日本を、もっと健やかに。

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AMDD's Opinions for the Basic Policy on Economic and Fiscal Management and Reform 2020

COVID-19 has quickly spread across the world, which has challenged healthcare systems and put public health in focus for both governments and the general population in countries around the world. These are not issues that can be solved by a single country, but world resources must be shared quickly and efficiently through international cooperation. In addition, Japanese patients face healthcare challenges that require critical care even during times of emergency to help the country remain stable and economically productive. In order to do this, the AMDD proposes as follows:

1. Stable supply of indispensable medical equipment: National stockpiling and Securing/training workforce for proper use of necessary medical equipment

With the advent of the COVID-19 epidemic in Japan, which is fortunately not currently in an acute phase, a shortage of ventilators and personal protective equipment (PPE) became apparent in March and April 2020. Given the possibility of the reoccurrence of a similar situation, the following should be considered:

- Medical devices, like other industrial fields (e.g., automobiles and electronic devices), have multi-national supply chains, from raw material procurement to finished product production. In response to the epidemic of infectious diseases since SARS (2003), there is a demand for medical device production to return to Japan. However, given Japan`s national circumstances in which many natural disasters occur each year, it is necessary to discuss carefully whether or not to rely excessively on domestic production and the valid reasons for multi-national supply chains.
- Medical device companies, both domestic and foreign, have made every effort to procure the necessary medical devices in Japan, despite challenges such as the inability to cope with a sudden increase in production. This time around, the situation was extremely fast, and the infection reached the global scale, so it was difficult to make a large increase in the production volume in a short period of time due, in part, to the soaring prices of raw materials. Assuming such a situation, it is necessary to consider a national stockpiling system for basic medical devices (syringes, PPE, etc.) and life-sustaining medical equipment (ventilators, ECMO, etc.), and we support the ongoing policy.

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- When considering national stockpiling, simple stockpiling of the main medical devices may be insufficient, unlike the case of drugs. Other requirements may be necessary. For example, it should be considered whether securing key components, circuits and essential medical gases, etc. are necessary.

  Equipment is only effective with the workforce who can use the equipment to deliver care. We need to consider the securing, training and occupational safety of the workforce necessary for operating the medical devices.
- It is difficult to predict whether we will see more global infections on such a scale within a short time frame. Nevertheless, the frequency of localized natural disasters associated with changes in the global environment is expected to increase. In parallel with considering the stockpiling of all necessary medical devices in a single country, it also is necessary to proceed with discussions about the stockpiling and interchange system of medical devices based on the framework of mutual assistance and reciprocal relations under international cooperation among multiple countries.

2. Securing optimal medical access regardless of whether it is an ordinary or emergency time: Simultaneous use of resources and sharing of knowledge through international cooperation:

COVID-19 has led to flexible and bold measures beyond the country, including medical device companies disclosing ventilator design specifications and a special approval for Remdesivir in Japan following the emergency use permit (EUA) in the United States. As for clinical testing, PCR and Antigen tests were quickly approved and reimbursed. In normal times as well, it is necessary to consider the simultaneous use of international resources and knowledge so that not only Japanese patients but also patients from many countries can quickly access the best and latest medical technology.

Also, in the case of medical devices, we need to take into consideration the following: Medical devices, unlike pharmaceuticals, generally have a narrow market. There are also difficulties in comparative clinical trials. Moreover, medical devices are "tools" that can be improved through actual clinical use. Therefore, utilizing existing real-world evidence will allow more effective utilization of resources and more knowledge can be gained.

- Realization of Medical Device Single Review Program (MDSRP) for higher risk-class medical devices*
- Expansion of referencing Japanese approval review for medical devices*
- Accepting various real-world evidence as approval application data through reference to the U.S. FDA practice of using real-world data to make approvals.
- Normalization of the IT systems to support online filing, user fee payments, etc. in order to ensure stable business continuity in both emergencies such as COVID-19 and from the

perspectives of speed and efficiency during normal times. * Including IVD

3. Appropriate and prompt introduction of innovation: Improving the pricing system and health literacy

In order for the medical device industry to continuously generate innovation and quickly deliver it to the market, it is necessary to maintain an environment (price calculation and listing) for evaluating innovation appropriately and promptly, while maintaining high transparency. In addition, it's important to improve and maintain a predictable price system.

It was also recognized that it's extremely important that reliable and accurate medical information be transmitted to the general public, especially patients, during the COVID-19 infection crisis. Improvement of health literacy is required because patients themselves make decisions about whether and how to seek medical consultation based on such medical information.

From the above viewpoints, the following points are recommended:

- Improvement of innovation evaluation: Develop an environment in which innovation is properly evaluated, such as expanding the "Challenge System (evaluation based on the actual performance)" for technologies and testing using medical devices. In particular, the "C2 Challenge System" needs to be introduced for existing technologies.
- Improving and maintaining of transparency and predictability of reimbursement revision process: High levels of transparency and predictability are necessary for the operation and potential revisions to key systems, including functional category rationalization, market expansion repricing, and repricing by FAP. Rule changes that damage predictability of these systems should be avoided.
- Strengthening the inspection system to make it more capable of coping with emerging and re-emerging infectious diseases: COVID-19 has revealed that there are problems with the inspection systems at public health centers, geographical research institutes, and medical institutions. There is a clear need to apply insurance for infection control measures (active monitoring of infected persons, carriers, etc.) and to review facility standard requirements for "Infection Prevention Measure Addition 1".
- Improving health literacy: Measures are needed to improve health literacy, such as improving the data base and building a reliable information provision system in order to provide accurate medical information for patients.
- Promotion of home medical care: Due to the spread of the COVID-19 infection, many medical institutions have devoted human resources and medical supplies to the emergency response, which has had a great impact on the treatment of ordinary patients. It is necessary to promote home medical care as much as possible in order to reduce the infection risk of

patients being treated and the burden on medical staff.

- Promotion of remote monitoring: Even if home medical care is promoted, it is necessary for a doctor to understand accurately the patient's situation and to provide appropriate treatment if necessary. Remote monitoring technologies that enable treatment are covered by insurance for some diseases but need to be expanded.

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