



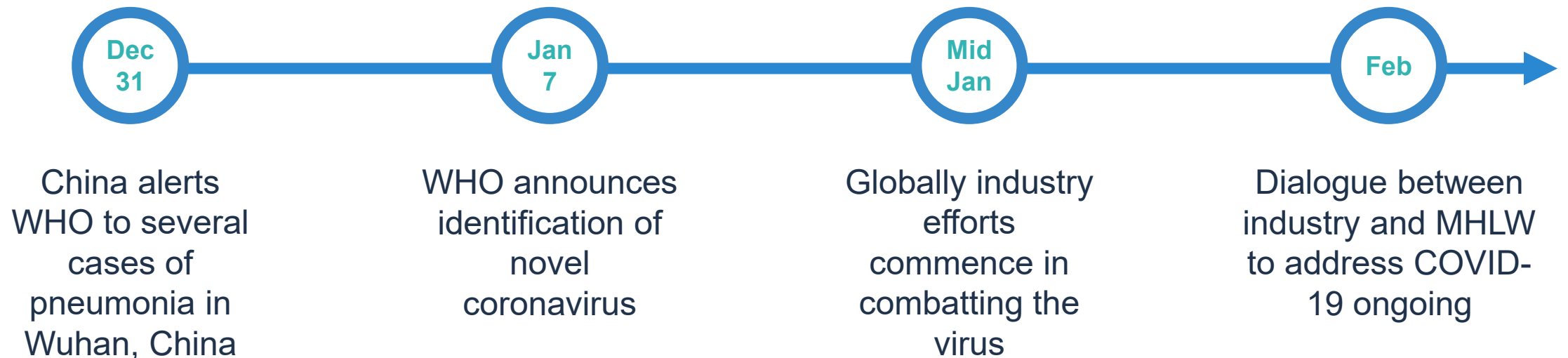
Patient-Centric Health Care in Japan: How to Balance Benefits and Burdens – 2020 PhRMA’s Direction and Initiatives –

Chris Hourigan | Chairman, Japan Based Executive Committee

February 19, 2020

COVID-19 – updating on a significant Public Health challenge

The industry is proactively working with Governments and health agencies to combat the virus, by donating necessary medical products, developing vaccines, and researching treatments



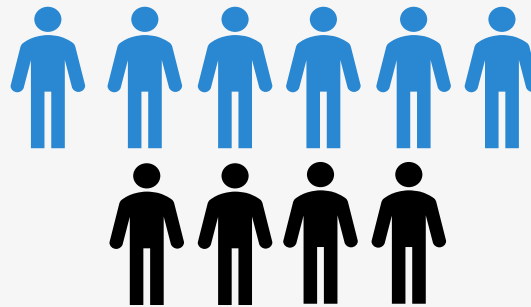
Patients: The fundamental purpose for which the pharmaceutical industry exists

Survey reveals Japanese patients have high expectations of the biopharmaceutical industry and expect early access to new medicines.

60%

of patients

Expect pharmaceutical companies to “enhance R&D for new medicines and vaccines.”



patients who actively participate in activities of patient organizations

Answered “New medicines should be available for patients as early as possible even if prices of new medicines become high.”

Prioritizing the patient voice

“We seek a world in which all diseases are eradicated.”

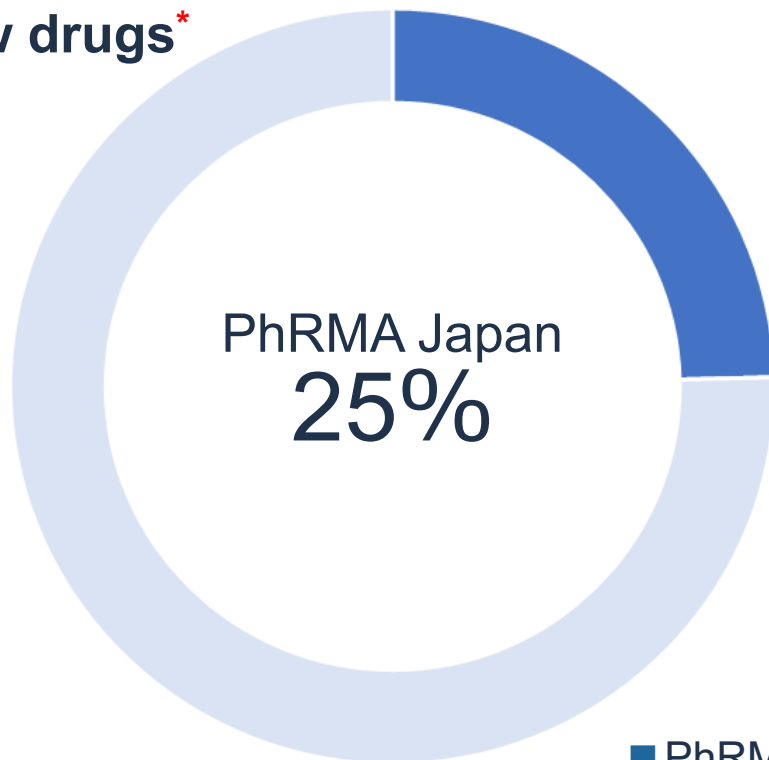
“We hope that more options for medical treatments are made available, including highly cost-effective genomic medicines.”

