European Federation of Pharmaceutical Industries and Associations

EFPIA Day 2022 Press Conference

Five Strategies to Enhance the Attractiveness of the Japanese Market






6 Oct 2022

Chair of EFPIA Japan

Takahiko Iwaya

Overview of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Japan

Establishment

2002 (converted to general incorporated association in 2022)

Overview

EFPIA Japan is comprised of European R&D-oriented pharmaceutical companies operating in Japan. Its mission is to contribute to healthcare and patients in Japan through fast introduction of innovative medicines and vaccines. It aims to strengthen dialogue with policy makers to improve healthcare in Japan.

Member

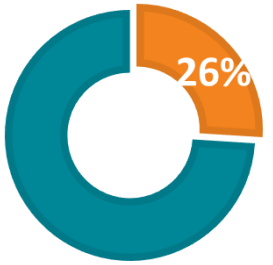
23 companies (as of September 2022)

Board companies

AstraZeneca K.K.	Bayer Yakuhin, Ltd.
GlaxoSmithKline K.K.	Janssen Pharmaceutical K.K.
Merck Biopharma Co., Ltd	Nippon Boehringer Ingelheim Co., Ltd.
Novartis Pharma K.K.	Novo Nordisk Pharma Ltd.
Sanofi K.K.	UCB Japan Co., Ltd.

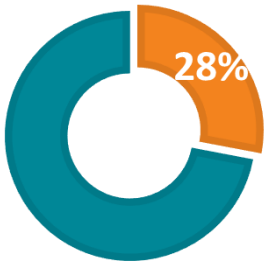
Percentage of the total sales of EFPIA Japan member companies in the ethical drug market in Japan [1)]

26%



Proportion of new drugs launched by EFPIA Japan member companies among new drugs launched recently in Japan [2)]

28%



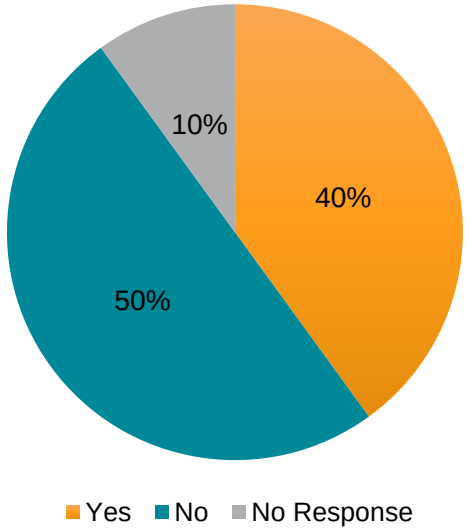
1) Approximately 2.8 trillion yen (EFPIA Japan 2021)
2) 46 components (EFPIA Japan 2019 – 21)

We are concerned that policies biased toward drug cost reduction may cause recurrence of a drug lag, resulting in deterioration of the quality of medical care, and induce a negative cycle

Number of companies with drug development programs affected by the drastic pricing reform in 2018 and associated market environment changes [1)]

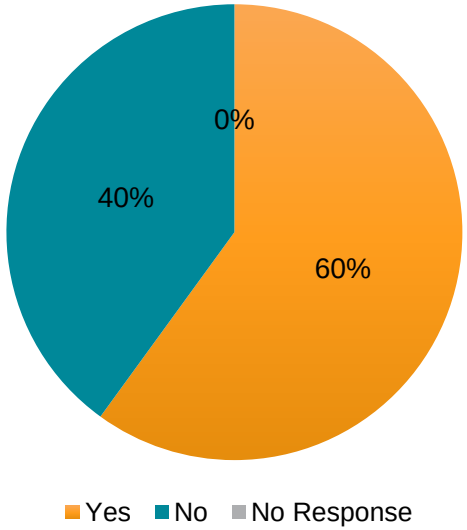
Number of projects under clinical development (In clinical trial phase to NDA submission) [2)]

