White Paper

The Evolving Health Technology Assessment for Medical Devices and Diagnostics in the Asia Pacific Region and Key Considerations for Value Assessment Frameworks

SIRINTHIP PETCHARAPIRUCH, Principal, Real World Insights, IQVIA Asia Pacific
CALLIX WONG, Consultant, Real World Insights, IQVIA Asia Pacific

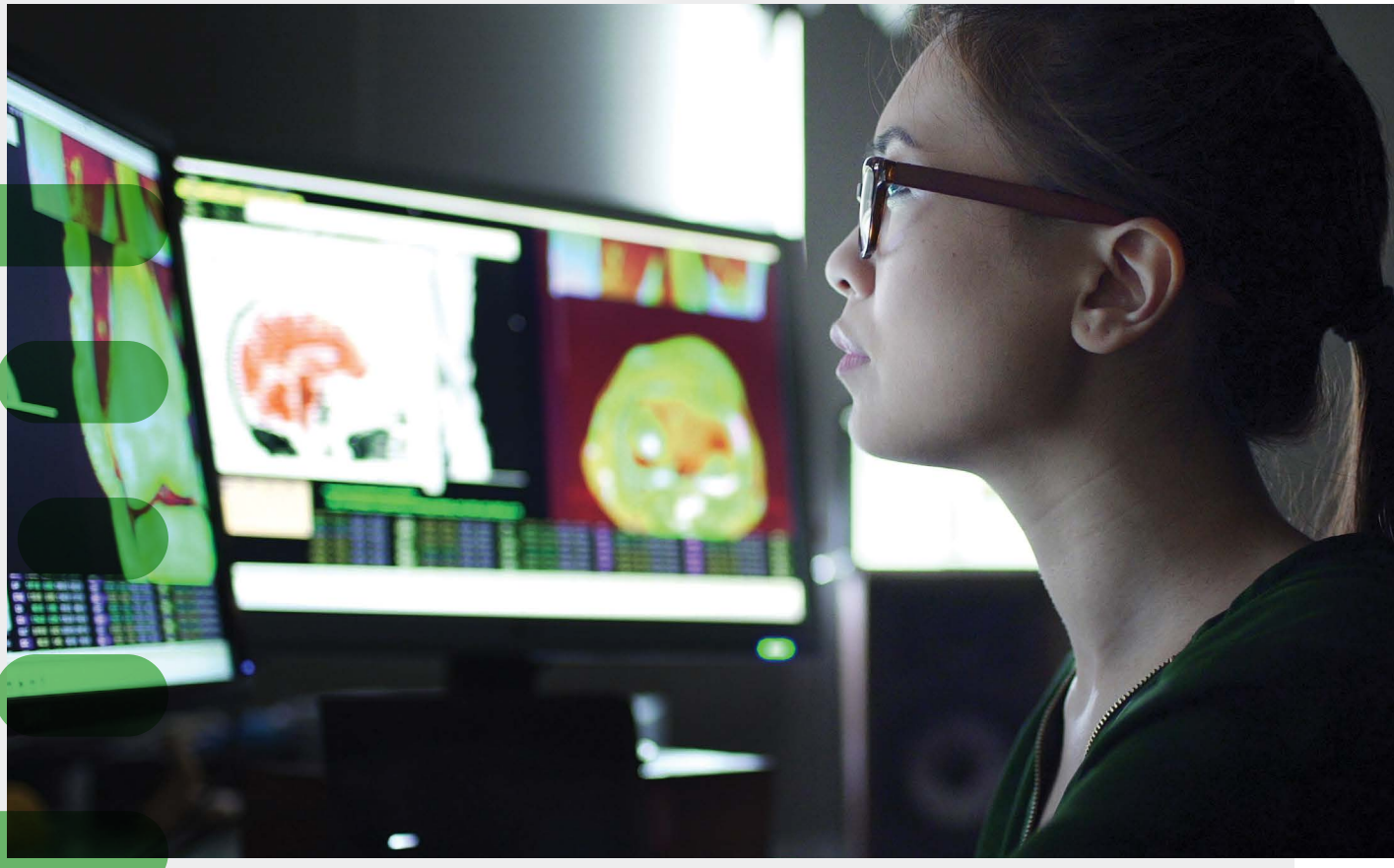

Table of contents

Foreword by APACMed

The MedTech industry is facing a rapidly changing healthcare ecosystem across Asia Pacific (APAC). Epidemiological shifts, changing regulatory and policy environments, increasing healthcare cost containment pressure, and evolving reimbursement systems are all key drivers impacting patient access to medical devices across the region. At the same time, several emerging markets have moved to, or are moving towards, universal healthcare. These changes have ignited increased interest in different methods of assessing medical technologies to inform value-based policy, pricing, and reimbursement decision-making. Among countries across the region, there are differing levels of understanding around which, when, and how medical technologies should be evaluated – and specific approaches and guidelines on the assessment of medical devices are largely absent. This landscape presents a unique opportunity for stakeholders from across the healthcare ecosystem to work together to ensure value is the heart of healthcare decision-making.

