APACMed
The voice of MedTech

AMDD
Enabling a Healthier Japan

Value-Based Market Access Symposium: Japan

Summary Report

October 2024

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1 Content

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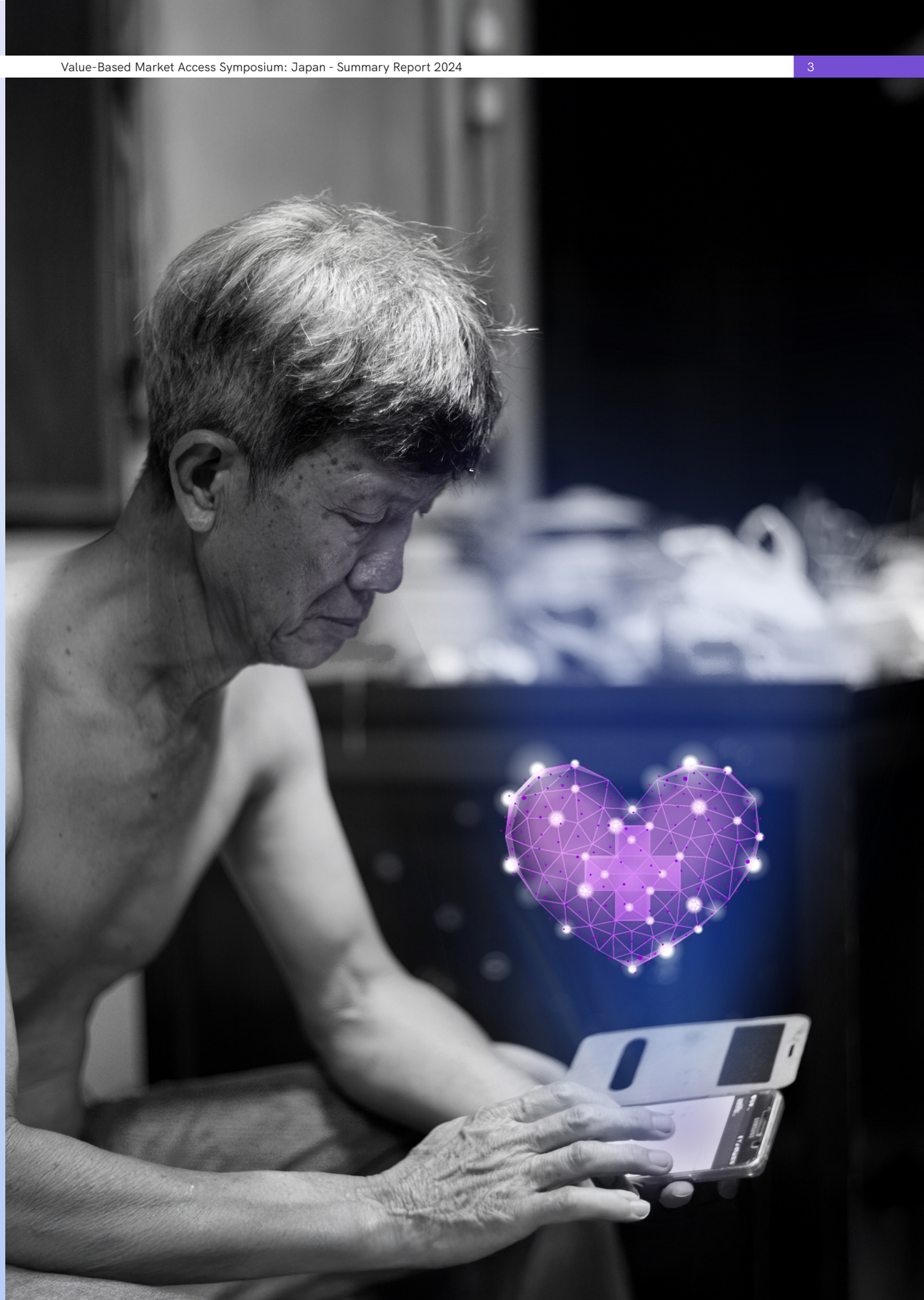


2 Introduction

Value-Based Healthcare (VBHC) has emerged as a transformative global trend, emphasizing the delivery of better patient outcomes and the efficient allocation of healthcare resources. Japan, with its unique healthcare system and advanced aging society, is no exception to this shift. The role of medical devices in VBHC is particularly significant, offering not only the potential to enhance patient outcomes and quality of life (QoL) but also to optimize healthcare costs through improved efficiency. However, the value of medical devices in achieving these objectives remains insufficiently recognized, leading to growing challenges in introducing and sustaining innovation in the Japanese healthcare landscape.

