



EU-Japan Health Innovation Forum 2023 日欧ヘルスイノベーションフォーラム 2023

Ensenble, partnering for a sustainable health innovation system

~イノベーションの力で未来を切り開く~

12 Apr 2023 @ Europe House / Online



【Opening】 16:00-16:10	Opening Remarks	Mr. Hubertus von Baumbach, President of EFPIA (video) Mr. Takahiko Iwaya, Chair of EFPIA Japan
[Part1 Lectures about	t Initiatives encouraging innovation]	
From Industry 16:10-16:25	(1) Opening the future with the power of innovation	Ms. Kanako Kikuchi, Board Member of EFPIA Japan
16:25-16:40	(2) Opportunities to enhance Japan's global market attractiveness	Mr. Paul Hudson, Chief Executive Officer, Sanofi
From Government		
16:40-16:55	(1) EU's vision for innovation	Mr. Jean-Eric Paquet, EU ambassador
16:55-17:10	(2) Policies of promoting innovation in Japan	Mr. Shinichi Isa, State Minister of MHLW (video)
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[Part2 Dialogues; "The importance of continuously seeking for innovations and expectations for the future"]		
17:15-17:55 (40 min)	Moderator: someone professional Panelist 1. Patient Panelist 2. HCP Panelist 3. Government Panelist 4. Industry	Ms. Naomi Sakurai, Japan Federation of Cancer Patient Groups Dr. Watanabe, Director of Japan Medical Association Mr. Katsufumi Jo, Assistant Vice Minister of MHLW Mr. Kasper Bødker Mejlvang, Board Member of EFPIA Japan
[Closing] 17:55-18:00	Closing Remarks	Mr. Takahiko Iwaya, Chair of EFPIA Japan

European Federation of Pharmaceutical Industries and Associations

Opening Remarks

Mr. Hubertus von Baumbach, Chief Executive Officer, C. H. Boehringer Sohn AG & Co. KG (Video Message) Mr. Takahiko Iwaya, President and Representative Director, Sanofi K.K.



Internal

Part 1 Lectures

Lectures about Initiatives encouraging innovation





EU Japan Health Innovation Forum 2023

- Opening the future with the power of innovation -



EFPIA Japan is delivering patient-centered innovations

*** Establishment**: 2002 (became a general incorporated association in 2022)

Overview: EFPIA Japan is comprised of European R&D-oriented pharmaceutical companies operating in Japan. Our mission is to contribute to healthcare and patients in Japan through the early introduction of innovative medicines and vaccines, and we aim to strengthen dialogue with policymakers to improve healthcare in Japan.

***Membership:** 23 companies (as of April 2023)

*****Board Companies

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

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



What EFPIA Japan thinks about innovations are:

Patients' voices are a source of innovation

Healthcare innovation aims to:

- Bring hope to patients and change & save lives of patients and their families
- Extend healthy life expectancy, energize society, and contribute to better communities
- Make science and medical practice to progress
- Each one, even one who is supporting others, may become a patient one day.
- Stakeholders should understand each other and help to create innovations



INNOVATION



EFPIA Japan executes the five strategies to continue creating innovations and bring them to patients



Drive pharmaceutical innovations while sustaining universal healthcare



Be engaged in the development of cost-effectiveness assessment processes that ensure patient access



Promote the improvement of R&D and regulatory environments



Support the enhancement of health literacy



Leverage innovative technologies such as regenerative medicine, gene/cell therapy, and digital and develop talent



Drugs & Vaccines innovations in Japan

1. Do innovations occur spontaneously?

2. How can patients access innovations?





Drugs & Vaccines innovations in Japan

1. Do innovations occur spontaneously?

• Suitable infrastructures and regulations are needed

Agile regulatory frame in line with international standard and ready to address/review new technologies

- Appropriate financial conditions are required: Costs? OR Investment? Let's think about the total benefits that society may gain
 - Innovations will protect people suffering from new diseases or currently uncurable diseases
 - The percentage of pharmaceutical products in the total national healthcare spending has been around 20% as direct cost but also help to save overall HC cost

2. How can patients access innovations?

A patient-friendly system must be built to help patients benefit from the innovations they need while maintaining Universal Healthcare System



An innovation-friendly environment must be built through:

- *****Building an open ecosystem that fits Japan
- Introducing an International harmonized regulatory system that starts NDA review based on the topline results of confirmatory clinical trials
- * Creating opportunities that encourage collaboration between clinical research core hospitals and pharmaceutical companies
- * Creating opportunities to discuss how to promote industry-government-academia collaborations in the development of innovative new drugs





EFPIA Japan promotes the creation of an environment where the patient's voice can be heard: *Patient Advocacy Support by EFPIA Japan (PASE)*

***** PASE (Patient Advocacy Support by EFPIA Japan):

EFPIA Japan's patient group support project launched in 2017

- *** Overview:** PASE encourages patient groups to act more energetically and make policymakers reflect patients' voices in the healthcare system in Japan, thereby improving the healthcare environment surrounding patients.
- *** PASE Awards:** Every year, EFPIA Japan provides grants to organizations contributing to the advancement of patient rights advocacy activities.