Termination

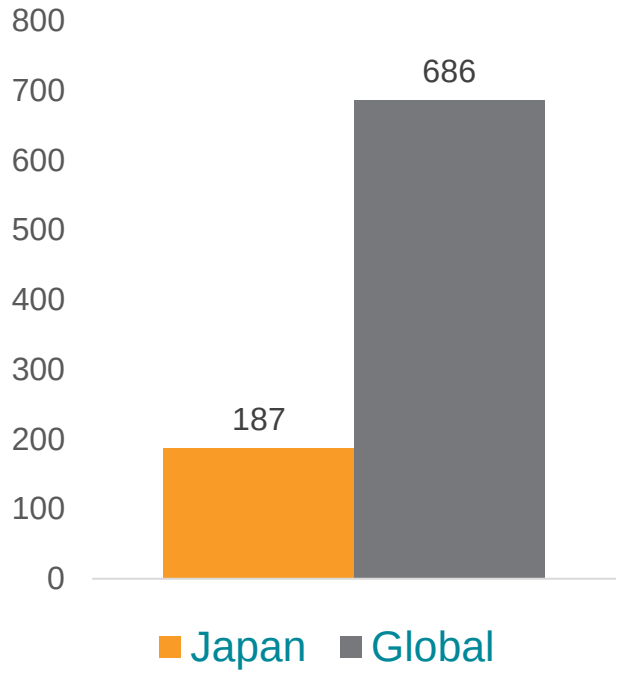


4 out of 10 companies decided to termination of launch

Delayed launch

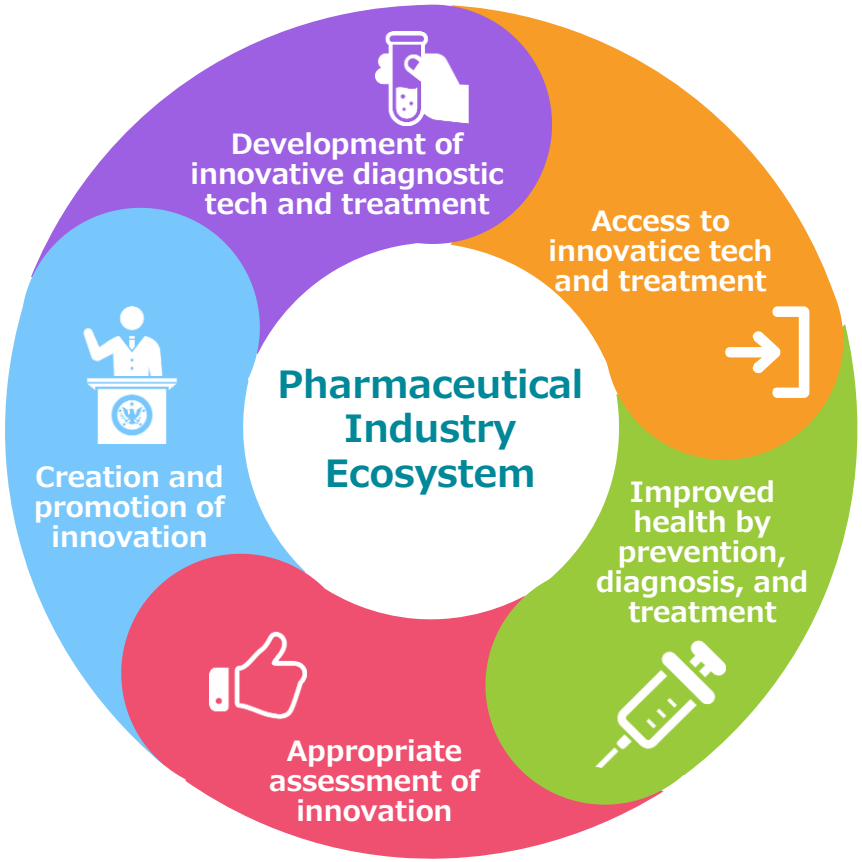


6 out of 6 companies who answered "Yes " Answer: **Increased** compared to that before the Drastic Reform



1) Survey on 10 EFPIA Japan member companies on the Board (September 2022)
2) Survey in all EFPIA Japan member companies (September 2022)
- Aggregated those who answered to both "Number of projects in Japan" and "Number of global projects" of under clinical development status (from clinical trial to NDA submission) in development pipeline.

To deliver innovative drugs to people in Japan, regardless of the origin country of the drug, it is essential to establish an ecosystem for the pharmaceutical industry and increase the attractiveness of the market



Three factors for making Japan an attractive market

- R&D and regulatory environment that drives innovation
- "Sustaining universal healthcare" while "driving innovation"
- Quality and efficiency of healthcare

EFPIA Japan executes five strategies toward the establishment of the pharmaceutical industry's ecosystem

1. Improve R&D and regulatory environment
2. Sustain universal healthcare while securing reward for innovation in the pharmaceutical sector
3. Contribute to health literacy enhancement
4. Build cost-effectiveness assessment approach that does not impede access
5. Utilize innovative technologies, incl. regenerative medicine, cell and gene therapy, and digital technology, and develop necessary talent

Improvement of R&D and regulatory environment is necessary to deliver the latest innovations to the people in Japan without delay from the US and Europe

Improvement of R&D and regulatory environment to promote the creation of innovative drugs

Development of an open ecosystem in Japan

Establish an international “open Japanese ecosystem ” regardless of the origin of seeds from academia ventures or the nationality of pharmaceutical companies that develop and obtain approval.