This paper, *The Evolving Health Technology Assessment for Medical Devices and Diagnostics in the Asia Pacific Region and Key Considerations for Value Assessment Frameworks* – published in collaboration with IQVIA and the Asia Pacific Medical Technology Association (APACMed), with significant contributions from key executives from the industry – sheds light on the evolving Health Technology Assessment (HTA) environment of medical devices and diagnostics (MDDs) across APAC, growing the knowledge base for agencies looking to incorporate these methodologies in their policy and reimbursement decision-making.

It explains the differentiating factors between application in the pharmaceutical versus MDD context and raises important considerations for assessing MDDs in markets across APAC. HTA and other approaches to value-based assessment should support decision-making that facilitates sustainable and timely access to technologies that improve patient outcomes.

The successful design and application of value-based assessments for medical technologies will require collaboration by, and input from, stakeholders from across the healthcare ecosystem. Industry is a vital partner in this process and welcomes the opportunity to be engaged in early dialogue with governments looking to apply value-based assessments of MDDs in their markets, working together to ensure that the methods employed are fit for purpose, support timely patient access to innovative and life-saving medical devices, and do not have unintended, prohibitive side-effects. Partnerships are at the heart of APACMed's patient-centric mission, and the Association facilitates collaboration between different stakeholders to raise awareness of, and advocate for, evidence-based policies that meet the demands of the diverse and complex healthcare markets in APAC.

This paper provides suggested principles of an ideal HTA system to promote a robust and sustainable healthcare ecosystem across APAC that encourages collaboration, investment, trade, and innovation. We hope that this will be an informative tool for governments and other stakeholders across the region and we look forward to collaborating closely to take these insights forward from paper to practice.

We are indebted to both the IQVIA team for preparing this paper and to the APACMed industry member contributors for sharing their time and expertise.

HARJIT GILL
Chief Executive Officer
Asia Pacific Medical Technology Association (APACMed)

Market access for medical devices and diagnostics (MDDs) in Asia Pacific

The Asia Pacific region is undergoing an exciting period of growth and change in healthcare. Challenges in addressing new demographic and epidemiological factors, and opportunities in the increasing adoption of universal healthcare systems, have led to the development of new and innovative healthcare products and services to help patients across the region better manage their changing health needs.

In APAC, Australia and Japan represent the largest MedTech markets, with China and India being the fastest growing markets.[1] Healthcare investment is estimated to grow by 11 percent, with expected funding of US$2 trillion dedicated to universal healthcare in APAC by 2030.[1] Key factors contributing to this growth include aging populations, increased incidence of chronic diseases, the move towards establishing universal healthcare systems with enhanced reimbursement mechanisms, and the increased government focus on the development of healthcare infrastructure.[2] This changing ecosystem presents a unique opportunity for governments, industry, providers, and consumers to work together to ensure that healthcare systems are designed to enable patient access to innovative and important medical treatments and services.

Market access solutions, co-developed by healthcare ecosystem stakeholders, seek to bring products and services to the right patient, at the right time, at the right price points. Traditionally more focused on pricing and reimbursement, the landscape of market access has evolved in recent years with the establishment of Health Technology Assessment agencies in many APAC countries. The role of the HTA agencies includes studying the value of technologies, interventions, and procedures to be included in universal healthcare schemes and supporting the coverage decision-making process of new therapies. Most of the activities thus far have been concentrated on which medicines to add to benefit packages, with the extension of HTA to device-based procedures still being in its early stages in several countries.[3]

Most HTA agencies in APAC have established HTA as one set of tools for evaluating medical technologies, following the basic microeconomic principle of comparing marginal benefit and marginal cost, and improving efficiency in resource allocation.[4]

> *"HTA is the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods."*
>
> *— International Network of Agencies for Health Technology Assessment (INAHTA)[5]*

It is important to note that HTA is just one of the available tools for the evaluation of medical technologies and, due to their unique characteristics, a one-size-fits-all approach might not be suitable in all contexts. There are several other approaches to evaluating the value of medical technologies, including Managed Entry Agreements (MEA), Most Economically Advantageous Tendering (MEAT), Multiple Criteria Decision Analysis (MCDA), among others, that have been implemented alongside HTA in some countries to improve patient access. There are instances where HTA might not be the only or the most appropriate type of assessment for patient access, so this should be considered in the decision-making process. This paper, however, specifically focuses on HTA as a tool to evaluate medical technologies and does not explore alternative approaches in depth.

