

EU-Japan Health Innovation Forum 2023 **- Partnering together for a sustainable health innovation system -**

The European Federation of Pharmaceutical Industries and Associations (EFPIA; headquartered in Brussels, Belgium) and EFPIA Japan organized the "EU-Japan Health Innovation Forum 2023" on Wednesday 12 April 2023.

Held at the Europe House of the Delegation of the EU to Japan, the Forum was participated by a broad audience both in person and online from Japan, Europe, the US and beyond. Prestigious speakers from the EU and Japan government agencies, scientific societies and patient associations, as well as the innovative biopharmaceutical industry, openly exchanged their views on the importance of innovation in Japan and the potential opportunities for improvements.



In the opening remarks, Mr. Hubertus von Baumbach, President of EFPIA, Chairman of the Board of Managing Directors, Boehringer Ingelheim, set out the theme 'Stronger together' and expressed his desire for the Forum to provide a platform for further collaboration in strengthening the health system efficiency and resilience.



Mr. Takahiko Iwaya, Chair of EFPIA Japan, President and Representative Director, Sanofi K.K., stressed the importance of the year 2023 for Japan. Japan assumes the G7 Presidency this year under the leadership of Prime Minister Kishida. It represents a great opportunity for Japan to showcase its commitment to human security and universal health coverage. In such an important year, EFPIA organized this Forum, for the first time, to discuss the importance of pursuing innovation in healthcare with key stakeholders and partners.

Featuring both individual presentations and panel discussions, the Forum enabled in-depth discussions and exchanges of different perspectives from multi-stakeholders.

Part1 Individual Presentations on Initiatives Encouraging Innovation

In this session, four Japan and EU representatives from the biopharmaceutical industry and government institutions shared their views.



As a representative of the innovative biopharmaceutical Industry in Japan, Ms. Kanako Kikuchi, EFPIA Japan Board Member and Representative Director and President, UCB Japan Co., Ltd., gave a presentation titled “Opening the future with the power of innovation”. She defined innovation in Japan through the need of patients and outlined EFPIA Japan’s five strategic imperatives to create and deliver innovation to patients. She also discussed concerns and root causes regarding Japan’s declining market attractiveness, and called for the development of a collaborative innovative ecosystem.

As a representative of the European / global innovative biopharmaceutical industry, Mr. Paul Hudson, Chief Executive Officer, Sanofi, gave a speech titled “Opportunities to enhance Japan’s global market attractiveness”. He reflected on the current situations in the UK and Spain, and proposed three important “wins” that should be swiftly implemented in the Japanese health system: 1) Ensure sustainable funding for innovation, 2) Improve the current pricing system for higher predictability and better recognition of innovation, 3) Improve the R&D environment and global regulatory harmonization to accelerate the introduction of innovative medicines.

As a representative of the European Commission, HE Mr. Jean-Eric Paquet, Ambassador of the European Union to Japan, gave a speech titled “EU’s vision for innovation”. He mentioned that the basic research for the COVID-19 vaccines was carried out in the EU, and the vaccines were delivered from the EU to Japan in the early stages of the pandemic. In addition, he emphasized the importance of the strong relationship between the EU and Japan. To illustrate the EU’s effort in driving healthcare innovation, Mr. Paquet referred to the European Health Data Space (EHDS), which will help the EU to achieve a quantum leap in the way healthcare is provided to people across Europe. He also mentioned about the Horizon Europe Program, which supports scientific and technological excellence and strengthens the European

Research Area. The Ambassador highlighted the current negotiations on Japan becoming an associate member of the Program, and opportunities for collaboration with Japanese academia and research institutions under this Program.

As a representative of the Japanese Government, Mr. Shinichi Isa, State Minister of the Ministry of Health, Labor and Welfare (MHLW) gave a lecture titled "Policies of promoting innovation in Japan". He said that constant promotion of innovation is a must to deliver innovative new drugs to the country and to continue growing as an industry. The following topics are currently being discussed by the Japanese Government:

1. Development of strategies related to the biopharmaceutical industrial policy,
2. Support of collaboration between academia and venture companies, and
3. Creation of an environment that fosters innovations.

Part2 Dialogues; "The importance of continuously seeking innovations and expectations for the future"

Four panelists from different backgrounds openly exchanged their views on two main themes, "looking back at recent healthcare innovations" and "expectations for innovations in the future".



