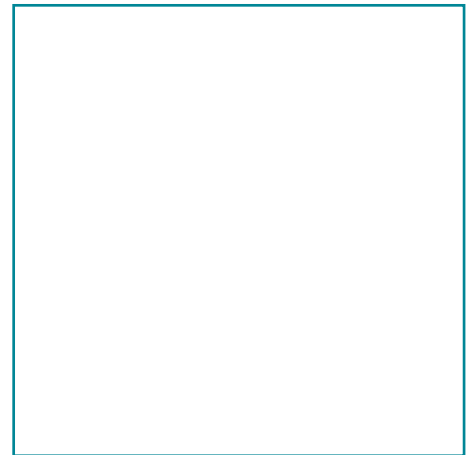
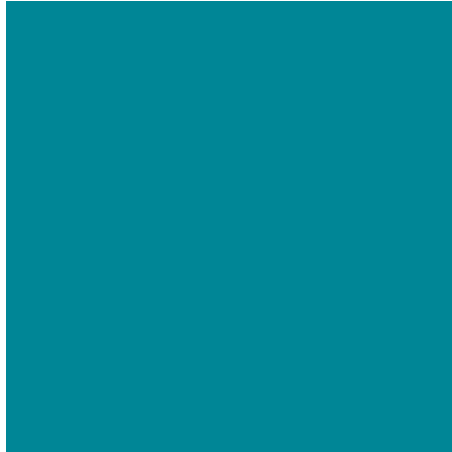




European Federation of Pharmaceutical
Industries and Associations

EFPIA Japan



Message from Chair of European Federation of Pharmaceutical Industries and Associations, Japan (EFPIA Japan)



As a super-aging society, Japan must address increasingly diversified healthcare needs, while also responding to urgent public health challenges as a result of the COVID-19 pandemic.

EFPIA Japan is fully committed to providing innovative medications to improve the health and quality of life (QOL) of patients in Japan. I am honored and truly humbled to be appointed as Chair of EFPIA Japan and will make the most of my experience working as a government official and in the pharmaceutical industry to help fulfill the mission of EFPIA Japan.

Established in April 2002, EFPIA Japan represents 23 R&D-based European pharmaceutical companies operating in Japan. Combined sales of its member companies account for about a third of the total pharmaceutical sales in the Japanese market and they generate about a third of all the new drugs launched recently in Japan. EFPIA Japan will continue working passionately in order to best contribute to healthcare and above all to support patients in Japan by delivering the expertise and insights of innovation-seeking European pharmaceutical companies.

EFPIA Japan is actively engaged in dialogue with the Japanese government and other stakeholders on important topics such as healthcare reform to maintain the universal health insurance system in this super-aging society, new healthcare models that incorporate digital technologies and community-based hospital-clinic collaboration and finally early introduction of innovative treatments and vaccines.

In particular, we make contributions to the policy debate with the aim to achieve the following outcomes:

- Increase incentives for innovative treatments and vaccines to improve the quality of healthcare in Japan, and ensure patient access to them
- Maintain the predictivity and stability of National Health Insurance drug prices and thereby encourage the development and introduction of new drug
- Ensure that all business operations are conducted in accordance with legal, ethical, and compliance requirement

Through policy recommendations to help achieve these outcomes and innovations by collaborative efforts of its member companies, EFPIA Japan will continue to be committed to ensuring a stable supply of medicines and vaccines, and enhancing its contribution to patients in Japan amid this current public health emergency.

Takahiko Iwaya
EFPIA Japan Chair

EFPIA Japan Member Companies (Total 23 Companies)

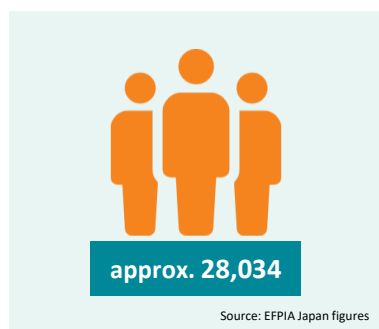
Alexion Pharma G.K.	Genmab K.K.	Nippon Boehringer Ingelheim Co., Ltd.
AstraZeneca K.K.	GlaxoSmithKline K.K.	Nippon Medac Co., Ltd.
Bayer Yakuhin, Ltd.	Guerbet Japan K.K.	Novartis Pharma K.K.
Bracco Japan Co., Ltd.	Ipsen Co., Ltd.	Novo Nordisk Pharma Ltd.
CHUGAI PHARMACEUTICAL CO., LTD.	LEO Pharma K.K.	Nxera Pharma Japan Ltd.
CSL Behring K.K.	Lundbeck Japan K.K.	Sanofi K.K.
Ferring Pharmaceuticals Co., Ltd.	Merck Biopharma Co., Ltd.	UCB Japan Co., Ltd.
GE Healthcare Pharma Limited	NIHON SERVIER COMPANY LIMITED	

