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AMDD Celebrates Its 5th Anniversary

Global Harmonization as a Key Task

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) celebrated its 5th anniversary in April this year. One of our greatest achievements so far, the "Pharmaceutical and Medical Device Law" enacted last year, has been a long-cherished wish for us. This year, we will work out the details for enforcing this law and focus on the three tasks described below.

The first task is "global harmonization," which encompasses three points. Firstly, we will redouble our efforts to "resolve the device lag and device gap" for in vitro diagnostics (IVD), in addition to medical devices. Secondly, we will actively advance global harmonization to promote global streamlining for manufacturing/quality management standards (QMS), compliance surveillance and post-marketing quality, and efficacy and safety surveillance (PMS) for medical devices. Third, we will introduce systems for global standards to ensure the safety of healthcare professionals exposed to various clinical risks.

The second task is "adequate evaluation of innovations." Now that the foreign average pricing (FAP) system seems to have completed its historic mission, it is a time to leave pricing to market forces. For this purpose, we will continue to promote the necessity of implementing appropriate evaluation criteria.

The third task is to foster participation between AMDD member companies. We will strengthen the benefits for participating by sharing the findings from medical device industries around the world and the latest information from the government. We will also

provide deeper understanding on the Foreign Corrupt Practices Act (FCPA) and Unique Device Identifiers (UDI).

Takashi Shimada, Chairman
American Medical Devices and Diagnostics Manufacturers' Association
President, Medtronic Japan Co., Ltd.

New Milestones in Collaboration

The AMDD was founded in April 2009 with the mission of "improving the welfare of Japanese patients using the latest medical technologies." Since then, it has been actively working to introduce state-of-the-art medical technologies to Japan.

Since its foundation, the AMDD has actively established a cooperative relationship with the government. For example, AMDD dispatched specialist members to the Action Program, developed by the Ministry of Health, Labour and Welfare, to accelerate reviews of medical devices. It also jointly submitted various proposals and requests to the government with related organizations to set appropriate insurance reimbursement prices and establish special regulatory frameworks for medical devices. Even in the tough environment of device lags and decreased reimbursement prices, it has consistently maintained a dialogue with the common goals of serving Japanese patients and contributing to the development of the medical device industry.

The enactment of the "Pharmaceutical and Medical Device Law" last year was very good news for us. We will continue our efforts so that future systems will be revised according to the characteristics of medical devices.

With the new milestone, the AMDD will continue to deliver state-of-the-art medical technologies from around the world to medical institutions and Japanese patients. The milestone will also strengthen the cooperation between the Ministry of Health, Labour and Welfare, Pharmaceuticals and Medical Devices Agency (PMDA), and other relevant agencies, with an aim of improving the quality of life (QOL) for not only patients but for all relevant people.

Kosuke Kato, Vice Chairman
American Medical Devices and Diagnostics Manufacturers' Association
Managing Director, Edwards Lifesciences Ltd.

Issue of Consumption Tax in the Medical Device Industry and the Role of the Industry

Introduction

The increase in consumption tax in April 2014, meant that the revision of reimbursement prices started on the back foot. With medical institutions facing an increasingly tough business environment, how would the medical device industry be affected? Also what kind of role should the medical device industry play?

1. Issue of consumption tax in healthcare

Generally, consumption tax is not believed to impose any burden on business operators.

In the case of medical institutions that offer insurance-covered medical care, a "sales-related consumption tax" is not imposed because insurance revenues that include reimbursement are derived from nontaxable transactions. However, consumption tax is imposed on the purchase of materials used for clinical practice, medical devices, and the like. Of this "purchase-related consumption tax," only the taxable sales portion (for example, pay beds and medical check-ups) qualifies for a deduction and the nontaxable sales portion (insurance revenues including reimbursement) does not, according to the consumption tax calculation rule. Therefore, medical institutions that mainly offer medical care that is covered by insurance cannot claim a deduction for the purchase-related consumption tax. These institutions have to bear the costs (the burden of nondeductible consumption tax) on behalf of consumers because most of their revenues from medical practices are derived from nontaxable transactions. Consumption taxes impose a heavy financial burden on medical institutions, and the impact on the management of acute care hospitals is considered to be especially large.

