Greeting from the chairman

While COVID-19 has subsided a little, it is still difficult to concentrate on normal work because of new viruses, so I would like to thank the representatives for gathering, even though it is online. We would like to express our sincere gratitude for your continued support for the activities of the committee.
We have worked on workplace vaccination of COVID-19 vaccines as EBC this year. And thank you for your cooperation regarding vaccination in areas other than Tokyo.
Thanks to you, we would like to extend our sincere gratitude to all of you for continuing business without any problems, and without any clusters occurring within the committee companies.
Today, I would like to report on the activities of the committee in 2021 and the 2022 activity policy.

Major annual events in 2021

Feb. Reiwa 2 fiscal year regular meeting (medical fees related)

Mar. Submission of medical fee revision request

Apr. IDATEN, PHOENIX, APAC Med study session

Apr.-Jun. Discussions with the Data Health Promotion Special Committee (Liberal Democratic Party)

Jul. PMDA : Meeting for MDSAP April 2022 Full-scale introduction
Reiwa 3 fiscal year regular meeting (medical fee related)
Established Digital Health Task Force

Aug. Regular discussion meeting (related to the PMD act)
Irish Government Commerce Agency Office in Japan
"Information on the Irish Medical Device Industry"

Sep. DiGA (German program medical device insurance listing program) Webinar held
(Ministry of Health, Labor and Welfare, PMDA, industry)

Oct. Exchange of opinions with the Economic Affairs Division (Chief Ando, Chief of Policy Office Horioka)
Foreign price survey

Nov. Statement of industry opinion at the Central Social Insurance Medical Council

Jan. Reiwa 4 Collaborative plan working-level meeting (planned)

◆ 2021 Activity Report

2021 is the second year since the revision of the PMD act was enacted. The committee has been working to realize the revised act without delay, including making it a principle to provide attached documents (*tempu-bunsho*) electronically, establishing a legal compliance system for MAHs and distributors and introducing a surcharge system due to falsification or hype on the sale of medical devices. 2022 will be the third year, and we will carefully proceed toward mandating the display of barcodes on packaging.

Furthermore, for system reform, we will work throughout the year on a collaborative plan with the government, and in January of the next year, we plan to hold a working-level meeting for both medical devices and IVD to discuss past efforts and new systems.
At this meeting last year, I mentioned that there was something good about the COVID-19 pandemic. That is the digital transformation of PMDA and the abolishment of the stamp (Hanko) as a COVID-19 infection prevention measure. From this summer, online applications related to notifications has been available. I also heard that it will be possible to apply for approval next year. The change to paperless for documents to be submitted to PMDA may be an interesting change that will lead to cost reduction for representatives, such as printing costs for pharmaceutical and medical devices affairs and cabinet space.

Regarding eHealth, this year we launched the Digital Health Task Force within the committee, which allows us to work across each subcommittee. A webinar was held by inviting the person in charge of studying the APAC MedTech activities.
Also, we invited the person in charge of formulating the insurance listing application program for program medical devices (SaMD: software as medical device) in Germany and held a webinar with the Economics Division of MHLW, Medical Device Review and Management Division of MHLW, PMDA and related organizations.
We were able to learn about differences and findings in the value and evaluation of program medical devices as reimbursement.

Regarding medical fees, we have continued to promote the evaluation of innovation. We have continued to disseminate our opinions as EBC regarding the handling of program medical devices by the reimbursement system and C2 challenges at regular meetings, through industry opinion statements and towards the revision of medical fees next year. Various devices, including AI, will be on the market in the future. We will continue to work toward a system that can respond to these issues and allow companies to develop as a business.

Regarding in-vitro diagnostic drugs, we will continue to apply for challenges, and we are currently in discussions with the government regarding repurposing of companion diagnostic drugs.

◆ 2021 Activity Policy

Regarding utilization of real-world data, which is of great interest to everyone, in approval reviews, we will identify issues in utilization and proceed with discussions with the government to realize its utilization. The revised Personal Information Protection Law is scheduled to come into effect in Japan next year, and the committee must endeavor to collect and disseminate information regarding the utilization and protection of overseas data. In addition, we will hold discussions with the government at the working- level meeting regarding issues related to program medical devices.

The reimbursement subcommittee will work on issues of special materials related to foreign prices, functional categories, and unprofitable departments. In addition, we will expand appropriate evaluation of innovations so far, including in the fields of radiotherapy and nuclear medicine diagnostic treatment for new companies participating in diagnostic treatment equipment, and we will continue to develop activities for the next medical fees revision. We will also concentrate on the final push toward the implementation of C2 challenges, which is related to the insurance listing of program medical devices.

The IVD subcommittee will further promote initiatives centered on collaborative plans, while identifying issues and conducting activities in anticipation of the next revision of the PMD act. In addition, we will start activities for the medical fees revision in Reiwa 6 (2024).

Thank you again for participating. We ask for your understanding and support for the activities of this committee, and wish you success in your business.

Yours sincerely