

Now is the time for Japan to reprioritize innovation

Vasant (Vas) Narasimhan, M.D. Chair of the PhRMA Board of Directors Chief Executive Officer of Novartis

November 2023

Japan has played a significant role in bringing innovative medicines to patients...



At Novartis, we are reimagining medicine



xRNA





С

Cell and Gene Therapy Radioligand Therapy

and we are delivering these treatments to patients in Japan





...and the biopharmaceutical industry has enabled Japan to improve health and drive economic growth



8,000+

Medicines in development worldwide (1500+ in Japan)

74% Potential first-in-class

treatments



81% Cancer patients returning to work within a

year of diagnosis



140,000+

Direct biopharmaceutical sector jobs in Japan

\$1.7 trillion

Global R&D investment in the last decade (¥14 trillion in Japan)



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; Ministry of Health, Labour and Welfare Statistics on Pharmaceutical and Medical Device Industry, Ministry of Internal Affairs and Communications Survey of Research and Development, 2022; Evaluate Pharma World Preview 2022 Outlook to 2028, 2022.

However, we need to prioritize innovation to address Japan's unmet patient needs and potential future challenges

Cardiovascular Disease

2nd

leading cause of death in Japan

20% of total health care expenditures Collaboration and dialogue is needed to realize a more sustainable health care system



Novartis is establishing strategic public-private partnerships in Japan

- Strengthening community care
- Optimizing clinical pathways
- Reducing overall care costs



Current policies have led to a reduction of R&D investments and access putting Japan at a competitive disadvantage



Continued focus on drug price cuts to achieve other savings targets



Drug prices falling at more than twice the rate of previous years



Complex and unpredictable rules that are unsupportive of innovation



Insufficient opportunities for stakeholders to provide input



Number of new medicines in development is growing more slowly



Biopharmaceutical industry R&D has fallen by 4% since 2015



Only major country with declining biopharmaceutical sales



Growing drug lag and loss reducing patient access to innovation

The Japanese government recognizes the need for change

"

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.

Prime Minister Kishida (February 2023)

We are no longer in a lukewarm situation that can be overcome with time, as the term drug lag would imply.... Our government must therefore spearhead the creation of a drug discovery platform toward a renewed Japan. 日刊蔡業

MHLW Expert Panel's Report Serves as Starting Line for Reform

Health Minister Takemi (October 2023)



Source: Prime Minister Fumio Kishida remarks to House of Representatives Budget Committee, February 15, 2023; Health Minister Keizo Takemi remarks to journalists, October 13, 2023; Ministry of Health, Labour and Welfare Report of Expert Panel on Comprehensive Measures to Achieve a Rapid and Stable Supply of Pharmaceuticals, June 2023; Basic Policy on Economic and Fiscal Management and Reform (*Honebuto Hoshin*), Sagehashi, MHLW Expert Panel's Report Serves as Starting Line for Reform: Asst. Vice Minister, PHARMA JAPAN, June 30, 2023;

We believe key policy reforms can restore sustainable growth and ensure Japan's leadership in life sciences

	Maintain drug prices during the patent period	Improve initial NHI price-setting	Reduce inefficient spending on non-innovative medicines
			GX
•	Exclude patented medicines from	Reform assessment criteria to	Promote clinically-appropriate

- Exclude patented medicines from market price-based revisions
- Improve market expansion and spillover repricing rules
- Reform assessment criteria to better recognize product value
- Expand scope of comparators allowed in pricing assessments
- uptake of generics and biosimilars
- Accelerate price reductions of long-listed products
- Reduce duplicate prescriptions
 and polypharmacy



Now is the right moment for Japan to foster biomedical R&D investments and increase access to medicines...

or

Improve health and economic growth



Faster patient access to the latest treatments and vaccines

\checkmark

A more effective and sustainable health care system



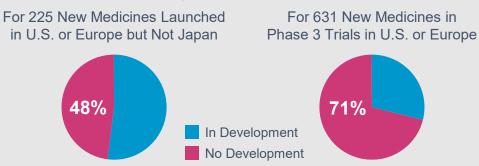
Increased investment, jobs, and economic productivity



Decreasing percentage of prior five years of global new medicines available in Japan 49% 45% 43% 40% 40% 41%



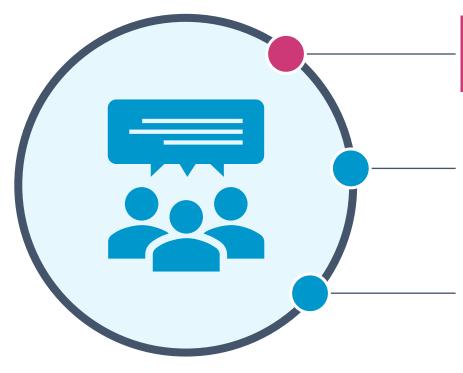
Increasing percentage of new medicines have not begun development in Japan



EXARMA

8

...and we must work together to develop a national strategy that promotes Japan's health and economy



Promoting a transparent and pro-innovation drug pricing system

Strengthening the environment for R&D and biotech start-ups

Improving and globally harmonizing regulatory requirements



Novartis is committed to bringing innovative treatments to patients and investments to Japan

Transforming patient care by bringing advanced radioligand therapies to patients



Investing \$100m in state-of-the-

art manufacturing facility in

Sasayama

Exploring potential partnerships with local academia on RLT research collaborations





Cambridge, Massachusetts is an example of a biopharmaceutical innovation ecosystem





The biopharmaceutical industry is ready to partner with Japan to improve patient lives

PhRMA



