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American Medical Devices and Diagnostics Manufacturers' Association

AMDD Vol.31 NEWSLETTER

AMDD 10th Anniversary Issue

AMDD would like to thank you for the warm congratulatory messages we received for the 10th anniversary of our establishment in 2009. These partners include all the government agencies and industry groups that worked with us on issues such as enacting a revision to the Pharmacy Affairs Law aimed at eliminating device lag and establishing an evaluation system for promoting innovation.

Greetings from AMDD on Our 10th Anniversary

AMDD's Mission and Direction over the Past 10 Years

We, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) are celebrating its 10th anniversary this year. We would like to express our deepest gratitude for the guidance and encouragement we have received from all those who have worked with us.

AMDD is an industry group consisting of approximately 60 Japanese corporations that handle medical devices and in-vitro diagnostics (IVD) with their headquarters located mainly in the United States. AMDD was established in April 2009 with the mission of delivering world-class advanced medical technology to Japan.

To achieve this mission, we are engaged in several activities. Firstly, we make policy recommendations on relevant regulatory issues so that advanced medical technologies can be delivered quickly and appropriately to Japanese hospitals and other facilities. Secondly, we liaise with governments on behalf of member corporations to support the comprehensive control and appropriate distribution of medical expenses. Finally, we communicate the value of advanced medical technologies.

Specifically, with the cooperation of related organizations such as the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA), we have been particularly active in our aim of eliminating the long-standing issue of device lag and building a regulatory system that takes into account the unique aspects of medical devices. Our work has led to the acceleration of device inspections, meaning device lag is all but eliminated. Additionally, in November 2013, our long-held vision of revising the Pharmaceutical Affairs Law to separate regulations on pharmaceuticals from those on medical devices was enacted and took effect the following year. This achievement was a welcome, giant leap forward in the development for medical devices.

The Road Ahead

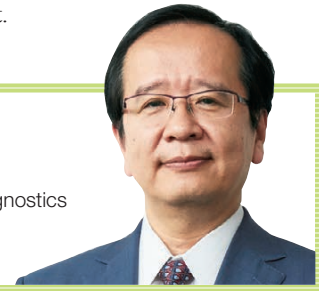
Current thinking on numerous issues facing Japan, such as an aging population, the sustainability of financial resources, and extending healthy lifespan tend to be thought of as unique to Japan. However, reinterpreting these aspects as challenges to establish low-costs for maintaining or restoring healthy lives, even with limited economic power and action, allows us to view these as global issues that also resonate in developing countries. With the remarkable progress of technologies such as AI, ICT, and the IoT, competition is tightening in the race for innovation that can target approximately 7 billion of the world's 7.5 billion people who do not enjoy advanced living standards. Big innovators are emerging that seek to scale up their efforts to supply these 7 billion people with infrastructure, energy, food, and medical access at low cost.

Such large innovations that tackle and solve global issues could provide solutions to issues facing Japan society and its healthcare. Building on our existing mission, we at AMDD also believe that we can play an essential role in conveying, as business opportunities, the issues that Japan faces to big innovators on the global stage.

We are heading toward a society in which population growth has peaked and healthcare can no longer be provided at the prices offered as before. So, as we ask questions about how to continue cooperating, as with the development of medical devices, there will be situations where policy will depend on revisions and improvements brought about by dramatic and disruptive innovations. Our aim is to arrive at a brighter tomorrow through the continued development of cooperative relationships that facilitate sincere patient-centered discussions to improve Japan's social security system.

AMDD has been walking this path for 10 years along with our member companies that are striving to introduce innovative technologies. Our success has been possible through the understanding and cooperation of our members, MHLW, PMDA, the Japan Medical Association (JMA), and other societies. And, so too for the next decade, in cooperation with the Japanese government and related organizations, and in collaboration with the U.S. government and the American Advanced Medical Technology Association (AdvaMed), we are committed to the development of healthcare in Japan. We at AMDD look forward to your continued guidance and encouragement.