“Information on the R&D of new medicines and the beginning of clinical trials brings great hope to patients. I hope the pharmaceutical industry and the government can address these challenges collaboratively from a global perspective.”

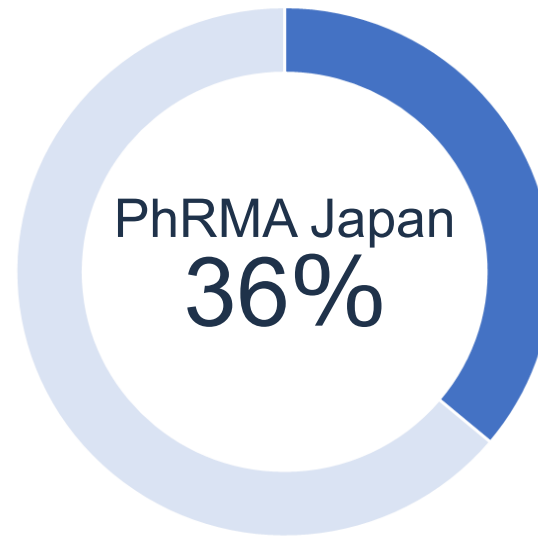
PhRMA Japan members continue to invent and innovate with the patient in mind

11 PhRMA Japan members (out of 67 companies) leading the charge to bring new drugs into Japan in 2019.

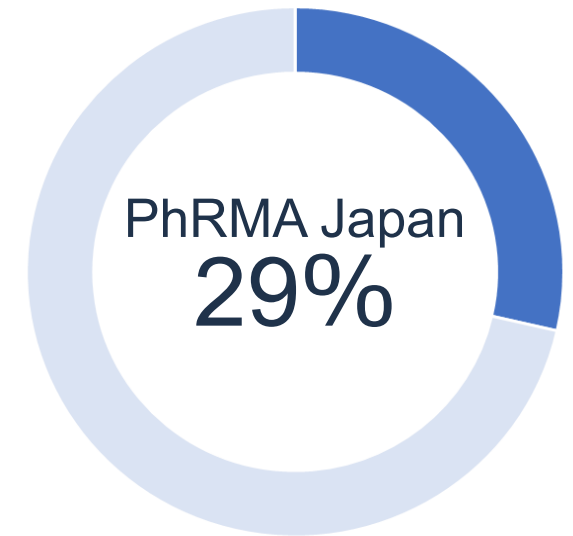
New drugs*



Oncology drugs



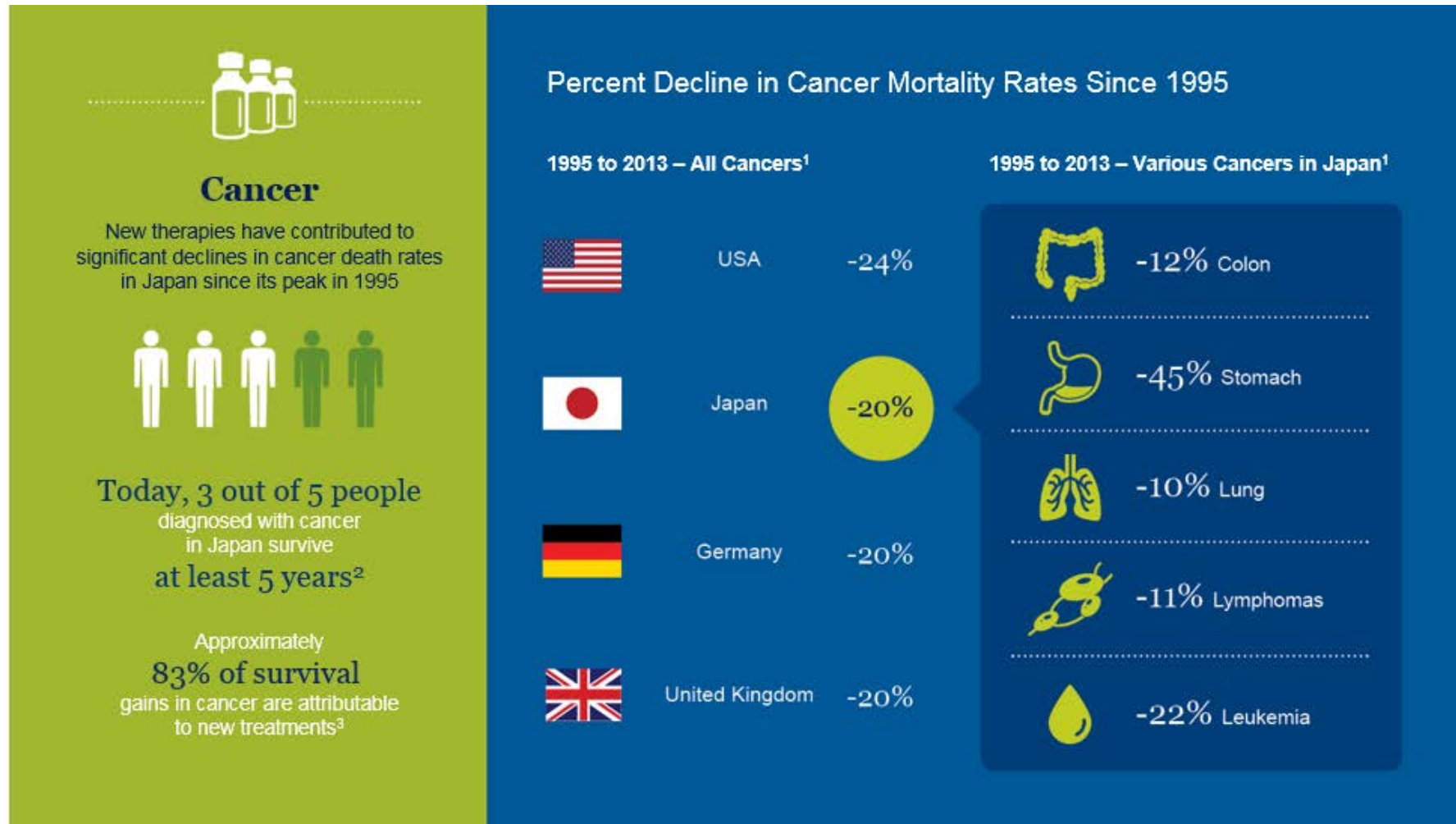
Orphan drugs



■ PhRMA Japan member companies (11) ■ Others

* New drugs: New molecular entity, new combination drug, new indication, new dosage etc.
Source: PMDA List of Approved Products