Board Members

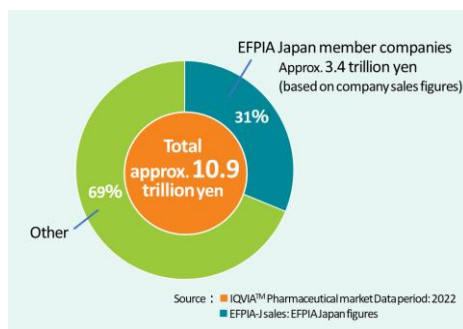
Chair	Takahiko Iwaya	(Sanofi K.K.)
Vice Chair	Takafumi Horii Kasper Bødker Mejivang	(AstraZeneca K.K.) (Novo Nordisk Pharma Ltd.)
Board of Directors	Paul Lirette Leo Lee Kanao Kikuchi Jan Stefan Scheld Ying Chen Jeremy Grossas	(GlaxoSmithKline K.K.) (Novartis Pharma K.K.) (UCB Japan Co., Ltd.) (Nippon Boehringer Ingelheim Co., Ltd.) (Bayer Yakuhin, Ltd.) (Merck Biopharma Co., Ltd.)
Director General	Yoshiaki Aono	

EFPIA in the Japanese Market

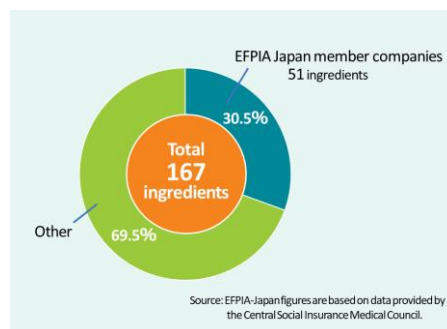
Employment by EFPIA member companies (2022)



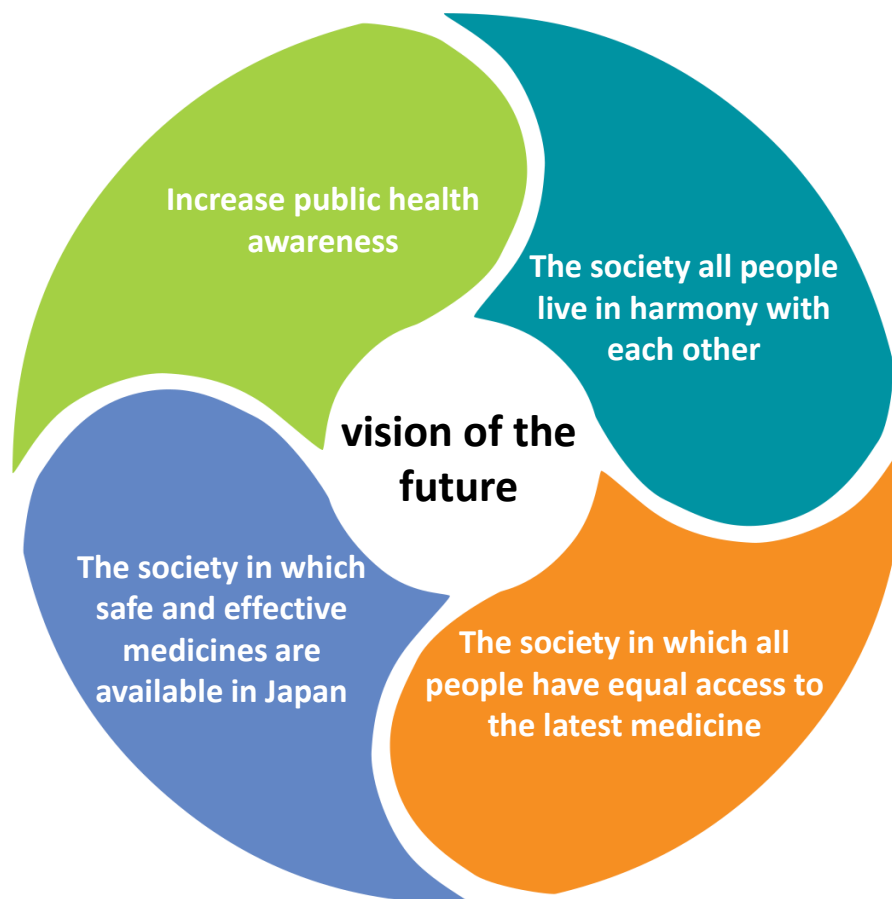
EFPIA Member Companies in Japan Sales (2022)