Kosuke Kato
Chairman
American Medical Devices and Diagnostics Manufacturers' Association (AMDD)



AMDD Enabling a Healthier Japan

10th ANNIVERSARY

On the Occasion of AMDD's 10th Anniversary

Congratulations on your 10th anniversary. We sincerely thank everyone at AMDD for their hard work in eliminating device lag and building a regulatory system that takes into account the unique aspects of medical devices.

The greatest unique aspects of medical devices are their diversity, from surgical knives to MRIs and pacemakers, and their continuous improvement. People often say that pharmaceuticals and medical devices are too different from each other, and that, therefore, there was no point in categorizing them under the same regulations. For us too, it goes without saying that the devices themselves are so rich in their diversity that it is impossible to put them all in the same basket.

In a report published by MHLW in July 2016 on the Advisory Panel for Promotion of Medical Ventures as a Driving Force for the Success in Innovation, three principles were cited as forming the fundamental thinking on the subject. One of those principles was "Macro to Micro." This does not mean a macro concept that treats large corporations and venture companies in the same way, but one that recognizes that numerous measures need to be taken from a micro perspective that recognizes the different characteristics of organizations so that venture companies and so forth can demonstrate their individuality. We think this concept is essential in the regulation of medical devices. Regulations for medical devices that are constructed from a macro perspective are extremely important. But in addition to this, in terms of highly diverse medical devices, it is also important to apply quality, effectiveness, and safety assessments that are tailored to each device. We believe this is the exact meaning for Macro to Micro. The same applies to fostering ventures in the field of medical equipment. But regulations should not be loosened to favor certain ventures. Rather, it can be understood as applying tailored regulatory science to individual medical devices to ensure quality, effectiveness, and safety, and applying support measures that are optimized to help foster individual ventures.

We believe that optimizing the regulation of each individual medical device is both an administrative government role and a joint role together with AMDD. In particular, the more medical devices that use the most advanced technology, the more difficult it is to establish evaluation guidelines in advance. We think that guidelines are best prepared by actually performing evaluations tailored to individual items during the course of their development and examination, and to then publish the findings as an examination report. Following that, it is extremely important that developers of revised and improved medical devices apply tailored regulatory science to the unique characteristics of their items while referencing published examination reports. As the frontiers of development are pushed, we have high expectations for more joint collaborations with AMDD in contributing to safe and secure healthcare.

Finally, I would like to set a challenge for AMDD to bring even earlier-stage development to Japan. On top of that, I would like AMDD to bring medical device developments to Japan that incorporate world-renowned Japanese technologies, especially those that are not in plain sight, such as academic research. And, I would say the same to other countries across the world.

Kiyohito Nakai, Ph.D.
Director
Medical Device Evaluation Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare (MHLW)

Congratulations! AMDD 10th Anniversary Wishes and Hopes

Congratulations to AMDD on your 10th anniversary. A generation ago, there was considerable opposition between reviewers and applicants when device lag was at its height. At the time, this pushed us to seek a breakthrough with the eventual formulation of the Medical Device Examination Rapid Action Program. Since then, a trusting relationship gained through the action program has grown further with the introduction of the Cooperative Plan for Rapid Examination of Medical Devices. Furthermore, in July of this year, the Cooperative Plan for Optimizing Medical Device Regulations and Examinations and the Cooperative Plan for Optimizing In-Vitro Diagnostics Regulations and Examinations were also formulated and published.

Looking back at the original action program, it is amazing to see how much of it has now been achieved. As a result, not only has the review period been dramatically shortened through collaboration with industry stakeholders, but we believe the most significant achievement is the establishment of a system for good communication premised on a relationship of deep trust between the industry and the government.

In the last 10 years, numerous innovative medical devices and IVDs have come to market. Transcatheter aortic valve replacement (TAVI), genetic panel testing, and countless other new medical devices are now available. Numerous products that are now assisting Japanese patients come from AMDD member companies who advocate policy proposals and activities that contribute to the development of healthcare in Japan.

This is in large part thanks to all industry stakeholders, and we extend again our sincere gratitude, especially for the hard work and cooperation of AMDD member companies and other related parties whose work has helped to launch high-risk medical devices and IVDs that require application for approval.

