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September 10, 2020

AMDD submitted public comments on the “Basic Plan to Promote Cardiovascular Disease Measures (Draft)”

The American Medical Devices and Diagnostics Manufacturers’ Association (AMDD) has submitted a public comment on the “Basic Plan to Promote Cardiovascular Disease Measures (Draft)”, which will be formulated based on the Stroke and Cardiovascular Disease Control Act (Act No. 105 of 2018).

The following is a description of the public comment.

Reference: The Basic Plan to Promote Cardiovascular Disease Measures (Draft)

<https://search.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000205741>

(Access date 9/10/2020)

(Machine translation.)

Opinion 1

1. Introduction p.1

Because it is difficult for the general public to understand what kind of disease is meant by “cardiovascular disease,” we think it should be specifically stated in the text or a footnote, e.g., “stroke and heart failure, as well as the arrhythmias, myocardial infarction, hypertension, valvular heart disease, cardiomyopathy, etc. that cause them.

Opinion 2

4. Individual measures [Development of a system for collecting and providing medical information on cardiovascular disease], p. 9

We think it should be clearly stated that the National Cerebral and Cardiovascular Center will work to develop a system to ensure that data from all medical institutions are collected



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and an environment to build evidence using real-world data.

Although there are several national databases such as NDB, DPC, NCD, etc., it has been pointed out in the discussion of the Council that utilization and research and development of medical data in the field of cardiovascular disease are difficult due to differences in data formats and management organizations, as well as limitations in use. The basic plan proposes to establish a public framework to collect and utilize medical information on cardiovascular diseases in cooperation with medical institutions such as the National Cerebral and Cardiovascular Center and other related academic societies and to further discuss the operation and provision of the collected medical information, including secondary use and cost-sharing, in the field of cardiovascular diseases. As stated in the basic plan, to promote the collection and utilization of medical information, it is necessary to establish not only "collaboration" but also a system to ensure that data from all medical institutions are collected at the National Cerebral and Cardiovascular Center. It is also necessary to establish an environment for building evidence-based on real-world data. These should be explicitly stated.

Opinion 3

4. Individual measures (2) Improving the system for providing health, medical, and welfare services (i) Promotion of health checkups to prevent cardiovascular disease. p13.

We believe that the importance of reviewing (adding and optimizing) tests and diagnostic items and early diagnostic and therapeutic interventions should be specifically described.

In the draft of the basic plan (measures to be taken), it is stated that "effective measures to improve the implementation rate of specific health checkups and specific health guidance...will be considered. However, the Specific Health Checkups, which are aimed at preventing and detecting lifestyle-related diseases, only contribute to the detection of some of the "strokes and heart failure and the cardiovascular diseases that cause them" mentioned in "Opinion 1". The importance of reviewing (adding and optimizing) the current health checkups items to detect these major cardiovascular diseases and early diagnosis and treatment interventions to prevent serious diseases should be mentioned. The prevention of serious illnesses will



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ultimately lead to an improvement in patients' quality of life (QOL) and rationalization of medical costs.

Opinion 4

4. Individual Measures (3) Promotion of Research on Cardiovascular Disease, p23.

The basic plan should include expansion of the budget for research and development, promotion and research and development of new technologies for early diagnosis.

Early detection and improvement of basic diseases is necessary to prevent the development of serious cardiovascular diseases, and early interventions to improve lifestyles and treat minor diseases will improve the nation's quality of life (QOL) and optimize medical costs. However, there are some cardiovascular diseases, such as atrial fibrillation, that are not easily detected by examinations and physical examinations at medical institutions, and in such cases, monitoring in daily life is necessary. The basic plan states that "the development of innovative diagnostic and treatment methods through the use of large-scale data and the use of digital technologies such as genome and omics analysis and AI-based image diagnosis, which have made remarkable progress, is required." However, there are no specific measures to be taken in this regard. It should specifically mention promotion of the development of new technologies such as promotion of monitoring in daily life, early diagnosis and development of treatments based on the causes of the disease as well as conventional symptomatic treatment.

The draft of the basic plan, p24, states that "In order to promote research from basic research to commercialization in an integrated manner, AMED will carefully select the results of promising basic research and promote research for the development of diagnostic and therapeutic methods and the prompt licensing out of the company," but this requires early approval. It is necessary to have a realistic support system that includes an exit strategy that will lead to the inclusion of the drug in insurance. In order to accomplish this, it is also essential to secure a sufficient R&D budget for AMED. The basic plan should also explicitly state these issues.

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