AMDD Enabling a Healthier Japan

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Japan's Healthcare Challenge

Characteristics of Japan's Healthcare

"Aging" is an important consideration for healthcare in Japan, but it is not simply about age. The speed at which Japan's population is aging is a defining characteristic. It took 25 years for the population's percentage of senior citizens, aged 65 and older, to grow from 7% to 14%. In contrast, it has taken around 100 years for France and Sweden. Japan is aging at four times the speed of France and Sweden. In just 25 years, Japan will need to face fundamental societal issues, such as social security system reforms, labor issues, and family dynamics. Furthermore, as Japan's population is aging more rapidly than other Asian countries, such as Korea and Singapore, we need to be able to share Japan's lessons and experiences with the rest of Asia.

While Japan has initiatives aimed at reducing the overall age of the population, the performance of Japan's healthcare has become comparable to that of the U.S. and Europe. Japan's national healthcare expenditures are approximately 42 trillion yen, or 9.6% of the GDP, while for Canada, it is 11.2%. Although the healthcare expenditures are not significantly different, the population aged 65 years and older in Japan is 23.3%, while Canada is 14.4%.

Although Japan's population is more aged than Canada's, Japan's health care expenditures are lower. This is an accomplishment that should be recognized. Health insurance in Japan is "universal health care," which covers everyone living in Japan, with copayment fees

considerably reduced for patients. Japan is a country with high quality health care and a world class medical insurance system.

Looking Towards the Future to Create New Processes

As things stand, it will be difficult to support sustainable innovation from the mid-21st century onwards.

Although venture corporations in regenerative medicine from the U.S. and Europe have been successively entering the Japanese market, research and development of pharmaceutical products and medical devices in Japan often lag behind the U.S. and Europe. The focus on absolute safety and efficacy requires approvals, which takes a considerable amount of time. It is important to expedite this process, while reducing costs.

Creating an environment that facilitates market entry is crucial for venture corporations, so research costs must be lowered. Newly developed pharmaceutical products and medical devices could be launched with a provisional price using the "conditional early approval system," and the official price would be later determined, based on real-world data.

New processes are vital. Safety must of course be ensured, but in terms of efficacy, once a certain degree of efficacy is presumed, the product could be launched. After this, the official price would be determined by taking costs and expected efficacy into account; the price could be revised using data which is gathered quickly and inexpensively. Both public and private sectors should work together to create an environment which makes this process smooth.

Currently, drug prices are determined by costs, such as development costs and selling or distribution costs, but going forward, the benefit to patients' value should be prioritized. Drug prices should not simply be a matter of reduction; rather, it may involve raising prices for products when necessary.

Japan is a medical device mecca. Japan has significantly more medical devices, such as MRIs and CTs, compared to other countries. In order to cover the costs of expensive medical devices, excessive medical care may be unavoidable. An effort should be made to consolidate the number of surgical assist robots and particle therapy facilities, which are otherwise likely to increase in the future.

There are many other innovative medical challenges to be undertaken, including the development of genome therapies for cancer and the use of artificial intelligence. The Ministry of Health, Labour and Welfare (MHLW) is determined to tackle all of these challenges.

Chief Medical & Global Health Officer, MHLW
Dr. Yasuhiro Suzuki

Graduated from the Keio University School of Medicine in 1984. Entered the MHLW the same year. Dispatched to the World Health Organization in 1998. Appointed to current post from July 2017, after serving as: Director of the Research and Development Division of the Health Policy Bureau from 2005, Deputy Director-General of the Pandemic Influenza Experts Advisory Committee from 2009, Director General for Health and Medicine of the Ministry of Defense from 2012, Assistant Minister for Technical Affairs of the MHLW from 2014, and Director-General of the Health Insurance Bureau of the MHLW from 2016.

About the AMDD Advocacy Committee

The topics of health care and social security are covered in the news every day, both in print and on TV. Healthcare issues are also frequently addressed in politics. In response to this trend, AMDD recently established the Advocacy Committee. The following is an explanation of the role and characteristics of the Advocacy Committee.

The Advocacy Committee

Until now, AMDD has responded in various ways to issues, such as regulatory affairs and reimbursement, within the medical device industry. The respective committees are involved in making proposals to the government, as well as releasing information to the public through PR activities. However, due to the recent heightened interest in health care, and particularly the enhanced awareness of issues related to health care expenditure, the required methods of communication are becoming more diverse than ever before.