2. Impact on the medical device industry

Medical institutions consider the burden of consumption tax a significant business risk. If medical institutions need to take action against consumption tax, they will likely consider cost management first. In other words, to alleviate cost burdens institutions will reduce costs for materials and facilities, which account for a large portion of the entire expenditure. Additionally, they will reevaluate material costs in terms of purchase, usage, and management, and take various actions aimed at streamlining their operations. For example, they may reevaluate instruments used for surgical operations and discard unnecessary equipment or instruments. They may cut the number of items and increase the quantity of each item; by decreasing the number of clinical material items in the same class institutions can accelerate negotiations to reduce unit price. Even worse, some medical institutions seem to be trying to create competition among manufacturers by encouraging partner hospitals to buy general-purpose products to cut purchase costs further through joint purchasing. Advanced acute care hospitals, which are more likely to consider installing state-of-the-art, high-spec medical devices, may suspend active investments or refrain from making the necessary capital investments even when the time to upgrade medical devices comes around, since the cost of large devices is high. If this situation occurs, only some

selected high-function hospitals can afford to buy expensive state-of-the-art medical devices, possibly resulting in the significant shrinkage of the market size in Japan.

3. What kind of role should the medical device industry play for medical institutions?

There is an urgent need to change since the burden of consumption taxes, which is considered as a business risk of medical institutions, has a significant impact on hospital management. Medical institutions will therefore encounter problems related to purchase activities or cost management, plan specific attitudes or strategies to resolve these problems, and make various efforts to survive. In contrast, middle- and small-sized medical institutions may have difficulty in taking definitive actions because their management structure is fragile. Even so, if we take no action, the planned further tax increase and medical expenditure reduction policy will devastate the management of private hospitals.

What, then, should the medical device industry do? How much do we understand about the management conditions of medical institutions to which we sell products? Cost effectiveness estimates are often provided when medical materials or devices are purchased, but most companies do not seem to verify managerial outcomes for medical institutions after purchase. Medical institutions have many problems, and there are a number of managerial needs. We need to reevaluate the problems and managerial needs of medical institutions and formulate action plans to establish our own support systems.

More specifically, we should not only try to secure revenues by increasing utilization and assuring insurance claims, but also to provide values that bring in new revenues by suggesting cost-effective products for the decision makers of medical institutions (for example, hospital directors, supply divisions, and operation committees).

The impact of the consumption tax increase on the medical device industry may have a great influence on various aspects of companies that offer medical materials or devices. We should take this opportunity to set prices or formulate product strategies bearing in mind the ways that we can provide value-added products for medical institutions.

Conclusion

The issue of the consumption tax burden that the healthcare industry and individual medical institutions are facing is further exasperated by the increase in the consumption tax rate. Related industries must regard this challenge as their own and take action as early as possible. If medical institutions cannot survive, related industries cannot survive either. It is also necessary to convince the healthcare industry that it is not a good idea to demand unreasonable actions just for their own sake. This includes price negotiations with related industries in response to the increase in consumption tax rate. Both companies and medical institutions should endeavor to establish strong relationships of mutual trust from a long-term perspective. The medical device industry is now expected to contribute to community healthcare and employment in cooperation with medical institutions by promoting adequately streamlined healthcare.

Mr. Tomochika Funamoto
Leader, Kyoto Prefecture, TKC Healthcare Accounting System Association

Mr. Tomochika Funamoto is a certified tax accountant (Kyoto Shimei Tax Accountant Corporation), registered healthcare management consultant certified by the Japan Association of Healthcare Management Consultants, and director in charge of tax systems of the incorporated nonprofit organization Koteki Byoin wo Yokusuru Kai (Organization for Better Public Hospitals). He has also been working on the ideal management project program (Kyoto University Graduate School of Medicine) and to improve the management of Toyonaka Health Center. He is also involved in public healthcare and nursing services such as management diagnosis for the hospital operation of Kyoto City, and the human resource development program of the Ministry of Economy, Trade and Industry. He wrote Iryo to Shohizei (Healthcare and Consumption Tax), which was published in January 2013 by Tokuma Shoten.

Patient's Voice
Patient Group to the World

Mr. Yasuhide Noda, Director General
Glaucoma Friend Network

A patient group of an intractable disease, glaucoma, helped establish an international patient group.

The patient group Glaucoma Friend Network, established in Japan in 2000, was invited to attend the 2004 American Academy of Ophthalmology (AAO) Annual Meeting held in New Orleans in the United States. The event led to a number of discussions related to glaucoma between patient groups from various countries, and as a result, the organization Glaucoma International Network (GIN) was established.

At the 2007 World Glaucoma Congress (WGC) held in Singapore, GIN was dissolved and reorganized into a new organization called World Glaucoma Patient Association (WGPA). I am one of the board members of the WGPA.