***** Education to patients about disease, treatments, etc.



The 5th PASE Award at EFPIA Day 2022 Source: Kibo-no-Kai, an award winner



EFPIA Japan believes that cost-effectiveness analysis system should ensures patient access

*****EFPIA's viewpoint: Four principles of cost-effectiveness analysis (CEA)

EFPIA has significant experience in the application of HTA in European markets. EFPIA suggests the following four principles for CEA system in Japan.

- 1. Should not be used for reimbursement determination in order to protect patients' access
- 2. Should be used as a complementary tool for the system of drug pricing and reimbursement
- 3. Evaluate ethical and social value of pharmaceuticals from a long-term perspective
- 4. <u>Involve all stakeholders in comprehensive evaluation to secure transparency</u>

(JP) EFPIA_HTA_Viewpoint-2019Jan.pdf



Decreased priority of the Japanese market may affect the launch of new drugs in Japan

Discontinue, postpone or delay product launch in Japan

Change in priority of the Japanese market vs other countries after the fundamental reform of the drug pricing system



Unit: Number of companies, n = 10

- Decreases in the NHI price at the initial listing, revisions in the future, and their predictability
- Need for developing products only for Japan (due to the 2-week prescription limit for newly launched drugs)
- Influence on other countries like China where Japan's NHI prices are referred to as pricing data



For global pharmaceutical companies to bring innovative new drugs to Japanese patients as soon as possible, Japan needs to have a supportive drug pricing system

- Maintain the current system that ensures prompt NHI listing and reimbursement following the NDA approval;
- Evaluate the value of innovative drugs appropriately;
- Provide incentives for launching new drugs in Japan earlier than other countries;
- Have a high predictability;
- Be sustainable



Summary: EFPIA sees the following challenges as opportunities and will continue to engage in dialogue with various stakeholders

*****Creating an environment that promotes innovation

Building a patient-friendly system to help patients benefit from the innovations they need

*Being engaged in the development of Cost-Effectiveness Assessment processes that ensure patient access

*****Building a drug pricing system that rewards and incentivizes innovation so as to support the stable delivery of innovative new drugs to Japanese patients





Thank you





EU Japan Health Innovation Forum 2023

- Opportunities to enhance Japan's global market attractiveness -



Japan has long been a reference in universal health coverage and historically a strategic market for the global biopharmaceutical sector

Japan's Universal Health Coverage has long been a model for many other countries in the world.



The time between marketing authorization and availability of new medicines in Japan is in average 60 days, compared to over 500 days in average in Europe.



As such, Japan has been a strategic market for the global biopharmaceutical industry, and our sector has historically been invested significantly in Japan:

- For our patients in Japan and around the world, our sector has been and continues to be at the core of the R&D and production efforts to fight COVID pandemic and other life-threatening diseases.
- Our sector invests the most in R&D in Japan, with 14 trillion of yen over the last decade.
- And our sector is supporting over 140,000 jobs across the country.

However, in recent years, Japan has been losing the key elements of its market attractiveness.

Pharmaceutical R&D expenditure in major markets (2001-2020)^[1]



Growth of pharmaceutical R&D expenditure in Europe has slowed relative to US and China



Pharmaceutical R&D employment has largely stalled relative to US and China in recent years



Innovation Pipeline is exciting and transformative – Japan should not be left out

Internal

 In 2022, global R&D funding from the large pharmaceutical sector remained high, with a record \$138 billion invested in R&D by the 15 largest pharmaceutical companies. This represents an increase of 43% since 2017.



FULL PIPELINE – No. of trials started from 2017-2022

PIPELINE SUMMARY – Key Therapy Areas (% of trials started from 2017 – 2022 inclusive)





To turn around the situation, there are 3 Win-Wins to be taken advantage of to drive a pro-innovation health ecosystem in Japan



Ensure sustainable funding investment on innovation.

