

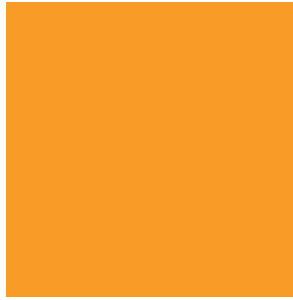


European Federation of Pharmaceutical
Industries and Associations

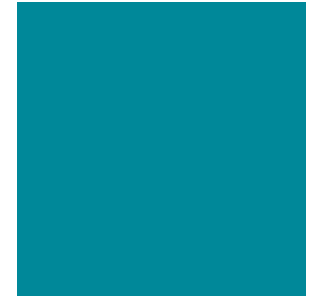
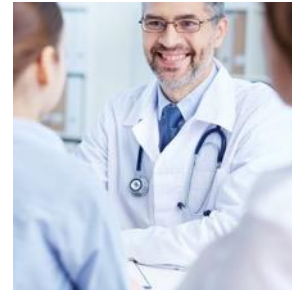


EFPIA Day 2024 Press Event

-To achieve compatible with promotion of innovation and sustainable healthcare-



October 10, 2024
Takahiko Iwaya
Chair of EFPIA Japan



About European Federation of Pharmaceutical Industries and Associations (EFPIA Japan)

- * **Establishment** 2002
- * **Overview** EFPIA Japan represents R&D-based European pharmaceutical companies operating in Japan
- * **Mission** EFPIA Japan is fully committed to providing innovative medications to improve the health and quality of life (QOL) of patients in Japan.
- * **Member company** 23 companies (as of April 2024)

Proportion of EFPIA Japan member companies' sales in the Japanese market (2023)*¹



Proportion of Number of Newly Listed Drugs by EFPIA Japan member companies (2023) *²

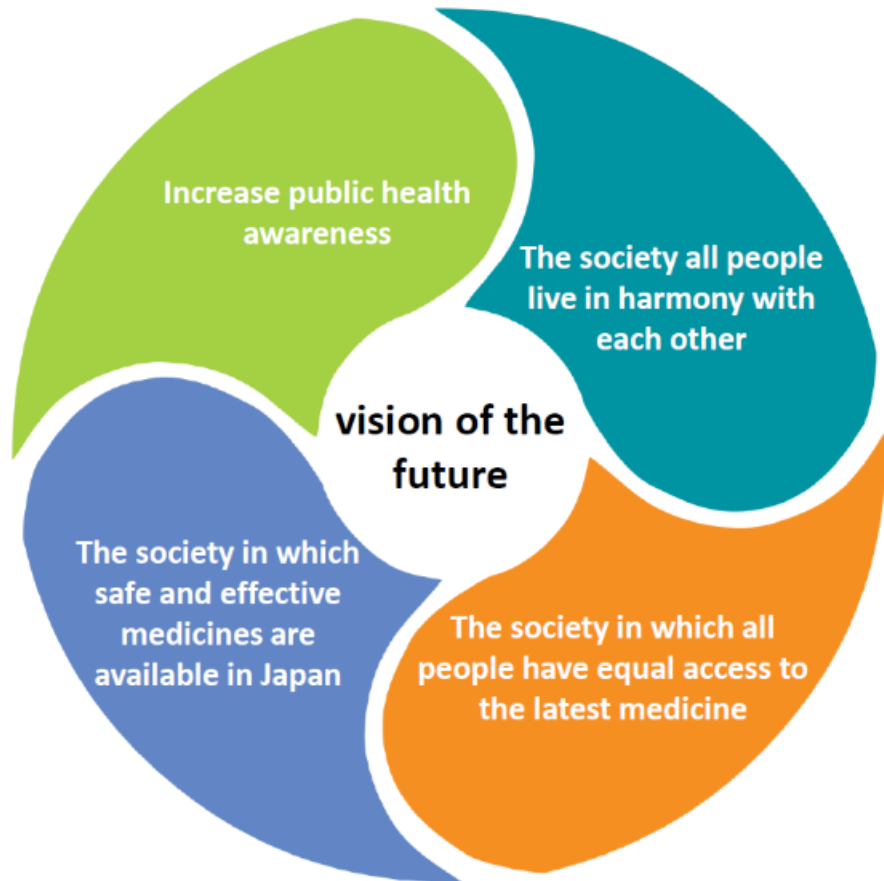


*1: ca. 3.2 trillion yen (EFPIA Japan survey for 2023)