No doubt in the next ten years we will see even faster change and reform. We expect to see the development of medical devices, wearable devices, and pediatric medical devices that incorporate AI in the near future, and "optimization" will be the keyword, as found in the title of the Cooperative Plan. The government intends to introduce appropriate regulations for these new products in a timely fashion. Going forward, our expectations for AMDD member companies is even faster and safer introduction of further improved medical devices into Japan.

Shinichi Takae
Director
Office of Medical Devices I
Medical Device Unit
Pharmaceuticals and Medical Devices Agency (PMDA)

Benefiting Patients Utilizing Advanced Technology

Sincere congratulations to AMDD on your 10th anniversary.

While Japan faces major changes during this period of rapid increase in its elderly population and a rapid decrease in the working generation, the government must confront social security reforms as it looks ahead to 2040. MHLW recently compiled a reform plan that has extending the healthy lifespan and medical and welfare service reform as its foundations.

Against this backdrop, AMDD, since its establishment in 2009, has been dedicated to eliminating device lag to provide valuable medical technology and information to medical sites. We would like to express our gratitude for the quick delivery of innovative medical devices to the Japanese public.

People now expect the use of cutting-edge technologies, such as robots, AI, and ICT. Looking to the future, in order to increase the overall number of staff while developing medical and welfare sites that can run with less human resources, we ask that you take full advantage of technologies that will benefit patients.

Healthcare is advancing daily and all eyes are on the high-added-value and knowledge-intensive healthcare industry, which is expected to play a central role in economic growth. MHLW will continue to drive initiatives in collaboration with other ministries and related organizations for the further development of the medical device industry.

In the next fiscal year, we have decided to defer the first revision of the payment system for medical services in the Reiwa Era. This discussion is currently ongoing at the Central Social Insurance Medical Council. In order to build a system that can provide better healthcare to the public, we are always interested in hearing from the medical device industry.

Last, but not least, we congratulate all of you at AMDD and wish you all the best for future success.

Akihisa Maeda, M.D.

Director
Office for Medical Devices Policy
Health Policy Bureau
Ministry of Health, Labour and Welfare
(MHLW)

AMDD Expected to Play a Role in Matching Global Tech with the Needs of Japan

Congratulations to AMDD and its member companies on its 10th anniversary. We would like to express our gratitude for making a significant contribution to the improvement and the quality of healthcare in Japan.

At the Ministry of Economy, Trade and Industry (METI) our aim is to realize a Lifelong Active Society in which everyone can live happily. The Japanese population is aging more rapidly than most of the world, with the current rate of seniors at 27%, and is now a “super-aging society.” But there have been remarkable changes in the environment surrounding the medical device industry in recent years. In addition to conventional types of healthcare, innovation is occurring in medical devices and services in new areas such as prevention/suppression and nursing care. Also, new technological innovation from differing fields, such as robotics, AI and the IoT, as well as venture capitalists and players from other industries, are all expected to enter the industry.

Since the Japan Agency for Medical Research and Development (AMED) was established in 2015, working with us in government, AMDD has provided seamless support for research and development from the basics to practical application. Soon we will reach the five-year mark and begin our second period of cooperation. We will work to provide infrastructure and development support to enable the creation of innovative medical devices in collaboration with AMED and other related ministries. As we look to extend new medical devices and services born from the needs of our developed nation to the global market, we look forward to further investment from, and in collaboration with, member companies that possess abundant experience, knowledge, and networks in other major countries. In recent years, we are seeing examples of investments that seek new solutions in response to issues associated with regional super-aging societies. These include the development of new medical devices that incorporate the technology and high-grade materials of domestic SMEs, and collaboration among medical institutions and local governments.

Additionally, we think it is important to convey overseas that Japan is gearing up to be a base for such innovation, and to establish locations to create opportunities that match world-class technologies with the needs of Japan. Toward that end, last year in Japan, the 1st Well Aging Society Summit Asia-Japan was held, bringing together roughly 800 venture capitalists, companies, investors, experts, and government officials. This year, the event will be held from October 16th to 17th to coincide with the G20 summit. At the event, we intend to share advanced ventures and initiatives for the future of healthcare and nursing care in Japan and other countries. We look forward to your participation.