The role of the Advocacy Committee is to create and strategically communicate AMDD's policy proposals and initiatives' key points to relevant stakeholders. In other words, the main purpose of the committee is to build relationships and gain support from individuals and entities which the other committees would not regularly reach directly, such as members of the Diet, local governments, government offices, and medical associations.

Current Activities

Activities have been focused on the reimbursement system, including making proposal revisions, as well as supporting and following up on AMDD projects which aim to improve the reimbursement system. Examples of these are the project started in 2014 to redefine the identity of AMDD and the project started in 2016 to propose a new insurance reimbursement system (value-based health care).

The committee has made various proposals, aligned with global trends, to ensure that medical devices are recognized and evaluated based on their value to society. AMDD believes that this will lead to the prompt availability of globally innovative medical technologies in Japan. The committee has been closely communicating with relevant parties, regarding the establishment of fair and transparent processes, the establishment of various systems based on global standards, and the creation of an environment that guarantees equal and fair competitive conditions.

The Advocacy Committee has made efforts to incorporate the perspective of economic efficiency, which widely benefits society, in order to make proposals more acceptable to stakeholders, rather than focusing on only the interests of the industry. The committee often collaborates with medical device industry associations in Japan and Europe to create proposals and explanatory materials within the joint framework of Japan, Europe, and the U.S. AMDD can make a strong appeal, with a unified voice and a consistent statement; however, with regards to matters that require more attention, AMDD can create proposals and make suggestions independently. Three medical device organizations jointly compiled materials, which were presented by their chairmen, including AMDD Chairman Kato, at the "Public-Private Dialogue on the Development of Innovative Medical Devices," where the Minister of Health, Labour and Welfare and relevant ministry and industry executives held discussions, in October 2017.

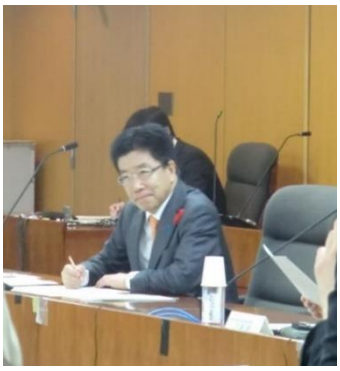
The support of the U.S. Department of Commerce and Department of State is extremely important for AMDD. We also work closely with the Advanced Medical Technology Association (AdvaMed), a medical device industry organization in the U.S., to approach the Japanese government. The U.S. embassy in Japan plays an important part in maintaining this relationship, and it has supported AMDD in various ways in the past.

Future Activities

The U.S. recently elected a new president, and Japan had a general election. With the changes and transfers in public offices in the U.S. and Japan, the political environment surrounding medical devices has continued to change this year. The Advocacy Committee is increasingly expected to log these political changes quickly, conduct analyses, compile the views of AMDD, and communicate their views through the best channels. Although the Advocacy Committee's resources are limited, with the strength and cooperation of members, the committee will strive for effective communications.

Representatives at the Public-Private Dialogue on the Development of Innovative Medical Devices (October 6, 2017)

Mr. Kosuke Kato, AMDD Chairman



Mr. Katsunobu Kato, Minister of Health, Labour and Welfare

Director of Healthcare Economics and Government Affairs,
Johnson & Johnson K.K.,
AMDD Advocacy Committee Chairman
Mr. Jun Sekiguchi

Patient's Voice
Nuclear Medicine Treatment in Cancer Care
High Hopes for RI (radioisotope internal radiation therapy)

Dr. Kenichi Oi
DDS, Program Director, Cancer Support Community Japan, NPO

Hope for cancer patients and their families lies in the establishment of accurate diagnostic methods and the development of effective treatments. Nuclear medicine, which has both therapeutic and diagnostic capabilities, has the possibility of progressing towards personalization.

Nuclear medicine treatments (radioisotope internal radiation therapy) such as radioiodine I 131 for thyroid cancer, strontium 89 chloride for bone metastases, yttrium 90 for malignant lymphoma, and radium 223 dichloride for bone metastatic castration-resistant prostate cancer is covered by insurance in Japan.

In the U.S., there are reports of radioembolization therapy as a treatment for unresectable hepatocellular carcinoma and colorectal liver metastases. Yttrium-90 microspheres are injected in cancerous tissue to stop blood flow and to reduce or eliminate tumors, with the synergistic radiation effects of yttrium-90.

