Regular meeting between the MHLW and the medical device industry

A regular meeting with the Ministry of Health, Labor and Welfare was held on July 12, 2023. This meeting is about insurance systems related to medical devices.
The participants were from the Ministry of Health, Labor and Welfare the director of the Pharmaceutical Industry Promotion and Medical Information Planning Division, the director of the Medical Division, and the heads of their respective divisions, and from the industry side were EBC, JFMDA, AMDD, and JACRI.

The items to be discussed are as follows:

1. **Diagnosis/treatment/home equipment**
    - ① Regarding innovation evaluation of medical devices (medical technology)
    - ② Insurance to promote safety
    - ③ Proposals related to medical fees related to home medical care
2. **programmed medical devices**
    - ① Policy support to promote SaMD development
    - ② Developing insurance coverage issues
3. **Specified health and medical materials**
    - ① Measures to ensure stable supply
    - ② Review of innovation evaluation
4. **In vitro diagnostic drugs**
    - ① Mechanism for evaluating innovations in testing
    - ② Optimization of insurance application examination (elimination of waiting time for “Insurance Medical Materials Specialist Subcommittee”)
    - ③ “Reviewing comprehensive evaluation” and “introducing a support system” for malignant tumor genetic testing
    - ④ Others - AMR countermeasures, POCT testing

Each item was explained and discussed in detail, but in this report we would like to focus on the items that have a major impact on our business.

1. Diagnostics/treatment/home equipment

In the case of medical devices that include technology fees, the qualification of C2 (new technology) should be clarified. This further improves predictability.

Regard of the medical devices publicly recruited that based on the results of the needs review committee, consideration should be given to adding points to the evaluation on the medical devices that include technology fees, pioneering medical devices, and medical devices for specific purposes.

2. Programmed medical devices

Recently, in addition to the conventional regulatory approval system, guidance for appropriate and rapid approval and development of SaMD, including the concept of two-stage approval, has been published, and an environment for efficient development and regulatory approval is being prepared.
Furthermore, in order to speed up market introduction, we will utilize new evaluation treatments after first-stage approval, create an environment that makes it easier to utilize real-world data in preparation for second-stage approval, and reform the way doctors work.

We would like to see some institutional support, such as evaluating SaMD that contributes to medical treatment based on medical fees.

There are two types of SaMD, one for disease diagnosis and one for disease treatment, and each has a different clinical position, so it is necessary to design a system according to the characteristics of each SaMD.
In particular, the evaluation axis when evaluating based on technical fees, Selection of applicable technical fees, Definition of functional categories when evaluated as specified insurance medical materials (special materials), We would like to request that predictability be improved by improving the concept of cost accounting.
We would also like to request an evaluation of SaMD, which contributes to reducing the burden on medical personnel, leveling out the quality of medical care, and reducing medical costs.

3. Specified health and medical materials

Measures to ensure a stable supply of medical devices include responding to unprofitable products, criteria for selecting of unprofitable products, responding to soaring prices of raw materials and components, reviewing foreign price adjustments, and accounting rules for newly listed products are recognized for

further discussions.
Each item requires very detailed discussion, so we look forward to careful discussions.

Regarding challenge applications, the process of confirming their further usefulness is important. Companies also need to consider new investments, and it takes a certain amount of time to start them and plan clinical trials.
Furthermore, in addition to providing new technology, by making effective use of medical devices that are already on the market, it is also possible to suppress the purchase of new medical devices.
To this end, we would like you to consider a system that allows us to request a challenge application for a certain period of time from the time we apply for insurance.

4. In vitro diagnostic drugs

From the perspective of in vitro diagnostic medicine, discussions centered on the appropriate evaluation of highly useful tests, their early commercialization, and securing medical fee points that will be lead to appropriate evaluation.

A. Establishment of an innovation evaluation system for testing
① Consideration of evaluation methods for usefulness and innovation in testing
② Introduction of challenge application system
B. Optimization of insurance application examination (elimination of waiting time for “Insurance Medical Materials Specialist Subcommittee”)
C. “Review of comprehensive evaluation” and “introduction of support system” in malignant tumor genetic testing
D. Other issues surrounding testing
1. To increase the effectiveness of the “Antimicrobial Resistance Countermeasure Action Plan”
2. Contributing to enhanced local medical care through POCT testing

A.
There are no rules for evaluating innovation such as "groundbreaking,'' "improvement,'' "usefulness,'' and "marketability,'' which are applied to medical devices. These are factors that contribute to product development and early introduction, and we believe that such a system is also necessary for IVD.

Regarding the additinal score of medical fees related to evaluation, we would like to see an addition of “marketability'' evaluation for unmet needs.

Regarding challenge applications, the application environment in the IVD industry is similar to that of medical devices, so we would like to request that a system for challenge applications be established.

B.
During the period from January to March, the company will have to wait for review due to revisions to medical fees.
Moreover, the impact could extend into May. We would like you to consider ways to solve this problem. For example, continuing the review by circulating documents, etc. Or, for example, adopting the E2 minor examination method.

C.
Despite the existence of a wide variety of genetic tests for malignant tumors with different clinical significance and measurement techniques, the current system makes it difficult to conduct appropriate evaluations based on the value of each individual test.
Despite being an essential test for determining treatment plans and diagnosis, and due to insufficient evaluation of development/manufacturing/distribution costs and the costs necessary to maintain a supply system for quality-assured products,
there are tests that have poor business viability and profitability and pose a high risk of stable supply.
In order to appropriately evaluate the various tests included in "malignant tumor genetic testing," we believe that a system is needed to appropriately evaluate the value and significance of each test item and technology.
We also think it is necessary to introduce a system for calculating unprofitable items. (e.g. companion diagnostic etc.)

D.
Concrete measures are needed in the revision of medical fees to increase the effectiveness of antimicrobial resistance (AMR) action plans.

In order to deliver POCT tests with guaranteed quality and accuracy to clinics and home-based areas, we would like to see a different system for POCT tests than

current tests.
To this end, we should consider adding additional fees for POCT specimen management and other rapid specimens outside the hospital.

This is the only forum for the medical device/IVD industry to have direct discussions with the medical division, and we were able to make sufficient recommendations regarding the issues we considered. Continued discussions will be important in the future.