Sayaka Tomihara

Director
Medical and Assistive Device Industries Office
Commerce and Safety Industry Policy Group
Ministry of Economy, Trade and Industry
(METI)

International Collaboration Based on Trust is Essential

In 2010, I was appointed manager of the Medical and Assistive Devices Industries Office at METI. While nearly 10 years have passed since I started working with AMDD, I am glad to be able to give back to everyone in a field that is so deeply involved in healthcare. Back when I was appointed manager, we were struck by the Great East Japan Earthquake. I remember trying to secure gasoline to transport medical equipment to the affected areas. At that time, I was asked to cooperate with AMDD member companies if sufficient gasoline could not be procured in Japan alone and I want to thank you again for the support you gave me.

Times have changed over the past 10 years, but none more so than advancements made in IT. These advancements have brought transformation and opportunity, not only for medical devices, but for all industries. AI, the IoT, big data, and even 4G and 5G technologies are now indispensable to our everyday lives. In terms of cancer diagnosis, treatment and prognosis care, medical devices alone cannot solve all the issues. Here, collaborative work in a plurality of modalities, such as pharmaceuticals, regenerative medicine, and genomics, among others become essential, together with an integrated response in medical services. Moreover, as technology diversifies and grows, it becomes more difficult to meet the necessities of people, goods, money, and medical sites in Japan. This is where we hope new players will come into the industry. What is more, as pointed out by those in bioethics, the social acceptability of new technologies must be considered in advance. This makes it an important time to include knowledge from the humanities, as well as engineering and medicine, in any emerging concepts.

Against this backdrop, I see (1) international collaboration, (2) data utilization, and (3) venture development support as major issues in the coming years. And, above all, I think international collaboration will be key in terms of securing and enhancing the necessary players. I look forward to international collaboration with AMDD member companies, based on a trusting relationship.

The vision of Society 5.0 advocated by Japan in the 5th Science and Technology Basic Plan, which promotes the fusion of cyberspace and physical space, will soon be upon us. AMED, in its response to such an era, will strive to provide cutting-edge, reliable medical R&D results that lead to faster patient care, even if all we gain is a fraction of a minute.

Shiro Takegami
Managing Director
Industrial-Academic Collaboration
Japan Agency for Medical Research and Development (AMED)

10th Anniversary Celebration and Thoughts on the Next 10 Years

—Toward a Healthcare Industry that Excites—

Introduction

Congratulations to everyone at AMDD on your 10th anniversary. I look forward to being a part of the medical industry over the next ten years, which will no doubt be more exciting in this world of turbulent politics, economics, and society.

Time Flies Like an Arrow

Time flies. No sooner do we achieve high-speed network communication than we are suddenly thrust into the world of 5G. In the world of medicine too, over the next 10 years, online home healthcare and remote diagnosis and treatment will equal the technological progress we achieved over the past 20 to 30 years. But I think change may come at a speed that exceeds even that. Together, we must take on the challenges posed by an era of globalizing healthcare, which go beyond borders and break down continental walls.

Innovative Product Development

Simply tallying some of the concepts related to the future of medicine reaffirms the dreams held for the future of the healthcare industry. These concepts include product development that incorporates AI or the industrialization of regenerative medicine/cell therapy. On the other hand, challenges will naturally arise such as conforming to new compliance rules and regulations, as well as issues that affect national finances, such as social security and national medical expenses. However, we all have a duty to think about the future.

Living for the Future, Now

The late famous surgeon Dr. Masaki Kitajima, who suddenly past away at the end of May last year, was the first to introduce the da Vinci Surgical System into Asia. In 2000, he took on the challenge of minimally invasive surgery, which puts less burden on patients. He adamantly believed we should not “live for now,” but should “live for the future.”

In Closing

With that bright future dream as our target, we will continue to join hands in collaboration with AMDD.

Kenichi Matsumoto
Chairman
The Japan Federation of Medical Devices Associations (JFMDA)

AMDD
Enabling a Healthier Japan

10th ANNIVERSARY

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