**Note: This English translation is for reference purposes only. In the event of any discrepancy between the Japanese original and this English translation, the Japanese original shall prevail.*

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Takanao Tamai, Chairperson
American Medical Devices and Diagnostics Manufacturers' Association

AMDD's Policy Proposal on the

Basic Policy on Economic and Fiscal Management and Reform 2024

We are navigating unprecedented changes, including the pandemic and its societal impacts, escalating geopolitical uncertainties, evolving economic fluctuations, demographic shifts, and the advancement of generative AI. The Japanese healthcare system is also in need of transformation, and at AMDD, we are relentlessly working to ensure stable medical supplies and continue to deliver the benefits of cutting-edge medical technologies to patients.

Innovation and partnerships are key to adapting to these constant changes. Sharing the direction of the Basic Policy on Economic and Fiscal Management and Reform, and aiming at the extension of healthy life expectancy and advancement of medical innovation through public-private partnerships, AMDD proposes the following.

1. In order to promptly and effectively deliver digital health technologies and other medical technologies to patients, AMDD proposes:

    a. Central unification and organization of the form on cybersecurity measures by the government, which is required to be submitted by manufacturers to medical institutions when implementing cloud-based or internet-connected medical devices and in vitro diagnostics (IVD) in medical facilities.

    b. Further clarification of assessment criteria and enhancement of the assessment scheme in health insurance reimbursements for digital health technologies and other innovative medical technologies (including application of Medical Expenses Combined with Treatment Outside Insurance Coverage).

2. Global price hikes for commodities including materials and currency exchange fluctuations are significantly impacting our product cost structures and posing

issues for the stable supply of products to the clinical environment and patients. This situation is impacted further by the "2024 Logistics Problem" stemming from the work style reform in the industry.

Against this backdrop, AMDD proposes that the public and private sectors continue to work together hand-in-hand to resolve the diverse factors that interfere with stable product supply, including the dialogue at the Council for the Improvement of Commercial Transaction Practices of Medical Device, which was held for the first time in seven years last year.

3. Pertaining to the amendments to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices expected in FY 2025, AMDD proposes:

   a. Revision of regulations on advertising considering the attributes of medical devices.
   b. Organization and simplification of legal systems concerning clinical trials and clinical studies to enhance medical device development in Japan.
   c. Shifting the classification and positioning of IVDs from pharmaceuticals to medical devices (for international harmonization), and the review and streamlining of pre-approval studies at the National Institute of Infectious Diseases.

4. As abundant information on medicine and treatment is available online today, there is a crucial need to improve people's health literacy as well as to build a system for appropriate information delivery.

   In this context, AMDD proposes that the government leads the development and operation of a system that will enable patients, their families, and the general public to access reliable medical information in a timely and easy manner.