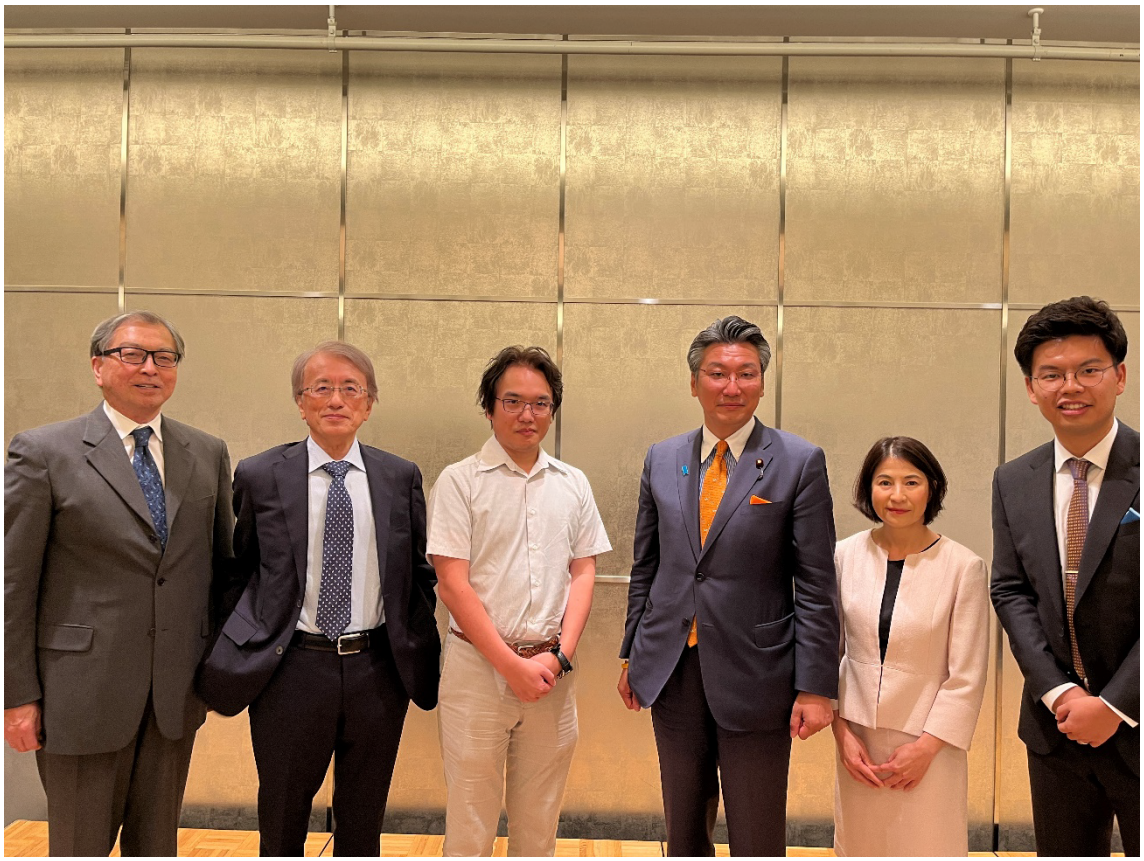
European Federation of Pharmaceutical Industries and Associations

October 2023
EFPIA Japan

EFPIA Day 2023 Event: EFPIA discusses the valuation of pharmaceutical products with multi-stakeholders

On 5th October 2023, EFPIA (European Federation of Pharmaceutical Industries and Associations, headquartered in Brussels, Belgium) and EFPIA Japan hosted a live webinar on the role of pharmaceutical value assessments and its role in the Pharmaceutical Innovation Ecosystem (PIE) in Tokyo. A multi-dimensional panel of industry representatives, health economists, patient organisations, parliamentarians, and local and global experts came together to discuss their visions and challenges of assessing the value of pharmaceuticals to propel them to the next stage of innovation.



In her opening remarks, EFPIA Japan Access Committee Chair Emiko Yoshikawa began by commending the universal health coverage in Japan, which enables timely reimbursement and patient access to medicines after regulatory approval, while highlighting that designs of pricing and its complemental cost-effectiveness assessment systems are crucial in maintaining the Pharmaceutical Innovation Ecosystem and to avoid drug lag/loss.

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Part 1: Presentations

Representatives from industry, academia and government gave presentations from their respective perspectives.