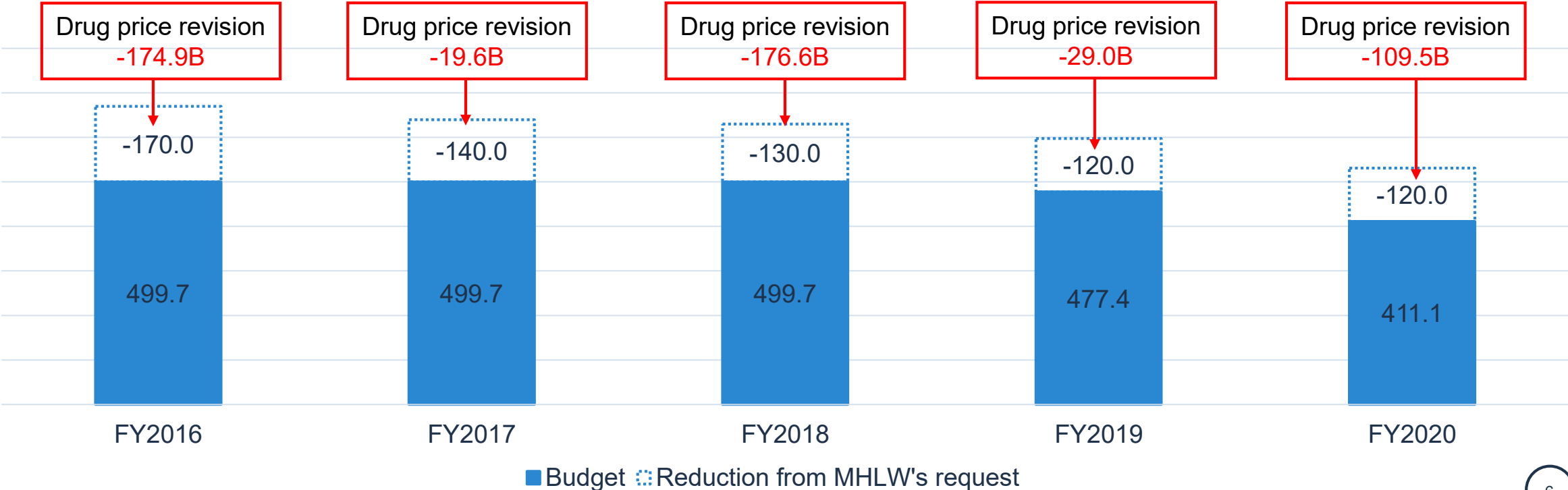
For many patients and their families, innovative medicines have significantly increased chances of survival



Social security spending cut relying on drug price revisions is unsustainable

5 year total saving from drug price revision reached 509.6B yen (75% of total saving).
Reform across the entire social security system is needed.

Social security budget growth (central government expenditure basis)



Academic groups and think tanks advocate for a comprehensive review of the social security system, including health care



Issued 10 recommendations for a sustainable social security system in January 2019.

Included policy proposals on how to:

- Secure appropriate public finances;
- Achieve an appropriate division of burden for health insurance; and
- Promote medical innovation, access and sustainability.

The Japan Research Institute, Limited

Research team toward building an efficient and effective medical care system

Issued comprehensive recommendations on how to build an efficient and effective medical care system in February 2020.

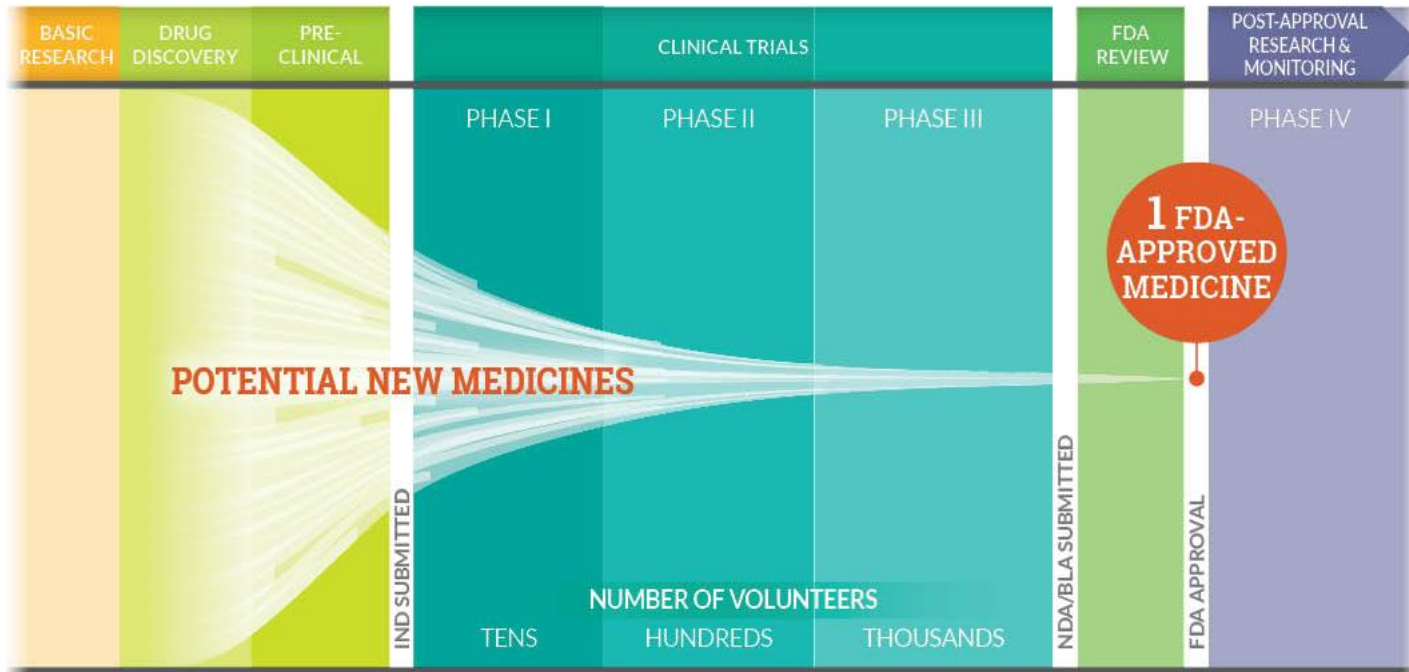
Recommendations included:

- Strengthen value-based health care;
- Optimize hospital stays and hospital beds; enhance home care; and
- Strengthen roles of pharmacists.

Predictability and transparency of the Japanese pricing and reimbursement system continue to be eroded

The R&D Process for New Drugs Is Lengthy and Costly

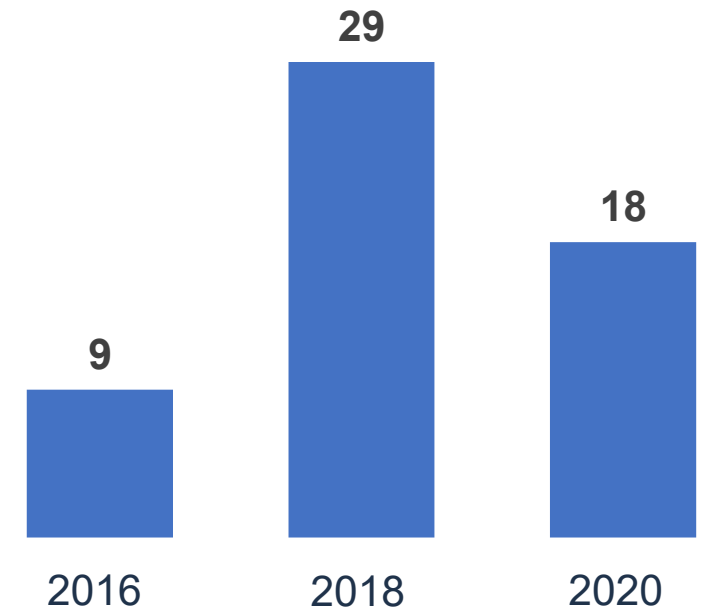
Developing a new medicine takes, on average, 10 to 15 years and costs \$2.6 billion.*
Less than 12% of candidate medicines that make it into Phase I clinical trials are approved.



Key: IND=Investigational New Drug Application, NDA=New Drug Application, BLA=Biologics License Application

Increasing number of changes to P&R rules

Number of rule changes in each pricing reform



Predictability and transparency of the Japanese pricing and reimbursement system continue to be eroded

PMP: non-science-based and discriminatory

Slight improvements were made to the PMP, however, continued validation is necessary to ensure it is functioning as a fair and science-based mechanism that is in line with international norms to promote innovation.

Future is uncertain

The Japanese government continues to pursue additional price cutting mechanisms, including expanded use of HTA and a move to annual price revisions.

Bring global leaders together to achieve the best health outcomes for Japanese patients

Launch a meaningful platform for discussion that involves all key stakeholders.

Pricing system

- Develop a mechanism by which the reward for innovation can be reflected in the drug price.
- **Focus off-year price revisions in 2021 on non-innovative products.**

Clinical development/Regulatory

- **Improve the cost and speed of clinical trials.**
- **Increase the number of products designated and approved under Japan's expedited approval pathways*** so they are equivalent to similar systems in the U.S. and Europe.**

Health Technology Assessment (HTA)

- Establish a system that incorporates **patient and societal viewpoints.**
- **Avoid the use of HTA for reimbursement listing decisions** as it could inhibit access to new drugs.

Vaccine system

- Develop a **transparent and prompt decision making process regarding their inclusion to national immunization program.**