Microspheres were one of the medical devices that were recommended for early introduction into Japan in the MHLW's "10th Investigative Commission on the Early Adoption of Medical Devices with High Medical Needs," in January 2009. Although hepatic arterial embolization and transhepatic arterial chemoembolization using microspheres is covered by insurance in Japan, radioembolization therapy has yet to be covered by insurance.

Cancerous tissue is frequently found deep, far from the surface of the body. When irradiating cancerous tissue deep within the body, irradiation of the surrounding healthy tissue is unavoidable. When attempting to deliver large amounts of radiation to the cancerous tissue without damaging healthy tissue, there are cases where it is more efficient to irradiate cancerous tissue from within the body, rather than to irradiate from outside.

In June 2015, the Cabinet approved a written response stating that, "the necessary response will be considered, and research and development will continue to be promoted," regarding the deregulation and popularization of nuclear medicine treatment in Japan. However, the spread and popularization of nuclear medicine therapy, which includes radioembolization, a noninvasive, highly effective therapy that places an emphasis on Quality of Life (QOL), is significantly delayed in Japan.

The Japan branch of the Cancer Support Community, a global nonprofit patient advocacy group headquartered in Washington, DC, in the U.S., has been providing psychosocial support, education, and healthy lifestyle programs to patients and their families in Japan since May 2001.

Striving to improve cancer care in Japan, the Cancer Support Community established the National Conference for Nuclear Medicine Theranostics in December 2016 with help from

the Japanese Society of Nuclear Medicine (an academic association), the Japan Radioisotope Association (an industry association), and PanCAN Japan (a nonprofit organization that provides support for patients with pancreatic cancer).

Going forward, the conference will conduct initiatives to improve the environment surrounding nuclear medicine treatment and promote appropriate nuclear medicine treatment through advocacy activities.

Voice from the Local Government
Support of Medical Device Development at the Saitama Leading Edge Project
Initiatives of the Saitama Medical Innovation Network (Saitama Prefecture)

Promotion Office, Leading Edge Industrial Division,
Department of Industry and Labor, Saitama Prefecture

The Strengths of Saitama Prefecture in Healthcare-Related Industries

Since FY2014, Saitama prefecture has been promoting their Leading-Edge Industry Design Project (Leading Edge Project), which aims to provide support for commercialization, productization, and industrialization of leading edge industrial fields, including: nano-carbons, medical innovation, robotics, new energy, and aerospace. Innovative research will receive resources from universities and research institutions, as well as access to special technology from corporations.

Saitama prefecture has a high potential to grow healthcare industries because it produces some of the most pharmaceutical products and medical devices in Japan. Saitama prefecture also has a high concentration of manufacturing companies including optics industries. This project seeks to further attract healthcare-related industries by utilizing Saitama's appeal and promoting innovation in the development of medical devices.

Establishment of the Saitama Medical Innovation Network

The Saitama Medical Innovation Network is a healthcare initiative from the Leading Edge Project. The network was established with medical device companies, universities, research institutions, and companies seeking to enter the market.

Saitama Prefecture and Saitama City work together to attract healthcare industries by holding seminars on the development of medical devices and providing opportunities for network members to meet. A total of approximately 350 companies and organizations from industry, academia, and health care participate in the network. Members are from both within and outside the prefecture.

The Saitama Medical Innovation Network's projects support phases from (1) market entry, (2) research and development, and (3) commercialization.

One example of the network's activities is matching the needs of the healthcare field with corporations. This initiative, led by the Saitama Industrial Promotion Public Corporation, is where healthcare industry manufacturers and sellers are matched with physicians, and the

manufacturers' listen to what is needed in the healthcare field. Matches are mediated by the Saitama Industrial Promotion Public Corporation; after the matches have a discussion, their coordinators advise the manufacturers about research and development.

The Saitama Medical Innovation Network also holds a "Medical Device Prototype Contest," to support commercialization of prototype medical and health devices. In this contest, winners are awarded monetary prizes (including a grand prize of 5 million yen), with the intent of subsidizing costs for regulatory approval after product development. It is a unique contest, which places the spotlight on prototypes, and subsequently helps corporations envision a product which creates revenue.

Participation in the network is not limited to medical device corporations, but is open to any corporation or organization related to, or interested in, health care. This includes corporations seeking entry into the market, universities, research institutions, medical institutions, and supporting institutions, from both within and outside the prefecture.

Interested parties should contact the Promotion Office, Leading Edge Industries Division, Department of Industry and Labor.
(Phone: 048-830-3737, e-mail: a3760-03@pref.saitama.lg.jp).

