficult to capture under the current requirements



Early launch in Japan should be promoted by allowing upward FPA after listing



Budget Headroom to Implement the Reforms

PhRMA supports a set of cost-saving policies proposed by various stakeholders

**Promote Use of
Generics and Biosimilars**



**Accelerate Price
Reduction of LLPs**



**Reduce Duplicate
Rx and Polypharmacy**



Establish an Effective Health Care System and Promote Innovation

Discussion on “the ideal state of health care in Japan” is being held with stakeholders¹



日本総研
The Japan Research Institute, Limited

非効率な医療の特定とその改善に向けた提言

2022年10月18日

株式会社日本総合研究所（パナソニックホールディングス）
「持続可能な未来の健康・医療政策の検討に向けた研究チーム」
川崎 真樹、野田 悠一郎、青山 満子、高田 洋介、
川内 亮介、辻 孝子、長崎 直樹、上田 健史

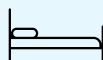
要旨
日本の医療費は高齢化の進行と生産年齢人口の減少、医療の高度化を背景に、今後も増加する見込みである。そのための社会保険料負担、特に医療給付費の適正な確保は、医療制度全体の改善を期待する上では不可欠な要素である。一方で、医療における非効率性を特定することで、より効果的・効率的な医療提供体制を構築することが求められる。
本提言では、医療について指摘される非効率性を整理し、それらを改善することで期待される医療費削減可能性を定量化することを目的とした。また、医療の非効率性の改善のためには、医療提供体制や医療技術におけるイノベーションを促すことが極めて重要であることから、医療への投資による国家への影響の整理を行った。
本提言では医療における需要と供給のバランスから、需要に対して供給が過剰である状況（ムダ）、需要に対して供給が不足である状況（ムラ）、ムラと過剰を併存している状況（ムラと過剰）を定義した。これらの観点から可能な限り定量化可能な課題に対し、政府統計資料・会員資料等の各種公開情報や有識者による意見を参考に、それぞれの要素・観点について、医療・医療費の非効率性の観点から整理を行った。整理の結果として、数兆円に上る医療費削減可能性を特定した。特にAI/デジタル/チーム医療の活用による医療費削減（約1.5兆円）の削減に期待を寄せた。ムラと過剰の削減による医療費削減の期待は、医療費削減の観点から整理を行った。また、入院による「過剰医療」や長期入院の項目で削減可能な項目が複数あり、削減に着手する必要があると考えられる。
非効率性を是正し医療費削減を達成することは少子高齢化社会において医療費負担を減らす重要な観点である。また、医療費削減における「ムラ」は、医療の質・アクセスを低下させ、国民全体の健康に不利な影響を及ぼす。同時に、最良の社会となった日本において、在籍する誰もが最良の医療を受けられるよう、イノベーションを推進する必要がある。期待されるイノベーション、医療提供体制の改善を実現するためには、期待される非効率性の改善とイノベーションの推進を両輪で大膽に進めなくてはならない。

Recommendations for Inefficient Medical Care Identification and Improvement

- “To improve inefficiencies in health care, fostering innovation in health care delivery and technology is crucial.”²
- “Identified potential savings in health care amounting to trillions of yen.”³



Excess beds : 2.2 trillion yen



Long-term hospitalization : 2.6 trillion yen

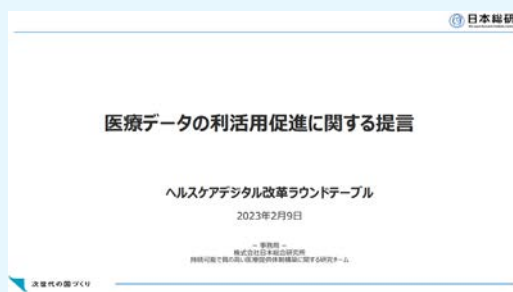


Duplicate prescriptions, polypharmacy and leftovers: 5.7 billion yen

(October 2022)

Recommendations for Promoting Use of Medical Data

- “Enhance the development of healthcare and sustainability of the system and return it to the public using data.”⁴



(February 2023)

Source:1. 日本総研「健康・医療政策コンソーシアム」設立について（2022年7月）：<https://www.jri.co.jp/page.jsp?id=103088>; 2. 日本総研「非効率な医療の特定とその改善に向けた提言」（2022年10月）：<https://www.jri.co.jp/page.jsp?id=103693>; 3: 「各要素は運動しているため、差し合わせることは適切ではないことに留意する必要がある。」; 4: 日本総研「医療データの利活用促進に関する提言」（2023年2月）：<https://www.jri.co.jp/page.jsp?id=104461>.

A New Forum Between Government and the Innovative Biopharmaceutical Industry Should Be Established

A new forum should be established for routine, substantive engagement on:



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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

Coming together to achieve common goals for patients



Innovation for all.