- o Investing in innovative medicines to preserve good health and extending productivity of the super ageing population
- \circ Investing in health ecosystem to enhance pandemic preparedness



Improve the current pricing system for higher predictability and better recognition of innovation.

- $\circ \quad \ \ \, \text{Providing high predictability}$
- \circ \quad Maintaining medicines' prices during patent period
- Incentivizing early new launches in Japan



Enhance R&D environment and regulatory harmonization with global standards to accelerate introduction of innovative medicines.

- Promoting industry-government-academia collaboration in the development of advanced therapy medicinal products (ATMP).
- Encouraging and supporting capability building, experience sharing, and talent development between EU/EMA and Japan.



We are committed to close collaboration with the Japanese government to codevelop Japan's health eco-system

- The European-based biopharma companies have been working closely with various governments in co-development life science strategy.
- We are committed to working closely with Japan government to co-develop a pro-innovation health ecosystem, to enhance Japan's health security and global market attractiveness.
- We suggest leverage this EU-Japan Health Innovation Forum as **an annual platform for the government-Industry strategic dialogue**, to co-develop end-to-end strategies for a better and brighter pharmaceutical sector in Japan.





France Innovation Santé 2030 is established in a concerted manner between the State and the pharmaceutical, device and diagnostic sectors. The strategic vision is co-constructed on the basis of shared diagnosis and challenges, and the operational follow-up of the measures is then ensured by people from the industrial sector with regular meetings with the different ministries concerned (health, industry, research) and Macron's office. The Danish National Life Sciences Council enables continuous alignment on key policy goals between various stakeholders, including industry, government stakeholders, and patient organizations.





ありがとうございました!



Internal



EU's vision for innovation

EU's power for innovation and DX for people, patients and innovation

Jean-Eric Paquet Ambassador of the European Union to Japan

EU-Japan Health Innovation Forum



For people, life and future

🖅 🖾 Ministry of Health, Labour and Welfare

EU-Japan Health Innovation Forum 2023

Innovation Promotion Policy in Japan

Shinichi Isa

State Minister of Health, Labour and Welfare

Ministry of Health, Labour and Welfare of Japan

Importance of Innovation Promotion

- The pharmaceutical industry is an important industry that contributes to the improvement of the nation's health and medical care and will be at the core of future economic growth
- Constant promotion of innovation is a must to deliver the innovative new drug to the nation and to continue to grow as an industry
- The followings are being conducted as the Japanese Government :
 - 1. **Develop strategies** on the pharma industrial policy
 - 2. **Support collaboration** with academia and venture companies

3. **Improve environmental foundation** for the creation of innovation

1. Strategies – Pharma Industry Vision 2021 –

(The vision that the pharma industrial policy aims to achieve)

- Improvement of scientific and technological capabilities and <u>realization of innovation are</u> <u>indispensable</u> for the development of the pharma industry, which is a <u>knowledge- and technology-</u> <u>intensive industry</u>, therefore, the pharma industrial policy is promoted with the aim of realizing the following 2 points:
 - 1. <u>Contribute to prolonging the healthy life expectancy of Japan through innovative drug</u> <u>discovery as one of the world's most advanced drug discovery countries, as well as to</u> <u>industrial and economic development through the improvement of medical research and</u> <u>industrial technology capabilities</u>
 - 2. <u>Pass on to the next generation a society where the nation can securely receive a good</u> <u>quality of medical care through quality assurance and a stable supply of medicinal products</u>



January 7th, 2023

LEQEMBI[™] (Lecanemab) obtained accelerated approval by the US FDA as a therapeutic agent for Alzheimer's disease

2. Collaboration – Trends in Drug Development –

Trends in drug development

Collaboration between pharmaceutical companies and academia/ventures is the essential requirement for innovative new drug development Horizontal division of work is increasing globally

Build the ecosystem, and promote the creation of innovation through collaboration

Formation of an open-innovation community where innovation is promoted organically, including entries from overseas or other industries, is required.

Strengths and challenges in Japan



- Academia and pharmaceutical companies/peripheral players are enriched
 - Nobel Prize-worthy innovative researches are being conducted
 - Domestic/foreign mega pharma companies and medium-sized pharmaceutical
 - companies with strengths in technology exist
- On the other hand, the support function provided by private organizations alone in translational research are not well established as in the US, and there was a background issue of difficulty in connecting the academia seeds to industrialization

Total Support Project for Medical Ventures (MEDISO)

MEDISO (MEDical Innovation Support Office) is a project to provide total support for issues emerged at each step from research and development to launch to connect the seeds for medicinal products and medical devices owned by academia and venture companies to practical use.



