Public-private dialogue meeting

Public-private dialogue meeting to create innovative medicines, medical devices, regenerative medicine products, etc. was held on November 13′ 2023.
Minister of Health, Labor and Welfare, the Deputy Minister, Deputy Minister of the Cabinet Office, Deputy Minister of Education, Culture, Sports, Science and Technology Parliamentary Vice-Minister of Economy, Trade and Industry and person in charge of relevant ministries and agencies participated.
The industry e.g. JFMDA, AMDD, EBC, JACRI, pharmaceutical organizations and academia participated outside of government. From EBC, Mr. Idei and Mr. Eda, two Vice chairpersons participated, representing Medical equipment and IVD, respectively.
The Ministry of Health, Labor and Welfare, the Ministry of Economy, Trade and Industry, and others gave explanations of their efforts, followed by various organizations expressing their efforts and opinions from industry.

【Medical device】
The EBC Medical Equipment and IVD Committee made the following comments:

1. **The state of medical care in an aging society**
   - Environment surrounding the medical device industry
   - Warning and new initiatives for device loss, examination loss, and unprofitable markets
2. **Medical DX - Expansion of remote medical treatment**
   - Regarding evaluations that contribute to work style reform for medical professionals
3. **About medical technology innovation evaluation**
   - Expanding the use of selective treatment (Sentei-ryoyou) and evaluation treatment (Hyouka-ryoyo)
   - Consideration of public knowledge application, etc.
   - Promotion of preventive medicine

In an aging society with a declining birthrate and an aging population, various environmental deteriorations are becoming evident when it comes to achieving and maintaining medical supplies.
In industry and medical institutions, there are many issues such as soaring raw

material costs, soaring labor costs, soaring utility costs, logistics costs, and the impact of exchange rates, and we believe that it is necessary to secure "social security financial resources" to support these issues. We also believe that solving problems such as device loss and creating a seamless system from prevention to prognosis will lead to lower medical costs and support the medical system.
Furthermore, creating a new mechanism for this purpose is an urgent issue.

Various studies have been conducted during the coronavirus pandemic, and there is still room for further utilization of ``remote diagnosis support,'' which has been implemented in some cases.
These can build a system to provide appropriate medical care to patients, and will also help eliminate problems such as the shortage of specialists and overwork of doctors.

As medical costs increase, it is extremely difficult to maintain universal health insurance under the current system.
In recent years, the development and introduction of programmed medical devices has been progressing all over the world, and awareness of medical care is expanding to the individual level.
There is a need to quickly introduce these programmed medical devices to the market and to establish an appropriate evaluation system for insurance.
For this reason, the EBC is proposing various forms of insurance in conjunction with two-stage approval.

Finally, we would like to talk about preventive medicine.
Early detection, early treatment, and prevention of recurrence are expected to not only reduce the burden on patients, but also significantly reduce overall medical costs.
Here, we will introduce low-dose lung cancer CT examination as an example. You can perform detailed examinations for lung cancer without worrying about X-ray exposure. We believe that this type of testing method should be widely used in health checkups.

Opinions such as those mentioned above were proposed, problems in industry were shared, and what kind of efforts should be taken between industry and government in the future was discussed.

The committee will continue to make recommendations regarding evaluation of the effects of medical DX, including remote technologies, appropriate insurance coverage for programmed medical devices, and approaches to preventive medical care.

【IVD】

The EBC Medical Equipment and IVD Committee / JACRI made the following comments:

1. Creating an environment for promoting innovation in clinical testing

- Creating a system to evaluate the value of innovative in vitro diagnostic drugs in terms of medical fees
- Initiatives toward international harmonization and reference country development to promote the global expansion and domestic introduction of innovative in vitro diagnostic drugs

2. Establishing a system for new infectious disease crises

As testing is an essential element in providing medical care and surveillance (ascertaining the situation), we will collaborate with the Cabinet Crisis Management Agency and the Infectious Disease Control Department of the Ministry of Health, Labor and Welfare to contribute to the development of testing systems.

3. Improving the environment to ensure a stable supply system

- Maintaining a stable and sustainable healthcare provision system
- Respond in a timely manner to rising costs such as soaring prices, rising wages, and increased logistics costs.

Even if innovative products are developed for in vitro diagnostic drugs, there is a lack of clear evaluation mechanisms, and there is a reluctance to address unmet needs for the small number of tests.

In order to promote the development and appropriate evaluation of innovative in vitro diagnostic drugs, we believe that there is a need for a system that allows innovation to be evaluated and reflected in medical fee scores.

International harmonization is becoming essential in bilateral negotiations and globalization. Additionally, there are some issues with international expansion, such as approval letters and review reports being only available in Japanese.
In order to address these issues, it is desirable to make in vitro diagnostic drugs independent from the classification of "drugs" and create a new category with laws and regulations tailored to their characteristics, as well as an environment that allows for international harmonization.

Everyone agrees that new infectious disease countermeasures are essential, and the government is working to put in place a system to do so. IVD industry is deeply involved in the testing system and the supply of supplies, and the industry should be involved from the early stages of establishing the system.
On the other hand, even during normal times, we would like the government to promote the policies of “maintenance of measuring equipment, etc.'' and “securing and training clinical laboratory specialists and clinical laboratory technicians'' at medical institutions.

The economic environment surrounding us is extremely harsh, with recent price hikes, rising wages, and soaring fuel and logistics costs, making it difficult to pass on prices. We would like to see a system that would allow these cost increases to be passed on to prices within the public medical insurance system.

The EBC and JACRI referred to the business environment and regulations governing in vitro diagnostics, including international harmonization.
Next, the EBC raised issues regarding the treatment of innovation under the Pharmaceutical and Medical Device Act and the evaluation of innovation, and proposed solutions.

We were able to share most of our recommendations, and it was hoped that further discussions would take place in the future toward a resolution.