Landscape of HTA for MDDs in Asia Pacific

There has been growing interest across the APAC region in assessing the value of medical technologies to inform health policy development and reimbursement decision-making. As more countries in APAC continue to adopt or refine Universal Healthcare Schemes, the general trend is shifting towards value-based healthcare.

THE RISE OF VALUE-BASED HEALTHCARE

Value-based healthcare is a delivery framework that allocates resources according to the health outcomes delivered by the healthcare system. It encourages consideration of quality, safety, cost impact, patient experience, and their participation in decision-making. It supports cost-effective care delivery and compliance with evidence-based guidelines.[6] Moving towards value-driven assessments, several international initiatives and associations (e.g. International Initiatives on the Assessment of the Value of Medical Technologies, which is a working group under the Professional Society for Health Economics and Outcomes Research, and Health Technology Assessment International) have emerged to explore both how HTA can be used as a supportive tool in the lifecycle of medical technologies to benefit patients, healthcare systems, and society; and how other novel tools and value frameworks can be used to inform decision-making and achieve healthcare system objectives.

ASIA PACIFIC'S EVOLVING HTA LANDSCAPE

Although the use of, and interest in, HTA has been increasing, HTA frameworks are at different development phases among countries, partly reflecting the different stages that healthcare systems across the APAC region are currently in. The HTA landscape in APAC is dynamic, with a mix of markets ranging from nascent to mature states. In this paper we identify three broad categories based on level of establishment of HTA system and their impact on pricing and reimbursement decision-making:

1. **Rising HTA** – These are countries in the early stages of establishing HTA bodies, systems, and processes. The role and impact of HTA in healthcare decision-making is still to be formalized, with limited resource and data for implementation of the value assessment framework. Examples of such countries include Indonesia, Vietnam, Philippines, and India.

2. **Advancing HTA** – The countries in this category have a system in place but they are still evolving. These countries may or may not have dedicated HTA agencies. The impact on healthcare decision-making is selective, especially for MDDs. Such countries include Singapore, China, Malaysia, Japan, and Thailand.

3. **Mature HTA** – Countries that fall under this category have well-established HTA bodies, systems, and processes. In these countries, HTA has a high level of impact to the countries' healthcare decision-making. HTA itself is formalized and legislation to incorporate HTA in decision-making is in place. Such countries include Australia, South Korea, and Taiwan.

Key differences in the HTA processes between some Asia Pacific countries

While some countries in APAC have established formal HTA processes, the methods vary greatly, with some countries evaluating cost-effectiveness and others assessing price as an independent criterion. Furthermore, the intended use of HTA varies, ranging from decision-making for reimbursement and coverage, procurement, or funding, to informing the development of clinical practice guidelines. Australia, Singapore and South Korea have specific guidelines available for the evaluation of MDDs (Australia's guidelines detail both process and requirements). On the other hand, Thailand has a separate chapter dedicated to the evaluation of MDDs within its HTA guidelines. Though Taiwan falls within our "Mature HTA" classification, Taiwan has not published any HTA guidelines specifically for the assessment of MDDs.

The length of the HTA process also varies, with South Korea, China, and Singapore having both full and rapid assessment processes. The latter gives priority to feasibility and timeliness of an assessment over comprehensiveness. In most cases, it is unclear how HTA is used in decision-making and how HTA adoption is linked to technology uptake within the healthcare system. Evidence required for the HTA process in APAC also varies from one country to another (See Table 1). Apart from clinical and economic evidence, countries like Australia and Taiwan also importantly consider and incorporate the patient voice in their HTA process.