*2: 48 ingredients (EFPIA Japan survey for 2023)

EFPIA Japan aims to realize the “vision of the future” for the health and society of the Japanese people

5 basic strategies to realize EFPIA Japan's four states as its vision of the future



1

Support the enhancement of health literacy

2

Drive pharmaceutical innovation while sustaining universal healthcare

3

Be engaged in the development of cost-effectiveness assessment processes

4

Promote the improvement of R&D and regulatory environment

5

Leverage digital technologies and develop digital talent

While we support the latest innovations related to the pharmaceutical industry, we will continue to discuss in order to realize our vision

NHI price revision 2024

Evaluation of innovation, Resolution drug lag/drug loss

- Maintain drug prices for innovative new drugs during patent period
- Evaluation of New Drugs Rapidly Launched in Japan
- Promote development of pediatric drugs
- Enhancement of effectiveness evaluation for innovative new drugs
- Review of Market expansion re-pricing

Gate Opening Summit for Innovative Drug Discovery

Position the pharmaceutical industry as a growth and key industry, and promote and implement practical initiatives and projects to achieve the three strategic goals.

1. "Prompt Delivery of Novel Drugs to Patients"
2. "Become one of the world's leading drug discovery sites"
3. "Cyclically develop investment and innovation"



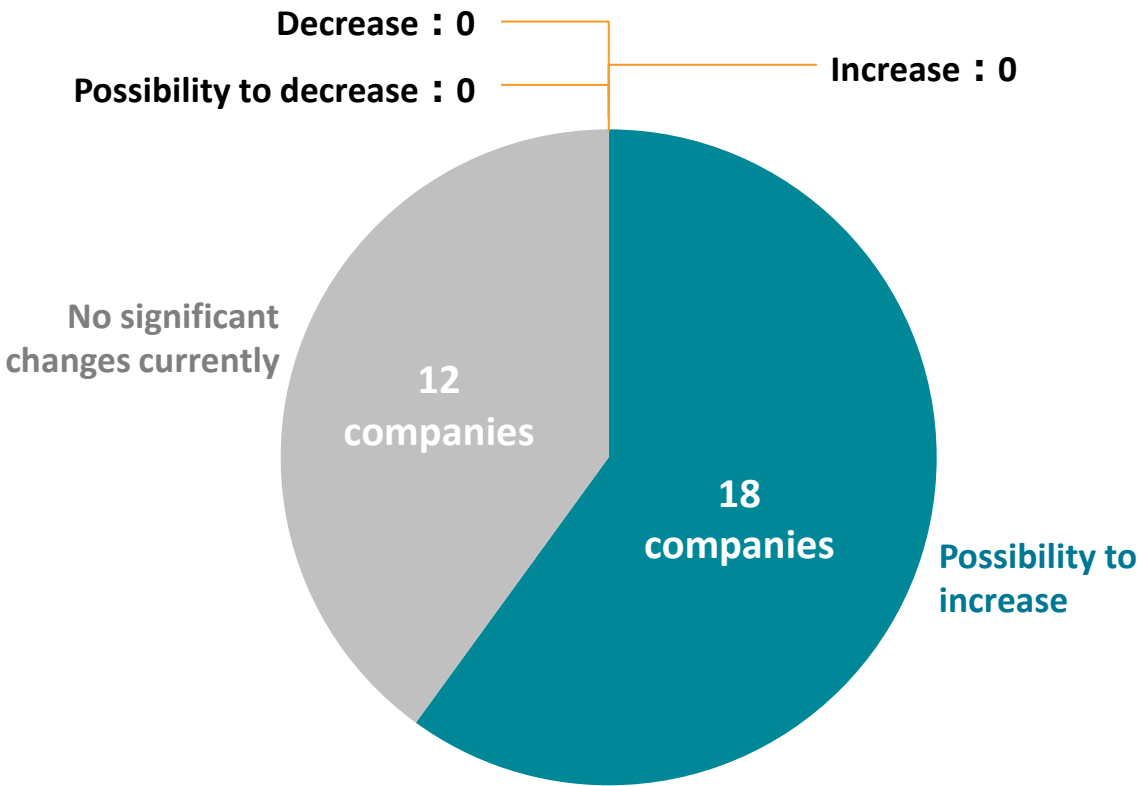
July 30, 2024
@Prime Minister's Residence

Further reform of the NHI drug pricing system is needed to make the Japanese market more attractive and to increase the priority of investment in the Japanese market