AMDD Holds Extraordinary General Meeting

On September 14, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held an extraordinary general meeting. AMDD Chairman Kosuke Kato (Managing Director, Edwards Lifesciences Corporation) opened with an overview of the Medical Technology Policy Institute, that was slated to be established on October 1, 2017 as a new organization within the association. The institute's mission is to conduct mid-to-long-term research and suggest government policy changes in order for medical technologies, including medical devices and in vitro diagnostic devices, to make greater contributions to Japan's health care. At the extraordinary general meeting, the establishment of the institute and budget additions were approved after deliberations.

Dr. Yasuhiro Suzuki, Chief Medical & Global Health Officer, Ministry of Health, Labour and Welfare gave the keynote address entitled "Japan's Healthcare Challenge."
(Please refer to page 1 for a summary of Dr. Suzuki's address)

(From left)
Mr. Kosuke Kato,
AMDD Chairman

Dr. Yasuhiro Suzuki,
Chief Medical & Global Health Officer, MHLW

AMDD Participates in the Kasumigaseki Summer Holiday Event, "Kasumigaseki Kid's Day"

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) participated in "Kasumigaseki Kid's Day" on August 2 and 3, in Kasumigaseki. During the event, AMDD exhibited in a booth within the MHLW office entitled, "Let's Touch Cutting Edge Medical Devices that Save Lives." This year's exhibits were divided into the themes "diagnosis," "emergency," "treatment," and "in-home care" with the goal of making it easier for children to understand.

The children went around the booths, spending an enjoyable day of their summer vacations actually touching medical devices from the four themes. The children seemed to be surprised by the vast variety of devices.

Many companies from AMDD participated, created quizzes for the respective themes, and earnestly explained the medical devices and treatments to the children.

The Value of Medical Technology <Diagnosis and Treatment of Cancer> Reducing Discomfort and Enhancing Diagnostic Capabilities to Increase the Rate of Mammography Screenings

One reason that patients avoid undergoing breast cancer screenings with mammography is because of the discomfort and pain of testing.1

A next-generation mammography device was developed, incorporating the opinions of Japanese patients, technicians, and physicians in order to reduce the pain and discomfort of testing. Technicians corrected breast positioning, and applied the minimum pressure required for the exam. Based on the input from technicians, patients use a self-pressurizing function with a wireless remote control, and the patients apply the pressure themselves, to the extent that they do not experience discomfort. In addition, the device's exterior is designed to alleviate the nervousness which patients often feel upon entering the examination room; the breast support plate, that comes in contact with the patient, is thin and rounded and the face guard is also curved to reduce neck pain while taking the X-ray. In recent years, the diagnostic capabilities of mammography have been enhanced with the development of digital breast tomosynthesis (DBT). Multiple studies have reported results where recall rates have been reduced and cancer detection rates have been increased, using simple mammography and DBT screenings concurrently. The next-generation mammography devices that are gentle on women are expected to be widely used to increase the rate of mammography screenings.

*1: Digital Mammography A Holistic Approach, Peter Hogg, Judith Kelly, Claire Mercer, 2015

(Text: Ryosuke Higashio, GE Healthcare Japan K.K.)

Product Name: Senographe Pristina™
Proprietary Brand Name: X-Ray Diagnostic Device for Breast Cancer Mammography Senographe Pristina
Medical Device Registration Number: 228ACBZX00013000

AMDD Revamps Regular Member Meetings — Monthly Meetings and Lecture Meetings —

The AMDD conducts regular meetings, and under the leadership of the Membership Committee, the content of these meetings was revamped in April 2017.

"Lecture Meetings" and "Leadership Forums" are currently being trialed. Prominent instructors for the respective industries provide lectures to executives of the member companies. The lectures are themed with societal and industry trends. Lively discussions have followed each lecture.

<Past Meetings>

Lecture Meetings

- "Value-Based Healthcare" (Speaker: Dr. Shohei Nakano, Japan Association for the Advancement of Medical Equipment)
- "Healthcare Systems Required for the Advancement of Medical Technologies" (Speaker: Mr. Tetsuyuki Tatsuoka, Deloitte Tohmatsu Consulting LLC)

Leadership Forums

- "Risk Management for Business" (Speaker: Mr. Shigeru Nakajima, Lawyer, Nakajima Transactional Law Office)
- "Diversity and Inclusion as a Management Strategy" (Speaker: Mr. Akira Matsumoto, Chairman and CEO, Calbee Inc.)

July Leadership Forum

Value of Medical Technology

Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

Note: All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.