Introduction of a new drug approval system based on key results from confirmatory clinical trials

Introduce a system to start new drug approval review based on major results of confirmatory clinical studies that have already been introduced in the U.S., and shorten the time from formal approval application to approval.

Establishment of sites for promotion of collaboration between Clinical Research Core Hospitals and the industry side

To realize efficient clinical trial operations
Discuss, for example, the introduction of DCT, improvement of case accrual capacity, and aggregation of IRBs.

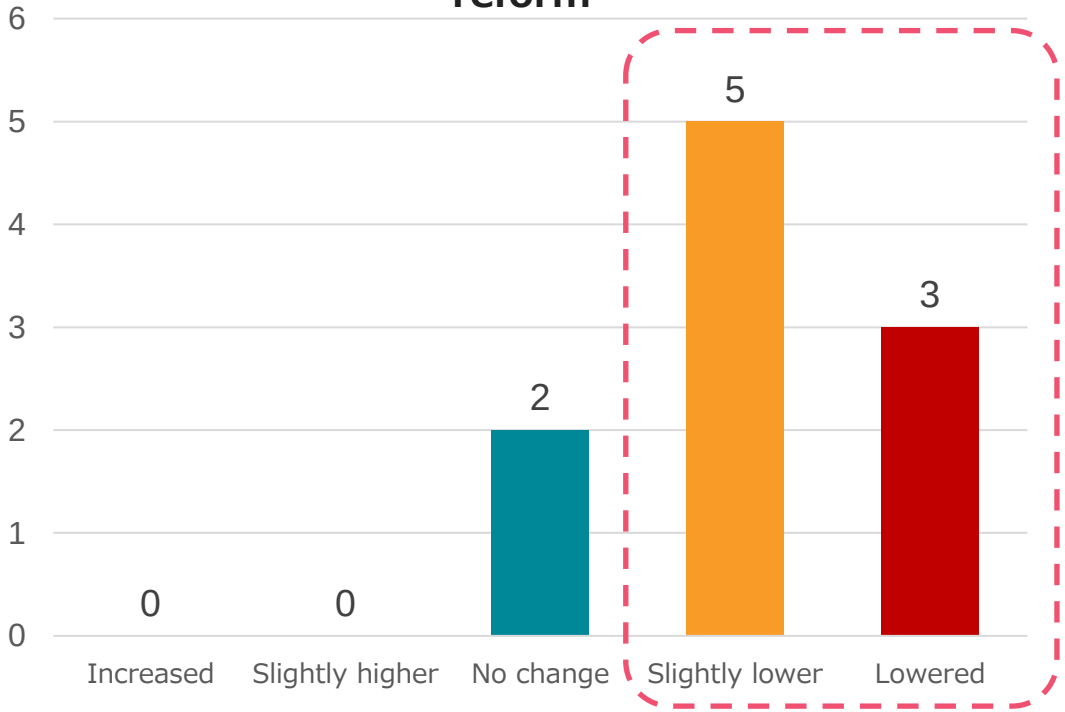
Establishment of a forum for discussion to promote industry-government-academia collaboration in the development of highly innovative drugs

Enhancement of technical support systems for academia by the government, provide opportunities for industry-government-academia collaborative discussions from the stage of considering regulatory requirements and development guidelines

Japan needs to increase the market attractiveness by improving the drug pricing system as the Japanese market is becoming less of a priority among EFPIA member companies

Lower priority of the Japanese market

Change in priority of Japanese market relative to other markets after the fundamental drug pricing reform



Survey in 10 EFPIA Japan member companies on the Board (September 2022), Unit: Number of companies, n = 10

Attractive drug pricing system to increase market priority

- Secure high predictability that encourage investment in R&D of new drugs
- Grant incentives for first launches in Japan ahead of the world
- Protect drug prices for new drugs during the patent period in line with the US and Euro
- Maintain the current system that allows prompt NHI price listing and reimbursement after regulatory approval

Systems and regulations for reference of future considerations

- Official margin
- Reimbursement at purchase price
- Reference pricing
- “Reimbursement ” like UK VAPS *

