Meeting of Representatives

"Project to Develop the Human Resources that will Carry the Future of Medical Devices"
(Abbreviation: Mirapro Project)
Report

December 10, 2020

European Business Council (EBC) Medical Devices and IVD Committee

Project Overview

Purpose

1. **Revitalizing the medical equipment manufacturing and distribution industries and developing human resources to which to entrust the future**
2. **Improving the ability to make policy proposals for the future of the medical device industry**
3. **Constructing a human resource network with industry, government, and healthcare professionals**

Period of implementation and past meetings

Period of 2 years (11 meetings scheduled)

1st meeting: Thursday, July 29, 2020

2nd meeting: Saturday, September 19, 2020

3rd meeting: Monday, November 30, 2020

Breakdown of participants in the first period

Industry (14 groups, 29 people), MHLW (10 people), PMDA (9 people), METI (1 person)

Participating organizations: JIRA, JEITA, Nichi-Iko, MT JAPAN, JAHID, Home Health Industry Association, JDTA, JOIA, JMOIA, JAIMA, JFMDA, JCLA, AMDD, EBC

Participants from the EBC

Ms. Narumi Hayashi, Pharmaceutical Affairs Department, B. Braun AESCULAP, Ltd.

Mr. Tomohiko Matsukawa, Public Policy Department, Philips Japan, Inc.

Themes (Planned)

Planned themes for each session

For the first half of the period: Fiscal year 2020 (Jul, Sep, Nov, Jan, Mar)
To discuss the present situation and the foreseeable future of the medical device industry

	Themes and lecturers	Purpose	Committee in charge
1 7/29 (Wed)	The present situation and the foreseeable future of the medical device industry: Learning the “change” (Lecturer: Mr. Nakano, JAAME)	To learn from predictions about the future global position of Japan and the medical device industry and discuss what will be expected of us	Industrial Policy Office
2 9/19 (Sat)	Efforts to take safety measures in medical settings and expectations to promote their development (Lecturer: Dr. Nagao, Nagoya University Hospital)	To learn how medical devices are used in medical settings; to study the related regulations and actual conditions in medical settings; to discuss promising medical devices and what the industry should be like.	PMS Committee
3 November	Innovative technologies that support medical devices (Digital, AI, Big Data, etc.)	The lecturer will introduce the technologies that are currently visible and discuss their impact on industry associations.	Industrial Policy Office
4 January	Current state and future of health care financing and the insurance system	To learn about the current state and future prospects of health-care financing and the insurance system from the viewpoints of the government and the industry; and discuss their ideal form.	Materials and Device Insurance Committee
5 March	Summary of issues in the medical device industry – About medical device distribution – Looking back	To learn about the stable supply of medical devices, including current status and issues; and discuss items that should be addressed as regulations among the important issues that have been discussed.	Sales and Maintenance Committee (Legislation Committee)

Planned themes for each session

For the latter half of Period I: Fiscal year 2021 (May, Jul, Sep, Nov, Jan, Mar)
Discuss regulations necessary for the medical device industry

	Theme and lecturer's image	Purpose	Committee in charge
1	Collection, utilization, and system of clinical evidence	To discuss how the collection and utilization of clinical trial and post-marketing data should be studied in Japan and overseas	Clinical Evaluation Committee
2	International harmonization of regulations and attempts at internationalization	To learn about the current state of international harmonization and internationalization of regulations; and discuss the ideal state	International Policy and Strategy Committee
3	The healthcare industry as a whole and the definition of medical devices	To discuss the current situation and the ideal situation for products that straddle the gap between medical device and non-medical device (health apps, welfare equipment, etc.), both in Japan and overseas	Legislation Committee
4 5	Ideal form for medical device regulations – Lessons to learn from medical device regulations of the past – About quality assurance for medical devices – Thought on pre-marketing and post-marketing regulations, etc.	To decide upon a framework for considering the results of issue identification in the first fiscal year, and to discuss the ideal form for medical device regulations in Japan while learning about the status of regulations in each country.	QMS Committee Legislation Committee (PMS Committee) (Clinical Evaluation Committee)
6	Summary of proposals on ideal form for medical device regulations	To review and summarize proposals thus far	Legislation Committee

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Summary of each session

1st Session

Lecturer: Dr. Shohei Nakano, Managing Director of Japan Association for the Advancement of Medical Equipment

Theme: The present situation and foreseeable future of the medical device industry – Learning from "change" –

Content of Group Work

What actions would be needed to realize the following scenarios for 2040?

(1) Scenario of unique regulations for Japan as a single market

(2) Scenario in which Japan becomes the leader in low-cost generic drug regulations in Asian and emerging countries as a developed country facing new problems (declining birthrate and aging population, curbing medical expenses)

(3) Co-regulation scenario in which PMDA cooperates with FDA (mutual recognition, etc.)

2nd Session

(Lecturer: Dr. Yoshimasa Nagao, Vice Director, Nagoya University Hospital)

Theme: Patient safety issues in medical devices

Content of Group Work

(1) The medical community feels that improvements in the safety of medical devices have been slow. Why has progress been slow?

(2) What measures are there to reduce medical device incidents without relying solely on warnings?

(3) Create an error classification form (checklist) that would be helpful in the development of safe medical devices.

Summary of each session

3rd Session

Lecturer: Dr. Takashi Suzuki, Medical Device Strategy Institute, Japan Association for the Advancement of Medical Equipment

Theme: Artificial Intelligence in Medical Devices

Content of Group Work

(1) Think of one medical device that uses AI.

(2) Discuss the following points of the "post-marketing performance change" of the medical device.

- **Name all of the stakeholders**
- **Who is responsible for post-marketing performance changes?**
- **What advantages or disadvantages does post-marketing performance change bring, and for whom?**

For a report on the 2nd session and lecturers' overall evaluations of the 1st and 2nd sessions, see IKIREN Journal No. 111 (AUTUMN).

http://www.jfmda.gr.jp/ikiren_news/

Thoughts on the work thus far

Narumi Hayashi, Pharmaceutical Affairs Department, B. Braun AESCULAP, Ltd.

All of the participants were highly motivated, and we had very meaningful discussions each time. In group work we must get results within a short period of time, but it was a great learning experience because the diverse expertise of the participants made it possible to discuss things that I could never have discovered by myself.

Since I had no previous active participation in industry associations, I was meeting most of the people for the first time. At the same time, because I was a participant from EBC, I was asked questions, particularly about overseas regulations, several times by the participants. Through this project, I hope to expand my network of contacts so that we can share our expertise, and I would like to do my best to make this rewarding for both myself and others.

Tomohiko Matsukawa, Public Policy Department, Philips Japan, Inc.

Each table included representatives of both industry and the government, so we learned by listening to the government's views and conveying the industry's views while considering the differences in position on each theme.

Because each of the industry groups handles different types of products, they approach the issues from very different standpoints, and that made for mutual exposure to fresh perspectives. I would like to continue to deepen my knowledge through discussion of various themes while expanding my network of contacts, and I hope to recycle knowledge back to the EBC through my activities in the JFMDA.