On 21 October 2024, the Asia Pacific Medical Technology Association (APACMed), in collaboration with the American Medical Devices and Diagnostics Manufacturers' Association Council (AMDD), organised a **Value-Based Market Access (VBMA)** Symposium in Tokyo, Japan. The symposium brought together policymakers, healthcare stakeholders, and industry representatives in Japan to discuss these critical challenges, with the aim to foster meaningful dialogue between the medical device industry and policymakers on the role of VBHC in Japan, emphasizing the need to align medical device policies with VBHC principles. Additionally, it introduced the concept of "MedTech-specific HTA," distinguishing it from the traditional pharmaceutical-focused HTA. This distinction will provide a foundation for shaping future healthcare policies that accurately assess the unique value of medical technologies. By examining global trends and the latest methods for evaluating medical device value, the discussions laid essential groundwork for future policy reform discussions that ensure medical devices are not only cost-managed but appropriately valued for their contribution to VBHC.

Key Definitions

Value-Based Health Care
A delivery model that centers around patient outcomes. 'Value' in value-based health care is defined as measuring health outcomes against cost for such delivery. (Adapted from, Teisberg E, Wallace S, O'Hara S. Defining and implementing value-based health care: a strategic framework. Acad Med. 2020;95(5):682-685.)

Healthcare Technology Assessment
A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system (Adapted from HTAi)

Pay for Performance
Reimbursement model where manufacturers or providers of medical devices receive payments based on the achievement of predefined performance metrics or patient health outcomes. This approach aims to incentivize quality improvement, cost efficiency, and better patient outcomes, aligning financial rewards with the value delivered by the medical technology.

> *"...This symposium marks a significant step in a collective journey to see healthcare in Japan evolve in the face of rising costs, aging population, shifting policy priorities. During this critical period, the importance of VBHC cannot be overstated. We need to re-evaluate how we deliver care, not just in terms of patient access, but in terms of achieving outcomes what truly matter to the patients, providers and policy makers alike...This event provides a unique platform for us to share innovative health technology assessment (HTA) approaches unique to medical devices, and to discuss developments in value-based payment models as we explore how these strategies can be tailored to the means of Japanese healthcare systems..."*

Anirudh Sen
Director & Head, Market Access & IVD,
Asia Pacific Medical Technology Association

3 Keynote Address #1
Value-Based Healthcare: A pathway to more equitable, sustainable healthcare

Dr. Gabriela Prada
Senior Director, Health Policy Systems,
Global Government Affairs at Medtronic
and Professor at the University of Ottawa

The economic impacts of an aging population and rising chronic diseases on the healthcare sector necessitates the shift from volume-based to value-based healthcare.

Driving Forces for Change
The increasing aging population and the rise in chronic diseases have significant and lasting economic impacts on the healthcare sector, demanding a shift towards a new paradigm. For example, in the United States, a substantial budget ($345B USD in 2019) is allocated to conventional healthcare, which hinders investments in better care and innovation. Chronic diseases, where treatment largely depends on the patient, require innovations that enable personalized treatment and home care rather than just medication for single symptoms.

Value-Based Health Care (VBHC)
VBHC defines "value" as the cost invested to achieve patient outcomes. This value can be considered from clinical perspectives (meeting pathophysiological expectations), functional perspectives (patient functionality), and quality of life (health condition improvements or unexpected changes). Transitioning from traditional volume-based payments to value-based payments promotes efficiency and better health outcomes. The criteria for reimbursement, contract and tender allocation should consider total costs (price, life cycle and total operating costs) as well as efficiency gains and healthcare outcome improvement.

Global Examples of VBHC
Globally, concrete examples of VBHC are already in action.
- Canada has implemented the bundle approach, a system to track patient progress outside hospitals, increasing support while reducing overall costs.
- In the U.S.A., insurers and manufacturers have established diabetes metrics to measure medical device effectiveness, easing the assessment of patient outcomes.
- Saudi Arabia has adopted the "Diabeter" model from the Netherlands for Type 1 diabetes, achieving significant results in reducing hospitalisation rates and costs through virtual patient tracking and labour efficiency.
- Poland's obesity treatment program has also saw medical facilities collaborating with authorities and universities to track patient value over two years.