Project for Enhancing the Drug Discovery Ecosystem

Supplementary budget for 2022: 300 billion JPY * supplementary budget for 2021: 50 billion JPY

- Drug discovery ventures are highly difficult to achieve commercialization due to their special business models: 1. Long development period, 2. Large amount of development funds, 3. Low success rates, 4. No sales unless regulatory approval is obtained. In particular, the risk involved in Phase I and II clinical trials is still high, however, the development funds jump to the scale of 5-10 billion yen.
- Globally, the development of new medicinal products has shifted to drug discovery ventures. <u>In the new</u> <u>drug/venture ecosystem in Japan</u> vulnerable than that of the US, <u>the smooth raising of funds that drug</u> <u>discovery ventures need is difficult.</u>
- → Based also on round-table discussions, the scope of eligible business that supports practical development in collaboration with VC is expanded other than those related to infectious diseases in order to truly enhance the drug discovery ventures ecosystem.

Diagram for risk and funds of drug discovery development

Diagram for the project



Project for Improving Biopharmaceutical Manufacturing Bases, etc. Supplementary budget for 2022: 100 billion JPY * supplementary budget for 2021: 223.78 billion JPY

Details of the project

Project objectives/overview

- Having the capabilities to develop and produce vaccines domestically is extremely important from the perspective of diplomacy and security, as well as contributing to the preservation of the health of the nation. Therefore, the Cabinet approved the strategy for strengthening vaccine development and production as a national strategy in June 2021 to commit continuously on a long-term basis.
- Many of the vaccines for COVID-19 are innovative biopharmaceuticals different from conventional vaccines, such as genetic vaccines, however, the number of manufacturing bases for such innovative vaccines is currently limited in Japan. In addition, many of the components required for vaccine manufacturing (culture media, culture bags, etc.) are dependent on imports, resulting in issues, including delivery delays.
- In this project, it secures the dual-use equipment that manufactures biopharmaceuticals, meeting the needs of companies under normal circumstances and can switch to vaccine manufacturing under emergency circumstances as a preparation for future variants and new infectious diseases. In addition, it provides support for formulation and filling equipment that are indispensable for vaccine manufacturing, as well as manufacturing equipment of components necessary for medicinal product manufacturing.

Outcome objective

• Build the structure that can initiate prompt vaccine manufacturing domestically in the event of future variants or new infectious diseases occurrence by supporting the formation of dual-use manufacturing bases compatible with multiple drug discovery technologies and methods (modality).

Condition (eligible subject, eligible act, subsidy rate, etc.)



Diagram of the project

(1) Project for improving manufacturing bases for vaccine

 Support is provided for the installation, etc., of dual-use equipment with dual-use capabilities, which can manufacture biopharmaceuticals that companies normally produce under normal circumstances and vaccines for infectious diseases under emergency circumstances, such as pandemics.

<Diagram of the project>

- Renovations necessary to convert existing facilities/equipment to dual-use
- Installation of new dual-use equipment, facility improvement, etc.

<Diagram of dual-use equipment>



(2) Project for improving manufacturing bases for formulation and components, etc.

• Support is provided for the installation, etc., of formulation equipment and manufacturing equipment of components, etc., indispensable for vaccine manufacturing.





Formulation equipment

Single-use bag

Filters

32

3. Environmental foundation improvement – Promotion of Whole Genome Analysis, etc. Action Plan –

"Whole Genome Analysis, etc. Action Plan 2022" (Developed on September 30, 2022)

The stance of medical care aimed by the promotion of whole genome analysis, etc.

- Aiming to "conquer cancer and intractable diseases, etc." in the future by proceeding with the accumulation of strategic data and promoting research and drug discovery using such data to deliver high-quality medical care for the nation is the stance of medical care aimed by the promotion of whole genome analysis, etc.
- In addition, the early introduction of the analysis results into daily medical practice and the realization of personalized medicines are further promoted.



* PPI: Patient and Public Involvement, ELSI: Ethical, Legal and Social Issues

*The term "Cancer" in this action plan presumes cancer types, including refractory, rare, childhood, and hereditary cancers, for which a certain effect is expected from the whole genome analysis, etc., but it is difficult for the private sector alone to conduct research and drug discovery, etc.