Patient representative: Ms. Naomi Sakurai, Director of the Japan Federation of Cancer Patient Groups,

Healthcare professional representative: Dr. Koji Watanabe, Executive Board Member of the Japan Medical Association,

Japanese government official: Mr. Katsufumi Jo, Assistant Vice-Minister for Pharmaceutical Industry Promotion and Medical Information Management of MHLW, and

Industry representative: Mr. Kasper Bødker Mejlvang, President and Representative Director, Novo Nordisk Pharma Ltd.

"Looking back at recent healthcare innovations"

Ms. Sakurai: I appreciate the opportunity to participate in this kind of dialogue as a patient. When I was diagnosed with cancer in 2004, Japan had a drug lag. Patients raised public awareness of this problem and led the government to enact the Cancer Control Act and formulate the cancer control promotion basic plan based on the Act. Japan started to

overcome the drug lag problem in a slow but consistent manner. However, there are still a significant number of patients who die of diseases for which no effective treatments are available in Japan. I strongly hope that all relevant stakeholders reflect on patients' voices in their discussions on healthcare innovations.

Dr. Watanabe: Compared to when I was practicing as a pediatrician, physicians now can use a greater number of effective drugs for their patients. However, it is still difficult to conduct clinical trials in children with chronic intractable diseases because of the small number of eligible patients in Japan, and this situation remains unsolved for a long time. I think this is an important issue that needs to be solved immediately.

Mr. Mejlvang: Patients' voices motivate us to develop innovative new drugs. To continue drug development, we must continue investment. In order to be able to boast that Japan is a country that values innovation, it is necessary to maintain the price maintenance premium for innovative new drugs during the exclusivity period and to change the repricing system to reward the value of drugs rather than to reduce drug prices as the market expands. We would like to participate in discussions with the Japanese government on pricing reform in a responsible manner.

"Expectations for innovations in the future"

Mr. Jo: The Japanese government aims to ensure that Japanese people enjoy healthy lives and a stable society. We believe that innovation in healthcare is very important. I expect innovations will raise the level of conventional medical care. The expert panel in MHLW is working on potential solutions to address current issues in Japan, and I believe that patient engagement and innovation are the keywords for solving these issues.

Mr. Mejlvang: We always think about how to respond to the needs of patients. In Europe, patient groups are even heard at the European Parliament, and I believe that the patients' voices are important to promote innovation and medical reform in Japan as well. Denmark has a Public Private Partnership (PPP) program, which enables academia, medical institutions, local governments, and policymakers to have comprehensive discussions together to solve problems. I believe we must always be patient-centric.

Ms. Sakurai: I think we need visualization. The drug lag problem is there. Even though innovative drugs with a dramatic positive impact on patients have been developed, some of them are not available in Japan due to drug pricing and regulatory issues. To manage within limited financial resources, we believe that a drug discovery ecosystem that reduces waste and moves toward the development of innovative drugs is essential. We would like to be involved in the discussion to build such an ecosystem.

Dr. Watanabe: We are aware that there are many innovative drugs that are not available in Japan despite they have already been demonstrated to be safe and effective in many other countries. There are regulatory systems that help such drugs to be introduced in Japan. I

expect research-based biopharmaceutical companies to continue focusing on the development of innovative new drugs, including the global companies that are present today.

Mr. Jo: I think that the importance of innovative drugs is being reaffirmed these days in Japan. Taking this opportunity to reconsider the supply of drugs, we are currently discussing with the expert panel on potential solutions across the life cycle, from research and development support to regulatory affairs and drug pricing. I think it is necessary for patients and people or end-users of medicines in Japan to understand this point. I would like to work on visualization and promotion of Patient and Public Involvement (PPI).

Conclusion

Although we are not yet entirely out of the COVID-19 pandemic and are experiencing difficult geopolitical circumstances, we vow to never cease fighting for patients and people across the globe through discovering and delivering innovative treatments and vaccines. As long-lasting partners, the EU and Japan have helped and learned from each other, and will continue working closely together during this time of global turbulence.

Through the open and active exchanges among stakeholders across different backgrounds, the Forum demonstrated a common understanding on the urgent need for a pro-innovation health ecosystem, and the significant opportunities ahead for patients in Japan, the society, and the biopharmaceutical industry, both from Japan and the EU, to jointly achieve enhanced health security and economic prosperity.



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