FY2024 Public-Private Dialogue:
EBC・JACRI・AMDD Proposals

Public-Private Dialogue for the Creation of Innovative Pharmaceuticals, Medical Devices, Regenerative Medicine, and Other Products

2024.11.21
EBC Medical equipment & IVD Committee

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1. Creating an environment for promoting innovation in clinical testing ～Evaluation of Innovation and Economic Efficiency in Medical Treatment Fees～

[Current situation]

- In the 2024 revision, a marketability premium was introduced for tests used for rare diseases. However, for in vitro diagnostic reagents, even if innovative products are developed, the system for evaluating them is not sufficiently clarified. (For medical

devices, there are systems such as breakthrough premium, improvement premium, and economical premium.)

- At the Central Social Insurance Medical Council (Chuikyo) general meeting on May 15, 2024, an opinion was expressed that the evaluation of innovations in tests, etc. should continue to be considered as an appropriate evaluation method based on evidence of efficacy and safety.
  (Reference material: See p. 6 *1)

[Issues]

- Since there is no guarantee of securing development costs or predictability of development incentives, it is difficult to maintain the motivation to quickly introduce innovative products that have accompanied recent advances in science and technology to Japan.

[Proposal]

In order to promote the development of highly innovative in vitro diagnostic reagents, we would like to see a system introduced that evaluates innovation and economic efficiency in clinical testing and reflects this in medical treatment fee points.
(Reference material: See pages 7-8 *2)

In vitro diagnostics are essential for proper diagnosis and treatment. Proper diagnosis through testing enables optimal treatment and procedures to be implemented, which in turn enables the effective use of medical resources.

2. Review of the classification of in vitro diagnostic reagents under the PMD Act. ～separated from pharmaceuticals～

[Current situation]

- In vitro diagnostics (IVDs) are classified as "medical devices" overseas and are regulated similarly to medical devices, but in Japan they are classified as "pharmaceuticals," and there is no international harmonization of regulations.

- IVDs have different properties than pharmaceuticals.
  - ✓ In comparison of pharmaceuticals, which are used directly on humans, IVDs are not used directly on humans.

✓ While the efficacy and safety of pharmaceuticals are determined by the "substance (active ingredient)," the performance (efficacy and safety) of IVDs is determined throughout the entire testing process.

[Issues]
Due to differences in domestic and international regulations, the development burden is increasing both in overseas and domestic marketing.

[Proposal]
From the perspective of international consistency, we would like to see the review of classification of in vitro diagnostics, separated from "pharmaceuticals," and regulated according to their characteristics.

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The realization of internationally harmonized and characteristic-based regulations is expected to eliminate device lag and improve business predictability. It is expected that innovative tests will be made available to patients both in Japan and overseas more quickly.

3. Creating an environment to ensure a stable supply system ～Timely response to rising costs such as rising prices, wage increases, and increased logistics costs～

[Background]

- Rising prices, wage increases, and increased logistics costs have caused the cost of materials, labor, and expenses (including distribution costs) required for the production and supply of in vitro diagnostic reagents to soar. In addition, it is difficult to pass on the increased costs to medical institutions, therefore putting pressure on corporate profits. If this situation continues, it may become difficult to ensure a stable supply.
- Even if in vitro diagnostic reagents become unprofitable, their supply cannot be halted as they are essential medical products.
- Measures against emerging infectious diseases, etc., require even more rapid product development and market access/stable supply.
  (Reference material: See p. 9 *3)

[Proposal]

✓ We would like the government to take concrete measures, such as requesting and instructing medical institutions and dealing with medical treatment fees, so that the price

increase can be smoothly passed on to medical institutions.

- ✓ Regarding tests required for public health purposes for emerging infectious diseases, etc., we would like to see a system established that can provide these tests to the public appropriately (such as by purchasing compensation) while ensuring predictability and business viability for companies.