Number of Newly Listed Drugs (2022)



EFPIA Japan has identified the following four states as its vision of the future:



Increase public health awareness

"Increased public health awareness leads to promotion of prevention, early detection, and early treatment of diseases, thereby extending healthy life expectancy;"

The society all people live in harmony with each other

"All people live in harmony, allowing each individual to be oneself despite illness or disability;"

The society in which safe and effective medicines are available in Japan

"Safe and effective pharmaceuticals are available in Japan without delay from other countries;"

The society in which all people have equal access to the latest medicine

"All people have equal access to the latest medicine and lead healthy lives;"

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

To realize EFPIA Japan's four states as its vision of the future, it aims to continuously strengthen the pharmaceutical industry in Japan and increase the market attractiveness based on its five basic strategies. Further, to execute the strategies, EFPIA Japan will build a resilient organization, strengthen collaboration between Japan and Europe, and make distinctive contributions to society.



1. Support the enhancement of health literacy

EFPIA Japan works with the government and the healthcare community to support the health literacy in patients, as healthcare recipients' literacy and interest in health is an important factor in improving the quality of healthcare.



2. Drive pharmaceutical innovation while sustaining universal healthcare

While maintaining the advantages of the current healthcare system in Japan that allows prompt price listing and reimbursement of new pharmaceuticals after regulatory approval, it is necessary to build a sustainable system to balance the financial sustainability and the market attractiveness. To this end, EFPIA Japan carries on in-depth debates with stakeholders on incentivizing new drug launches in Japan ahead of the world and on allowing more flexibility in the new drug evaluation processes.



3. Be engaged in the development of cost-effectiveness assessment processes

The use of health technology assessment (HTA) based on cost-effectiveness as a price adjustment tool after listing involves both scientific and operational challenges. EFPIA Japan believes that an appraisal with the participation of physicians and patients is necessary to appropriately evaluate the value of pharmaceuticals and address the shortfall of the current cost-effectiveness assessment system. EFPIA Japan is committed to the development and realization of appropriate cost-effectiveness assessment processes by reflecting solutions to the challenges faced by Europe ahead of Japan and incorporating the diverse value of pharmaceuticals.

4. Promote the improvement of R&D and regulatory environment



To enable Japan to remain internationally attractive and competitive in the development of innovative pharmaceuticals and vaccines, and ultimately ensure that the people in Japan continue to benefit from the latest innovations, EFPIA Japan regularly investigates the clinical trial environment, encourages networking of core clinical research hospitals, promotes a risk-based approach, and facilitates decentralized clinical trials.

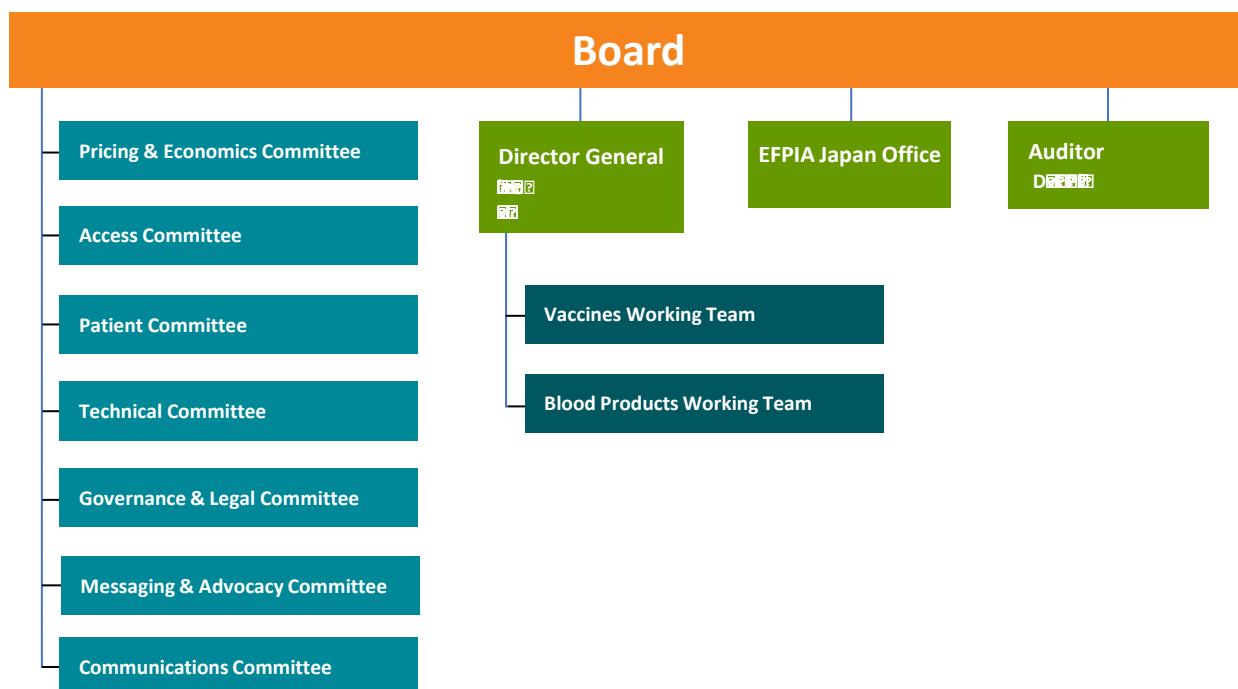
5. Leverage digital technologies and develop digital talent