<WGPA http://www.worldgpa.org/>

The WGC is held every two years in various areas around the world. Physicians, pharmaceutical companies, and patient groups gather at the WGC to discuss various issues for promoting early diagnosis and treatment of the intractable disease glaucoma. Following Singapore, the event was held in Boston, Paris, and Vancouver, and will be held in Hong Kong next year.

During the course of these discussions, WGPA decided to perform glaucoma educational activities concurrently around the world, which led to World Glaucoma Week. World Glaucoma Week provides educational activities for glaucoma concurrently around the world from early to mid-March every year. Various events such as open lectures, screening

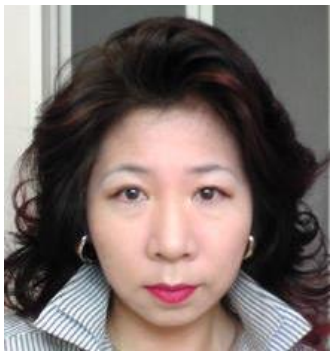
tests, and parades are organized in each country. These events are displayed on a map on the World Glaucoma Week website. In Japan, we continue to organize open lectures to further the public's knowledge about glaucoma and allow early diagnosis and treatment. Our aim is to decrease the number of patients with glaucoma, which is the leading cause of acquired blindness. This year in 2014, we organized open lectures at the following venues:

- Sankei Plaza (Otemachi, Tokyo) on March 8 (Sat) (ID: 1718_1389569052)
- Knowledge Theater (Osaka) on March 15 (Sat) (ID: 1717_1389568921)

<World Glaucoma Week http://www.wgweek.net/>.
We also organized open lectures and provided eye check-ups jointly with the Japan Glaucoma Society, Tajimi City, and the Tajimi Lions Club.

Glaucoma Friend Network http://www.gfnet.gt.jp/

Voice from the Local Government
Aiming for the Japanese and Overseas Markets
~ Supporting Medical Device Businesses ~



Ms. Ako Makiyama, Deputy Director
Division of Economy and Industry, Osaka Chamber of Commerce and Industry

Since 2003, the Osaka Chamber of Commerce and Industry (OCCI) has been working on a medicine-engineering collaboration matching program called the "Next-generation Medical System Industrialization Forum." This medical device business program provides projects aiming to enter Japanese and overseas markets with the support to develop collaborations regardless of the location of universities, medical institutions, research institutions, and target companies. The program focuses on commercialization in addition to research and development, and attempts to improve the business support framework beyond the boundaries of support for individual projects.

The forum holds regular meetings once a month, in which physicians and other medical professionals suggest to companies joint development projects for medical devices. If any company is interested in a project and joint development, the secretariat of the OCCI arranges an interview between the proponent and company to collaboration. To assist in commercialization, the OCCI utilizes nearly 20 specialists advisers to provide consultation and offer optimal support at all business stages including "formulation of business plans," "investigation of business models," "detailed examination of product concepts," "actions related to strategies and pharmaceutical affairs," and "formulation of policies to explore distribution routes and implementation of such policies."

In particular, the Kansai area has been designated as the "Kansai Innovation International Strategic Comprehensive Special Zone" for the last several years. Within the framework of this special zone, we have been strengthening support for commercialization and

aggressively assisting not only companies in the Kansai area, but also major companies in different industries, and medical device companies experienced in the medical device business but are planning to enter new fields. In addition, the OCCI has established partnerships with Minnesota in the United States, which is a global hub for medical devices, and Singapore, which may serve as a business hub in the Asian market. These partnerships were fostered to expand the medical device business of Japanese companies actively into overseas markets by utilizing the know-how of our partners. In the future, we will launch human resource development programs for companies to foster human resources specializing in the medical device business so that various companies can succeed in the medical device business.

The AMDD and its membership of leading companies in the medical device industry provide meaningful support to Japanese companies. For example, we asked AMDD's ex-chairman as well as the current chairman Mr. Takashi Shimada (President of Medtronic Japan Co., Ltd.) to provide keynote speeches about global trends in the medical device industry and their expectations for Japanese companies at OCCI-sponsored international events. We appreciate their continued guidance.

The OCCI is making efforts to improve the framework for supporting the medical device business by utilizing our networks in Japan and abroad while supporting individual projects. We provide support regardless of the company size or area, so please contact us if you are interested.

"I am glad I chose this treatment! II~ Essays from patients who chose advanced treatment" Published

Commemorating its 5th anniversary, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) published an essay book entitled "I am glad I chose this treatment! II~ Essays from patients who chose advanced treatment." The essay book includes stories from patients who received treatments or examinations based on advanced medical technologies and obtained lifesaving benefits or improved quality of life (QOL).