Future Directions
The future of healthcare systems is expected to become more personalized through elements like Pay for Performance (P4P) and digital transformation. Initiating these mechanisms with small steps rather than striving for perfection from the outset is crucial for their successful implementation.

4 Keynote Address #2

Navigating the Complexities: Evaluating Medical Devices vs. Drugs

Dr. Rosanna Tarricone
Associate Dean, Bocconi University School of Management | SDA Bocconi

The challenges and innovations in assessing medical devices, highlight the need for real-world data, transparency, and adapting HTA to rapid technological advancements.

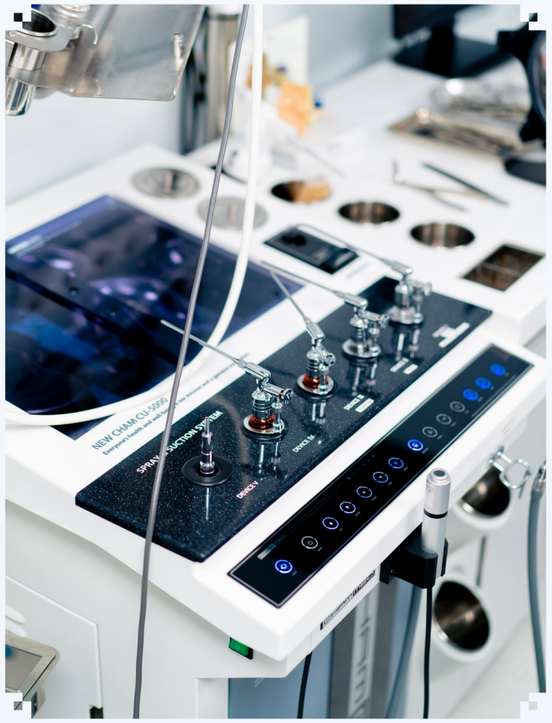
Challenges in Assessing Medical Devices
Technological innovation often outpaces economic growth, making investments in new technologies challenging. Health Technology Assessment (HTA) is crucial for conveying the true value of these technologies. However, HTA was originally developed with pharmaceuticals in mind and must account for the unique characteristics of medical devices. These include continuous innovation, the learning curve where device performance improves with use, and the organizational impacts of disruptive innovations, such as the need for new specialties, equipment, or organizational structures.

Utilizing Real-World Data for HTA
To measure the value of medical devices, countries are increasingly focusing on real-world evidence (RWE) as it can help determine whether the added value of the technological innovation is affordable.

- The European Union has invested about €25 million in a consortium to develop real-world evidence collection.
- In the United States, the FDA has issued guidance to manufacturers on generating real-world evidence for regulatory decisions regarding medical devices.
- Similarly, Canada has published guidance on reporting real-world evidence for medical devices.

Enhancing Transparency and Incorporating Patient Feedback
In the United States, multiple organizations conduct HTA, complicating transparency. Recent legislation, such as the Inflation Reduction Act of 2022, which penalizes pharmaceutical companies for high-priced drugs, could foreseeably extend to the medical device industry. To improve HTA for medical devices, it is essential to consider user experience, rapid technological advancements, organizational impacts, and to establish high-quality disease or device-based registries. Additionally, a lifecycle approach to regulation and HTA, rather than a pre-market/post-market dichotomy, is necessary to accommodate continuous evidence and the learning curve.

HTA Regulatory Overview and Future Directions
The role of HTA is growing worldwide, but its use varies between countries as either a cost-control measure or a tool for evidence-based healthcare policy. Global changes such as demographic shifts, the prevalence of chronic diseases, and the rapid pace of technological innovation demand a systematic approach to maximize resource allocation efficiently. While HTA offers a potential solution, it must adapt to the unique nature of medical devices. A seamless, integrated approach across different national systems is crucial for effective HTA.



5 Keynote Address #3

Value-Based Healthcare from AMDD's perspective

Dr. Makoto Tamura
Director, Medical Technology Policy Institute (MTPI), AMDD

In the context of an aging society with a declining birthrate, the national health insurance system faces a crisis. To maintain this system while providing better healthcare, a shift from the traditional cost-focused fee-for-service model to a value-based healthcare (VBHC) system is advocated. Proposals are made from the perspectives of three key healthcare stakeholders: patients, healthcare institutions, and individual technologies.