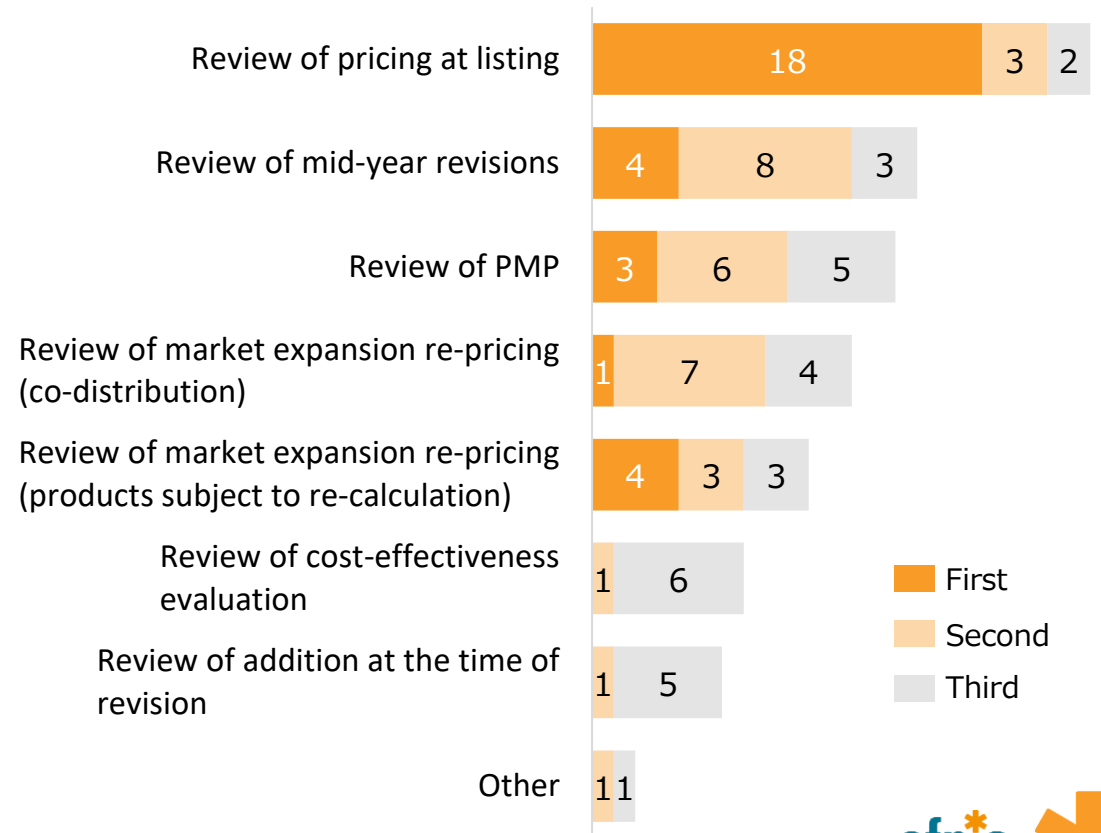
*EFPIA, PhRMA, JPMA

Results of the 3 associations* joint questionnaire survey on NHI drug price reform in FY2024

Q. Change in investment priorities for the Japanese market caused by the 2024 NHI drug price revision



Q. Details of expected NHI drug price revision to stimulate domestic development (each company, select first to third)



Source: 3 associations* joint questionnaire survey on NHI drug price reform in FY2024

Continuous discussion is needed for improvement of the R&D and regulatory environment to bring the new drugs to Japan

**International harmonization
(clinical trial environment)**

- Organizing the Need for Japanese Data in Japanese Approval Review
- Further improvement of the clinical trial environment

New scheme related to new drug review and approval

- Appropriate System for Designation of Orphan Drugs
- Appropriate regulatory review, etc. that contributes to the promotion of pediatric drug development
- The state of post-marketing use-results surveys, etc. and the state of utilization of real-world data

Importance of dialogue with multi-stakeholders including patients, public, industry, government and academia from drug discovery to regulatory affairs, drug pricing systems, and patient access is our proposal.



End to end strategy

- * R&D and regulatory environment to promote innovation generation**
- * Appropriate and transparent drug pricing system based on the value of innovative drugs**
- * Achieving an efficient, high quality healthcare environment and access to treatment**

To achieve compatible with promotion of innovation and sustainable healthcare



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Industries and Associations



Thank you