To effectively allocate limited healthcare resources, it is necessary to correct inefficiencies in healthcare. Digital technologies can play a significant role in this regard. To utilize digital technologies to increase the healthcare efficiency, allocate healthcare resources appropriately, and improve health outcomes, the government needs to take the lead in forming a framework for digital technology use, including the development of a data infrastructure and its incorporation into community healthcare. Further, talents with both macro perspectives on the healthcare system and patient-oriented micro perspectives, who can look ahead to the utilization of evolving technology seeds may serve as a bridge between the pharmaceutical industry and society. To this end, EFPIA Japan develops such talents in the industry building on the experiences in Europe.



Organization



EFPIA Japan committee activities (September 2023)

EFPIA Japan is focusing on the following activities

1. Put forth evidence-based policy recommendations to ensure appropriate reward for innovation and incentives for investment in research and development in the course of pricing reform discussions. **(Pricing and Economics Committee)**
2. Promote public-private dialogue on healthcare systems, including cost-effectiveness assessment aligned with the pricing system, diagnosis procedure combination per-diem payment (DPC), cancer genomic profiling and companion diagnostics, and intractable disease control, to improve patient access to medicines and ensure appropriate reward for innovation in the country. **(Access Committee)**
3. Support the improvement of a healthcare environment for patients by encouraging the activation of patient group activities, so that their voices are appropriately reflected in the healthcare system. Strengthen collaboration with patient groups in various disease areas through information exchanges and educational opportunities. **(Patient Committee)**
4. Contribute to improving the regulatory environment and the environment for executing drug development and post-marketing activities in Japan and enhancing development and evaluation technologies to ensure the availability of innovative medicines as quickly as possible with appropriate information and their safe use by patients. **(Technical Committee)**

5. Contribute to the further enhancement of compliance and integrity in the pharmaceutical industry and enable member companies to respond flexibly to changes from legal, ethical, and compliance perspectives.
(Governance and Legal Committee)
6. Develop and implement strategic advocacy plans in collaboration with other committees/working teams and other pharmaceutical industry bodies to advocate the importance of appropriate rewards for innovation and improvement of the regulatory environment to ensure patient access to innovative medicines in the country as quickly as possible. Create impactful and consistent messages that harmonize with all committees/working teams and promote EFPIA's policies. **(Messaging and Advocacy Committee)**
7. Develop and execute effective communication activities to advance EFPIA Japan's positions and initiatives, enhance its presence, and promote policy advocacy, thereby facilitating stakeholders' understanding.
(Communications Committee)
8. Contribute to the public health of the country by introducing world-class innovative vaccines to Japan as early as possible. Aiming to improve the predictability of the vaccine market in Japan, continue dialogue and collaboration with government and academia, and put forth policy recommendations to policymakers on regulations, including biological product standards and national assay, life-long immunization program, and awareness-raising on vaccination and infectious disease control. **(Vaccines Working Team)**
9. Promote patient access and regulatory harmonization for blood products through dialogue with the government. Enhance EFPIA Japan's presence and position as a trusted partner for blood law stakeholders.
(Blood Products Working Team)

EFPIA Japan key activities in 2022

EFPIA Japan offers a patient group support program “PASE”

Patient Advocacy Support by EFPIA Japan (PASE) is our initiative to support further development of the healthcare environment surrounding patients by encouraging revitalization of patient group activities in Japan so that their voice is appropriately reflected. We will make our best efforts to ensure “patient-centered healthcare” in Japan by supporting patient groups that contribute to development.



5th PASE award ceremony (October 5, 2022)