Patient Perspective - Expansion of the shared billing scheme / 保険外併用療養費制度
Since 2024, the scope of the shared billing scheme will expand to include medical devices, as highlighted in key policies. Shared billing scheme increases the number of treatment options for patients. Future expansion directions include extending evaluation treatments to specific insurance medical materials and addressing high-cost medical devices that are not adequately covered.

Healthcare Institution Perspective - Expanding Pay-for-Performance (P4P) for digital health technologies
The active utilization of P4P is proposed to reduce data collection costs for evaluating digital technologies, and to facilitate the evaluation of technologies that are challenging to assess standard reimbursement schemes. Metrics impacting patients should be considered for integration into the medical facility standards.

Individual Technology Perspective - Expansion of "Economic Premium"
The pricing of medical devices should consider product value rather than its cost base. It is recommended to expand "value-based pricing" to include specific insurance materials and comprehensive product fees, incorporating factors like complication reduction. Conversely, repricing based on foreign prices and market expansion should be reduced or eliminated.

6 Panel Discussion

Nizawa Takuya
Office of Medical Devices Policy, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management Health Policy Bureau, MHLW, Government of Japan

Dr. Akihiro Machitori
Head of the Department of Radiology, Kohnodai Hospital, National Center for Global Health and Medicine

Dr. Kazushige Ichinohe
Vice President, Houju Memorial Hospital

Moderator
Yuta Inokuchi
Partner, L.E.K. Consulting

Dr. Hiroshi Nakamura
Professor | Dean
Keio University

Akie Seno
Director, Market Access, APAC, Smith + Nephew

Dr. Tamura Makoto
Director, Medical Technology Policy Institute (MTPI), AMDD

1. Expansion of the Shared Billing Scheme / 保険外併用療養費制度
The expansion of the shared billing scheme, as mentioned in Honebuto policy plans, is expected to focus on ensuring that patients do not face disadvantages and that product characteristics of medical devices are considered. To enhance patient and societal value, discussions should address information asymmetry and ensure transparency to prevent conflicts of interest. For instance, providing patients with clear information and ensuring they understand their treatment options is crucial to avoid unnecessary costs. Simplifying the logic behind these treatments can help to increase the support for the expansion. Furthermore, high-cost medical devices that offer patients increased benefits such as faster recovery and reduced pain are not easily captured in the data. However, it is important to consider these benefits under healthcare insurance coverage. It will also be essential to highlight the cost benefits for healthcare institutions, such as reduced physician burden and swifter learning curves. As the healthcare landscape is in a transitional phase, continuing to provide clear logic and outcomes data to bridge information gaps and emphasize the value of medical devices will be key.

2. Introduction of Pay-for-Performance (P4P) in MedTech for Digital Health Technologies
The introduction of Pay-for-Performance (P4P) in MedTech, especially digital health technologies, has both advantageous and disadvantageous implications for Japan's healthcare system. The advantage of P4P allows for the collection of realworld data, making it possible to evaluate internal medicine technologies, which are traditionally difficult to assess. However, the disadvantages include complexity of designing appropriate metrics and the risk of upcoding, where healthcare providers might only treat patients who meet specific criteria to maximize reimbursement. To maximize value for society and patients, it is important to consider measures such as penalty systems for facilities not meeting basic performance metrics and narrowing the target patient groups to those who would benefit most, such as patients needing prevention with severe conditions. Additionally, the implementation of P4P in digital health could lead to task sharing, and cost savings by enhancing treatment adherence and reducing physician involvement. Ensuring transparent and fair evaluation criteria will be crucial to the successful adoption of P4P in the healthcare system.

3. Transition to Value-Based Pricing Tailored for Medical Devices
The shift towards a pricing system that considers the unique values of medical devices is crucial. This involves evaluating the clinical value and expanding the scope of the economic premium. The panelists emphasized the need to protect the clinical value of medical devices, recognizing the unique nature of medical devices where their effectiveness also depends on the physician's level of technical proficiency. Expanding economic value considerations to include visible benefits, such as reduced usage / cost, is encouraged. Additionally, incorporating opportunities to submit real-world data from other countries could better reflect the advantages of new technologies.

Furthermore, the panelists shared concerns with focusing solely on treatment and cost reduction for VBHC, may overlook the importance of diagnostic tools, including imaging diagnostics. It is necessary to develop models that measure the value of comprehensive diagnostics, especially for patients with multiple conditions. Utilizing real-world data to ensure the safety of evolving medical devices is also critical. The value of technologies that enhance diagnostic accuracy for specialists should be recognized, and manufacturers must clearly communicate the benefits to hospitals and patients. Proposals also include demonstrating the impact on outcomes if new technologies increase the number of tests and valuing technologies that reduce unnecessary tests and treatment-related procedures.

