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AMDD's Policy Proposal on the

Basic Policy on Economic and Fiscal Management and Reform 2025

We are dedicated to fostering innovation and building partnerships with stakeholders to ensure that cutting-edge medical care reaches Japanese patients quickly and reliably. In light of recent geopolitical uncertainties, economic changes, demographic transitions, and technological advancements, the medical sector also requires swift and appropriate actions.

As we enter the era of 100-year lifespans, it is imperative to shift the perception of older adults from being "supported" to becoming active "supporters." To achieve this, the widespread adoption of innovative medical technologies that extend healthy life expectancy is essential. At the same time, enhancing public health literacy to empower individuals to make informed healthcare decisions will be critical.

To continue promoting innovation and delivering high-quality healthcare through public-private partnerships, AMDD proposes the following measures for this fiscal year's "Basic Policy on Economic and Fiscal Management and Reform:

1. Review of the insurance medical material system to adapt to inflation and cost increases associated with escaping deflation.
   Introduce a mechanism to adjust reimbursement prices, known as "GYAKUZAYA (negative margin)" correction, in cases where the purchase price at medical institutions exceeds the reimbursement price.

   Background**:**
   Rising global commodity prices, material costs, and currency fluctuations are significantly impacting the cost structure of medical devices and in vitro diagnostic (IVD) products. These factors, coupled with workforce shortages in the logistics industry due to work style reforms, are creating challenges in maintaining a stable supply of medical products. To address these issues, AMDD proposes a comprehensive review of the medical device reimbursement system.

2. Further promotion of international harmonization to address device lag and device loss.
   a. Promote further international harmonization of pharmaceutical regulations and the utilization of real-world data (RWD)
   b. Standardize and streamline clinical trial and clinical study to stimulate medical device development in Japan.

   Background:
   Although international harmonization of pharmaceutical regulations is progressing, there are instances where, due to the low evaluation of certain products under medical reimbursement rates, resources cannot be allocated for conducting separate trials for Japan in addition to the U.S. As a result, medical devices that can be used in the U.S. may not be available or are limited in use in Japan. To improve the quality of healthcare and extend healthy life expectancy, it is necessary to create an environment where the latest medical devices can be smoothly developed and utilized in Japan

3. Promotion of reimbursement evaluations for digital health technologies
   a. Expand outcome-based evaluation.
   b. Introduce evaluations for innovations that reduce the burden on healthcare professionals.

   Background:

   The further development of medical DX is expected to improve operational efficiency in healthcare, expand telemedicine, and advance medical research, thus enhancing the quality and safety of healthcare.

   Discussions at the Central Social Insurance Medical Council have highlighted the need for an appropriate and rapid evaluation system to integrate valuable innovations into clinical practice. For further development, it is essential to establish a new evaluation framework to create a supportive environment.

4. Promotion and acceleration of secondary use of medical data through public-private collaboration (e.g. use in product development)
   Accelerate the realization of items* regarding "Promotion of Digital Health" in the FY2024 Basic Policy and Regulatory Reform, enhance the use of medical data for product development by sharing challenges and case studies between government agencies and the private sector, and foster public understanding of medical data utilization.

   *The items to be addressed are: the establishment of a “National Medical Information Platform” based on the “Roadmap for Promoting Medical DX”; the development of an environment for secondary use of information shared on the platform for the development of new medical technologies and drug discovery; the promotion of the utilization of data in public databases for medical and nursing care; and the establishment of a foundation that enables researchers, companies, etc. to utilize high-quality data safely and efficiently.