3. Environmental foundation improvement – Medical DX Promotion –

- Contribute to individual health improvement by being able to understand lifelong healthcare data centrally by oneself from birth to present
- With the consent of the person, possible to receive high-quality medical care seamlessly through the sharing of necessary medical information among medical institutions, etc., nationwide
- Promote operational efficiency and effective use of human resources in the medical setting through digitalization
- Promote pharmaceutical and healthcare industries such as drug discovery and clinical trials, etc., through secondary use of healthcare data



3. Environmental foundation improvement – Regulatory Harmonization Initiatives with EMA –

MHLW/PMDA has conducted international regulatory harmonization with EMA, combining multinational and bilateral collaboration

Multinational cooperation:

Improve common global regulatory basis through collaborations in developing common guidelines for pharmaceuticals, etc. (ICH) and in a place where the direction, etc. of regulatory harmonization regarding regulatory affairs are instructed and coordinated (ICMRA)

Bilateral cooperation :

Implement regulatory harmonization from a perspective of practical operations through collaborations in specific disease areas, including rare diseases, participation of PMDA experts in EMA reviews (Open Project), and mutual dispatch of expert personnels

[Multinational cooperation (examples)]

ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)

- OInternational conference where <u>drug regulatory authorities and</u> <u>representatives of pharmaceutical industry collaborate</u> to develop guidelines for regulations of pharmaceuticals
- OStarted in 1990 (Europe and Japan are both early founding <u>memebers</u>)

ICMRA (International Coalition of Medicines Regulatory Authorities)

OA place where <u>the direction</u>, etc. of regulatory harmonization regarding regulatory affairs are instructed and coordinated

 \bigcirc Composed of top officials of drug regulatory authorities from approximately 30 countries and regions, including Asia, Europe and the US

O Started in 2013

OChair: Executive Director of EMA (EU) Vice-Chair: Chief Executive of PMDA (Japan) and others

[Bilateral cooperation (examples)]

Collaboration in specific disease areas (FDA also participates)

- Collaborate on regulatory concepts and responses, etc. by area (cluster)
- $(\mathsf{Example}) \boldsymbol{\cdot} \mathsf{Concept}$ of development and review collaboration in the rare disease area

• GCP*Initiative (sharing of GCP audit information between Japan, the US and Europe) *GCP: Good Clinical Practice

Participation in EMA review (Open Project)

 In light of COVID-19, PMDA reviewers participated in EMA reviews and provide opinions. It will be expanded into other areas in the future.

Mutual dispatch of expert personnels

 $\bigcirc \mbox{Long-term}$ dispatch of experts from PMDA to EMA as liaisons

OShort-term dispatch of topic-specific experts from EMA to PMDA

3. Environmental foundation improvement – Japanese Regulatory System to Asian Countries –



G 7 Nagasaki Health Ministers' meeting

Disseminate the directions and actions of G7 regarding strengthening prevention, preparation, and response to future public health crises, contributing to achieving more resilient, equitable, and sustainable Universal Health Coverage (UHC), and promoting health innovation that supports those efforts, aiming to "better recovery" from the COVID-19 pandemic.

<Overview of Ministers' meeting>

ODate: Saturday, May 13 and Sunday, May 14, 2023

- OPlace : Nagasaki City, Nagasaki Prefecture
- OVenue: Dejima Messe Nagasaki

Nagasaki City, the host city, has been actively interacting with foreign countries for a long time serving as a trading port, and is the place where Western medicine was introduced in Japan. The city has a proven accomplishment of contributing to global medical care and public health areas, mainly through Nagasaki University, which owns the National Research Center for the Control and Prevention of Infectious Diseases and the Institute of Tropical Medicine, and is a perfect place to have discussions about various international health issues.





Dejima Messe Nagasaki

Night view of the Port of Nagasaki

<Agenda (draft)>

The following 3 points are main agenda:

- 1. Build and strengthen the global health architecture to respond to the public health crisis
- 2. Contribute to achieving more resilient, equitable, and sustainable Universal Health Coverage through the enhancement of the health system
- 3. Promote health innovation to respond to various health issues

(*) Universal Health Coverage (UHC)

The state where every person can receive healthcare services, including appropriate prevention, treatment, and rehabilitation, at a payable cost

Part 2 Dialogues

"The importance of continuously seeking for innovations and expectations for the future"



efpia European Federation of Pharmaceutical Industries and Associations

Closing Remarks

Mr. Takahiko Iwaya, President and Representative Director, Sanofi K.K.



Internal

The END See you again!

終了 ありがとうございました。



INNOVATION