Considering Prof. Tarricone's presentation, adapting Japan's current HTA system to better account for the characteristics of medical devices is essential. The HTA should reflect cost-effectiveness and efficacy in reimbursement prices and this approach should consider the learning curve inherent in medical devices and the appropriate timing for assessment. However, evaluating later using real-world data based on the learning curve carries the risk of not showing significant treatment effects. It is also necessary to consider limiting the scope of additional payments to patients deemed effective based on data.

Designated Discussant
Kei Maeda
Vice President, Cranial and Spinal Technologies Japan, Medtronic

Concluding comments by a designated discussant, Ms. Kei Maeda
The healthcare industry often emphasizes tradition, but a paradigm shift towards new concepts is necessary. Discussions should focus on avoiding patient disadvantages, ensuring transparency to prevent conflicts of interest, and employing clear explanatory logic. Recognizing the importance of task sharing, economic perspectives, and informed patient engagement will drive the industry forward, promoting innovative approaches and improving overall healthcare outcomes.

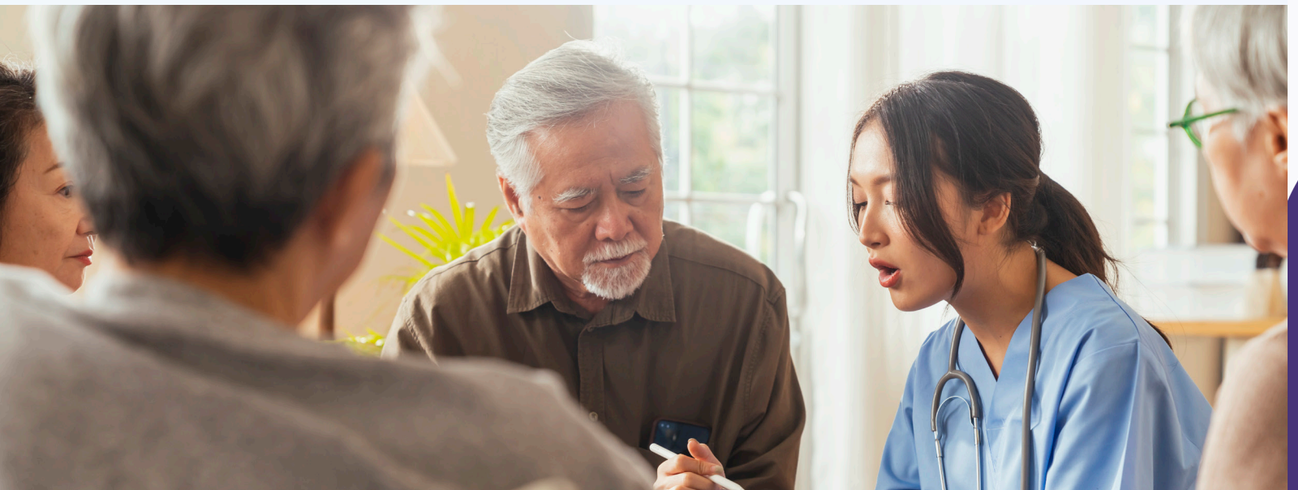
7 Call to Action

The symposium has provided a comprehensive exploration of the diverse perspectives and future directions essential for advancing the principles of VBHC. It is clear that a paradigm shift towards VBHC is critical to addressing the unique challenges posed by Japan's aging society and rising healthcare costs. By integrating innovative healthcare technology assessments, promoting value-based payment models, and ensuring that medical device policies align with VBHC principles, we can significantly enhance patient outcomes and optimize healthcare resources.

As we move forward, it is imperative that we continue fostering dialogue between policymakers, healthcare providers, and the medical device industry. Collaboration and shared commitment are key to implementing effective VBHC strategies that not only improve patient care but also ensure the sustainability of our healthcare systems. APACMed in collaboration with AMDD is dedicated to leading this charge, advocating for policies that recognize the true value of medical technologies and support continuous innovation in Japan.

> *"AMDD is committed to balancing patient choice with the sustainability of high-quality healthcare, advocating for VBHC as a key approach. Moving forward, we will continue to work diligently to support and invigorate the medical device industry in Japan, Asia, and beyond."*

Takanao Tamai
Chairperson, AMDD
President, Johnson & Johnson K. K.



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About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**.