*Voluntary Scheme for Branded Medicines Pricing and Access

By providing appropriate information and supporting patients, we facilitate patient health literacy and behavioral changes to promote efficient healthcare resource utilization

Information activities to increase patient awareness

http://efpia.jp/healthliteracy/index.html

http://efpia.jp/healthliteracy_interview_article_1/index.html

PASE - Patient Support Activities

第3回PASE大賞・助成金授与式（2019年9月27日）

"PASE (Patient Advocacy Support by EFPIA Japan)" is a patient group support project established in 2017 by EFPIA Japan. As part of the project, we provide PASE AWARD to offer grants to organizations contributing to the advancement of patient advocacy activities. 2022 marks the fifth time of the PASE AWARD.

We will make recommendations for a cost-effectiveness assessment system to appropriately reflect the diverse values of pharmaceutical products

Concerns

- Evaluation based on the incremental cost-effectiveness ratio (ICER) alone
- Therapeutics for rare diseases are also subject to CEA
- Potential use of CEA for decision making for reimbursement
- Potential impact on patient access to latest quality care, which is currently ensured in Japan and we can be proud of

Ideal CEA systems

Evaluation of social and ethical contributions and indirect economic effects of pharmaceuticals from a long-term perspective

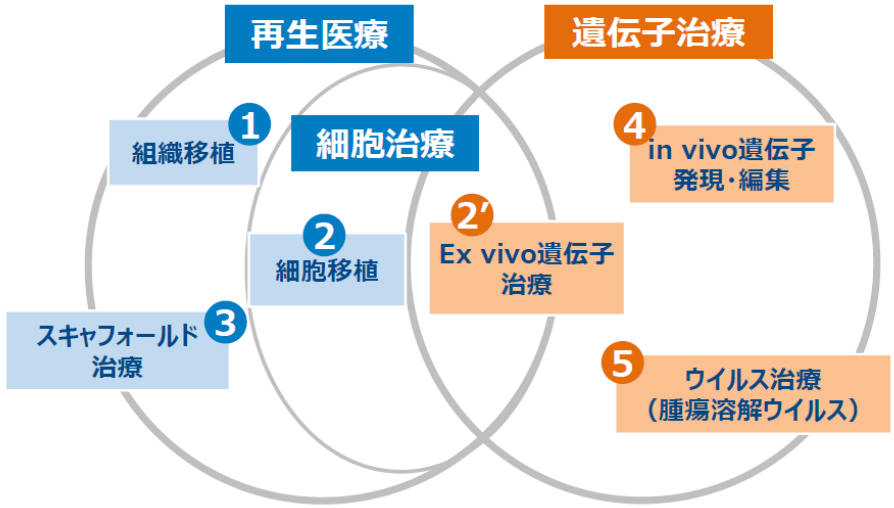
Ensuring transparency with involvement of all parties

Utilization of cost-effectiveness assessments as a supplement to the drug price system, not for decision making for reimbursement

EFPIA-J_HTA_Viewpoint_2020Jan_vf_JP.pdf

To improve the quality of healthcare, we will support the utilization of cutting-edge medical care such as gene therapy and regenerative medicine and digital technologies by sharing knowledge in Europe and developing human resources in Japan.

Application of innovative medical care



siryou4-2-8.pdf (kantei.go.jp)

Leveraging digital technologies and data through the Pharmaceutical Lifecycle

- Enhanced understanding of disease and treatment
- New Approaches to Delivering the Best Medicines to Patients

- Patient self-management with continuous feedback and communication
- Enhanced management of adverse reactions
- Evaluation of Medicinal Products Based on Real-World Data

- Support patient care
- Provision of information to healthcare professionals
- Realization of personalized medicine

- Further understanding of patient needs
- Improvements in Clinical Trial Design
- Accumulation of data during the study

- Automated safety and quality testing
- Accurate understanding of demand
- Tracking until delivery to patients

The use of digital technologies and data in the medicine lifecycle
http://efpia.jp/healthliteracy_digital-health/index.html

EFPIA seeks “Ideal Future” for people’s health and society in Japan in collaboration with diverse stakeholders

efpia Ideal Future State

Increase public health awareness leading to improved disease prevention, earlier diagnosis and treatment, thus extending healthy life expectancy

A society in which each person can live life to full despite illness or disability, and in which all citizens can live in harmony with each other

Safe and effective medicines developed around the world are available in Japan without delay from other countries

All citizens should have equal access to the latest medical care and can lead healthy lives without delay from other countries

efpia

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Thank you