Social Welfare and Healthcare Systems around the World and in Japan
Dr. Isao Kamae, Project Professor, University of Tokyo

Dr. Kamae outlined a global healthcare snapshot, its implications for Japan, and subsequent recommendations to create better value for patients.

With growing worldwide pharmaceutical expenditure and the risk of unforeseen resource conflicts, the importance of assessment quality and patient-reported outcomes inclusion is becoming increasingly apparent. This is especially vital in Japan, where the life expectancy-health expenditure correlation is close to the threshold where increased investment will cease to about meaningful effect increases in an ageing and shrinking population. A new system with a stronger focus on scientific evidence and better transparency and consistency is required to ensure optimal cost-effectiveness, while the Ministry of Health, Labour and Welfare should expand from optimising assessments to value creation and build compelling logic for a patient-centric cost-effectiveness assessment system.

Sustainable Pharmaceutical Innovation Ecosystem – Pricing and HTA to support sustainable innovation for patients
Lars Fruergaard Jørgensen, President of EFPIA

President Jørgensen highlighted how the industry can contribute to a patient-centric approach for Japan by drawing global examples of the challenges and impact of cost-effectiveness assessments and best practices.

Active contribution from key stakeholders (especially patients) enables good decision-making processes that are pivotal for innovation, as exemplified by the high number of assessment criteria in leading markets that include the patient perspective component. Current sub-optimal stakeholder involvement in Japan translates to less well-defined processes and potentially lower market attractiveness. To shape

future assessments and decision-making, Japan should build on current strengths, including the short duration of reimbursement and increase market attractiveness by involving patient stakeholders.

How Japan evaluates the value of medicine
Gaku Hashimoto, Member of House Representative

MP Hashimoto highlighted the importance of promoting innovation while ensuring the sustainability of universal health coverage, the current challenges with drug lag and loss along with recommendations for resolution, and the need for pricing reform to increase the Japanese market attractiveness.

A sustainable healthcare system is vital in Japan with its sizeable pharmaceutical industry and ageing population. While recent regulatory changes have largely alleviated the drug lag problem, drug loss remains a major challenge, along with an increasingly grave stable supply issue with generics.

To tackle this problem and increase market attractiveness, the pricing and HTA system needs to be more predictable and considerate of the patient's perspective to reward innovation better.

Scientific relevance and improvements in the evaluation system
***Dr.* Ataru Igarashi, Associate Professor, Yokohama City University**

Dr. Igarashi provided an introduction to using scientific evidence to strengthen pricing and HTA systems and drive the Pharmaceutical Innovation Ecosystem, juxtaposing the current practices of Europe and Japan.

The current cost-effectiveness assessment in Japan is limited to the price and drug effectiveness relationship, and variations among different clinical subgroups and other qualitative parameters are not considered in drug pricing. Instead of limiting the assessment to quantifiable considerations, additional factors such as unmet needs and caregivers' QOL should be considered to reflect the true value of treatments.

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Part 2: Panel discussion

Moderated by the EFPIA Japan Chair Takahiko Iwaya, a panel session followed to discuss how the value of medicines should be evaluated in Japan with the patient representative, Specified NPO PanCan Japan Chair Yoshiyuki Majima.

Japan, as a society, should reflect treatment values from multiple perspectives

The patient representative and Specified NPO PanCan Japan Chair Yoshiyuki Majima started with an illustration of his own journey as a pancreatic cancer patient to point out the significant problem of drug loss where access to drugs that are not yet approved or not being developed in Japan is the issue. This is especially pronounced for progressive and rare cancers, as the predetermined national healthcare budget does not account for the underrepresentation of rare diseases and patient subgroups.

Majima suggested that a broad perspective on the value assessment of medicines is important to bridge this gap, and to achieve this, the participation of patient organizations in multi-stakeholder dialogues should be increased. The practice of patient involvement in Europe can serve as a reference for Japan, and the expectation for EFPIA Japan is to provide a platform for patients and other stakeholders to exchange ideas.

EFPIA Japan Chair Takahiko Iwaya added that evaluations should be a reflection of the value of treatment from multiple perspectives, including the QOL of caregivers. The participants noted that the designation of advanced medical care as an example of a solution to provide patient access to treatments not yet approved in Japan, and suggested that regulations should be developed where patients can quickly access groundbreaking innovations, using private insurance in addition to public insurance.

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