



Speech by the Chair

Thank you very much for the busy representatives due to the Corona Disaster. I would like to express my thanks for the continued appreciation of the Committee's activities. I would also like to extend my heartfelt congratulations to all of you for your continued patronage. Today, I would like to report on the committee's activities in 2020 and the policies for activities in 2021.

Major Annual Events 2020

- In July, a request form was submitted to the MHLW and the Ministry of Economics and Industry
 - Requests: How to supply medical care in the aftermath of Corona and requests for promoting globalization
 - Logistics
 - Promoting Online Medical Services and Medical Care
 - Corporate Use of Healthcare Data
 - Appropriateness Assessment and Insurance System for Healthcare Technologies
- In August, Periodic Opinion Exchange Meeting (Pharmaceutical Safety and Environmental Health Bureau)
 - Periodic meetings to exchange views-in collaboration with AMDD
 - Legal revisions-GS1, RWDs, change lags, etc.
- In September,
 - 1) Exchange of opinion with Director-General and Deputy Director (Shingikan) of the visiting Office of Health Policy Bureau ;
 - 2) Visiting Counselor of the European Trade Department (Jacek Kozak) Exchanged Opinions
 - Delegation of the European Union in Japan
 - First Secretary Ms. Sarah Zennaroatre ⇒ Counselor Mr. Yatsuekkozark
- In October, exchange of opinions with the Director-General and the Deputy Director (Shingikan) of the Visiting Office of the Pharmaceutical Safety and Environment Health Bureau.
- In November, Public-Private Dialogue (Ministerial, Vice-Ministerial, etc.)
 - Improving the Quality of Medical Care using Digital Equipment
 - Medical delivery system
 - Proper evaluation of medical technology
- In December, Foreign Price Survey
- Periodic meeting in February (Scheduled for February 8, 2021) with Economy Affairs Division and Health Insurance Division

◆ 2020 Activity Report

Activities in 2020 include concrete actions to ensure that substantive changes such as the Pharmaceuticals and Medical Devices Act, UDI, MDSAP, governance, and digitization of Tempu-bunsho are properly implemented. In the collaboration working plan for rapid reviewing conducted in September 2020, we participated in institutional design from new perspectives such as IDATEN and PHOENIX. In the future, we will continue to work on the computerization of the Tempu-bunsho scheduled for August next year, governance, and UDI scheduled for December 2022, as we have done so far.

In the field of eHealth, we have made recommendations to adopt European's leading global standards.

While we have continued our activities with the ultimate goal of mutual recognition agreement between Japan and Europe, the enforcement of the European regulation MDR/IVDR in May has been postponed due to Corona. However, in the meantime, various documents such as IVD class classification and clinical evaluation reports have been issued, and in Japan, the utilization of health data has been mentioned. In Europe, however, the initiative of European Health Data Space has begun, and the integration of health data of member states and the development of laws have begun. We believe that it is necessary to disseminate and share such information to the government and other organizations.

This year, there was a personnel change at the director level within the Ministry of Health, Labour and Welfare. Therefore, I visited individual medical officials, heads of the Pharmaceutical Safety and Environmental Health Bureau and Health Policy Bureau, and deliberators to exchange their opinions with each other. We will continue to maintain good relationships.

At public-private dialogues, regular discussion meetings and regular meetings, from a European standpoint, we make recommendations on preventive medicine and preemptive medicine, appropriate evaluation of innovation, legal regulations, and improvements to medical fee revisions. The fact that the C2 Challenge has come to the fore is one achievement. I think that each subcommittee will report on the details, but we will continue to actively work on it.

◆ Activity Policy for 2021

Our activity policy for 2021 is based on the same four pillars as this year.

Regarding eHealth, we will continue to recommend that companies use PHRs and other healthcare information. We will prepare for the second and third stages of the revisions by working to resolve issues related to bar code label and its apps in the digitization of Tempu-bunsho. It is also important for individual companies to respond to governance under revision of PMD Act.

Although the implementation of MDR/IVDR in Europe is still unclear, we would like to hold study meetings with the government and other bodies in order to share the challenges and perceptions among them. In addition, since the training for PMDA has been publicly solicited, we hope that you will consider actively participating in it from member companies.

In terms of medical fees, we will promote the evaluation of innovation. As I mentioned earlier, the C2 Challenge is now on the table. This year, we will actively work toward realization. We believe that there will continue to be many discussions on AI, so we will strive to exchange opinions sufficiently with the government.

There have been a lot of hardships going on in Corona, but there have been some good things. One of them is digital transformation in the world. Telework and online meetings are now accepted. For example, in the communication with PMDA, what used to be a fax has been replaced by an email, although it is a countermeasure for a moment. Documents are also brought in by mail.

Face-to-face advice has become available on-line such as Zoom. At a meeting with MHLW and PMDA, PMDA said that there were still some papers that they were communicating with, but e-mail and on-line would be the standard. I wanted to continue the safety measures. It is also expected that telework staff will be given mobile phones. We will continue to discuss ways to improve mutual convenience.

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