Five years have passed since we published the first edition in 2009, and during this short period, numerous advanced medical technologies have been developed in various fields and introduced to Japan. The second edition that we have just published summarizes areas and technologies that we could not introduce in the first edition. Additionally the voices of patients who received advanced medical technology-based treatment that improved their QOL were also included, such as prompt social rehabilitation after treatment.

This essay book features treatment for 14 diseases and is structured like the first edition, which includes "stories of

"I am glad I chose this treatment! II~ Essays from patients who chose advanced treatment"
Supervising Editor: Makoto Kikuchi
(President of the Japan Association for the Advancement of Medical Equipment)

patients," "comments of attending physicians," and "introduction of technologies." In addition to featuring diseases affecting the heart and blood vessels, and gender-specific diseases, the second edition will introduce ear and bone diseases. It also includes a special interview between Mr. Don Konishi, a fashion designer who was diagnosed on a television health program for his valvular heart disease and underwent surgery, and his attending physician Akihiro Nabuchi MD, who is a cardiovascular surgeon in Osaki Hospital Tokyo Heart Center.

This essay book will be offered to opinion leaders, medical schools libraries, national and public libraries, and the general public. It will also be posted on the AMDD website.

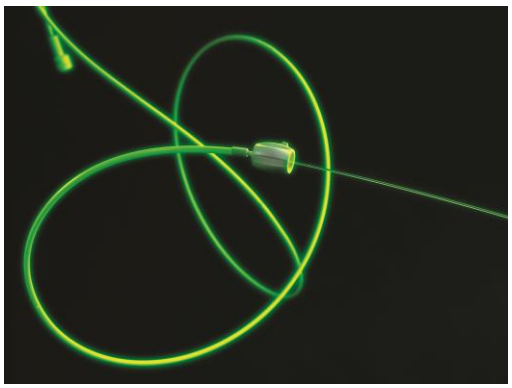
Value of Medical Technology <Diagnostic and Treatment Devices>

Treatment of Prostatic Hyperplasia Using a New Laser

Prostatic hyperplasia is a progressive benign disease that is common in middle age and elderly men. It is estimated that prostatic hyperplasia develops in 80% of men before the age of 80.

The most commonly used surgical procedure for this disease is transurethral endoscopic surgery using a high-frequency excision loop (transurethral resection of the prostate: TURP). In Japan, this procedure has been used as the standard of care for several decades because of its superior treatment efficacy. However, new treatment methods are being explored because TURP is known to cause some rare but serious complications.

One such alternatives is a treatment method that uses lasers of a particular wavelength. This technology has made rapid progress in the United States and Europe and combines optical fibers and laser generation devices that evaporate (vaporize) enlarged prostatic tissues through transurethral endoscopic surgery.



This method can shorten the duration of urethral catheterization after surgery and hospitalization while maintaining the same level of efficacy as TURP. This method also reduces the risk of serious complications. It was recently introduced in Japan and has started gaining popularity.

(Taro Hayamizu, AMS Japan Inc.)

New Structure of AMDD

Having celebrated its 5th anniversary in April 2014, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) welcomes the new directors to advance AMDD activities:

Chairman	Takashi Shimada	Medtronic Japan Co., Ltd. President
Vice Chairman	Kosuke Kato	Edwards Lifesciences Ltd. Managing Director
Director	Eriko Asai	GE Japan (GE Healthcare Japan Corporation) Managing Director, Japan Government Affairs and Policy
Director	Derrick Buddles	Stryker Japan K.K. Manager, Market Development
Director	John Harris	Nippon Becton Dickinson Company, Ltd. President & Representative Director
Director	Tamotsu Hiiro	Johnson & Johnson K.K. President
Director	Yusuke Naiki	Boston Scientific Japan K.K. President, Representative Director
Director	Kazuya Ogawa	Zimmer K.K. President and Representative Director
Director	William Phillips	St. Jude Medical Japan Co., Ltd. President
Director	Haruyoshi Sakamoto	Abbott Japan Co., Ltd. Representative Director and Chairman of the Board and President
Director	Matt Schmidt	Abbott Vascular Japan Co., Ltd. President and Representative Director
Director	R. Byron Sigel	Baxter Limited Director, Healthcare Policy and Market Access
Director & Auditor	Ryo Noda	Covidien Japan Inc. President
Advisor	Huimin Wang	Edwards Lifesciences Corporate Vice President, Japan & Asia Pacific
Advisor	Akira Matsumoto	Calbee, Inc. Chairman of the Board & CEO

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.