At a glance: HTA landscape in APAC

AUSTRALIA

In APAC, Australia has one of the more mature HTA processes. HTA has been implemented at different levels and entities since the 1970s.[7] Currently an evaluation by the Medical Services Advisory Committee (MSAC) is required for new medical technologies entering the private healthcare market that do not have a Medicare Benefits Schedule (MBS) item describing the medical service that uses the technology. The MSAC process is essential for the development of new MBS items, for new procedures, as it enables access to new healthcare technologies. It involves a comprehensive HTA review process, which includes the submission of extensive clinical and economic evidence. There is no option for rapid review available currently. Co-dependent (health technologies that need to be combined to achieve or enhance the clinical effect) and hybrid technologies (combination of characteristics of different health technologies in one entity) are assessed jointly by MSAC and/or Pharmaceutical Benefits Advisory Committee or Prostheses List Advisory Committee depending on the technology.[8]

SOUTH KOREA

HTA in South Korea was initially introduced by academia in the 1990s and was subsequently institutionalized within the National Health Insurance (NHI).[9] The National Evidence-based healthcare Collaborating Agency (NECA) conducts HTA review, with the Health Insurance Review & Assessment Service (HIRA) assessing cost-effectiveness and affordability components. In 2007, the new Health Technology Assessment (nHTA) program for medical technologies, including in-vitro diagnostics, was introduced. During the nHTA process a clinical specialty considers the evidence for safety, efficacy, and effectiveness and makes recommendations. The final decision resides with the "Committee for nHTA," which is a 20-member committee of mainly healthcare professionals. In 2014, the Ministry of Health and Welfare (MOHW) officially implemented the "Parallel Review" program,

which allows the industry to simultaneously seek both regulatory and nHTA approvals. The program helps shorten the timeline and improves patient access to MDDs that improve lives.[10]

TAIWAN

Taiwan set up its HTA division in 2008.[11] The Centre for Drug Evaluation (CDE) performs clinical effectiveness and economic assessment of new medicines and medical devices to assist the National Health Insurance Association in reimbursement and pricing decisions of the medicine or the device.[12] Not every MDD needs to undergo the HTA process. This is mainly due to two reasons: only new medical devices need to undergo the HTA process, such as those with new functions or better clinical effectiveness, and only the medical devices with budget impact greater than 30 million TWD annually need to undergo the HTA process. A comprehensive HTA review will be requested when the National Health Insurance Administration determines it is necessary. Patients are involved in the HTA listing process through submission of their inputs on the Bureau of National Health Insurance webpage. Patient representatives are also invited by the Pharmaceutical Benefit and Reimbursement Scheme Committee as observers in evaluation meetings.

THAILAND

Thailand's first local HTA guidelines were completed in 2008. In 2013, a second enhanced edition was completed.[13] The Health Intervention and Technology Assessment Program (HITAP) works alongside International Health Policy Program and academics as the technical support bodies for the HTA process for the non-pharmaceutical package development. HTA is used to inform pricing and reimbursement decisions in Thailand[14] and is only performed on selected MDDs.

SINGAPORE

In 2015, Singapore formed the Agency for Care Effectiveness (ACE), in order to improve its decision-making process through the evaluation of clinical effectiveness and cost effectiveness for patient care. ACE serves the Ministry of Health's Medical Technology Advisory Committee (MTAC), which is responsible for providing the final recommendation to the Ministry of Health (MOH) on the decision to use public funding for medical technologies (devices, diagnostics, medical services). Public healthcare institutions can submit requests for subsidy consideration and ACE works with MTAC to select the topics for evaluation.[15] It is worth highlighting here that in the evaluation of MDDs, organizational feasibility is also considered alongside clinical and economic evidence.

JAPAN

Japan launched a formal HTA process in April 2019 after a pilot cost-effectiveness analysis project was conducted through the Japanese Ministry of Health, Labour and Welfare's Central Social Insurance Medical Council (Chu-I-Kyo) in 2016. Six medical devices were chosen for this pilot phase. The selection criterion was devices with high budget impact with the view to potentially adjust the price according to the demonstrated cost-effectiveness. Focus was on post-launch price adjustment and not reimbursement.[16] With the formalized process, HTA is used to retrospectively assess whether the premium element of the price is justified, aiming primarily at innovative devices. The current HTA process provides a certain level of engagement opportunity between industry and government. However, it does not offer an opportunity for patient engagement yet.

CHINA

China is increasingly integrating HTA into their healthcare and pricing systems. HTA organizations in China have different institutional formats, e.g. governmental institutions, university-based centers, consultancies, and industry-based centers at both national and local levels with varying HTA processes. China National Health Development Research Centre

(CNHDRC), under the National Health and Family Planning Commission, is one of the key governmental institutes that guides and strengthens the implementation of HTA. Recent developments have seen HTA being used for price negotiations and procurement but it is still sporadic and not fully embedded into policy-making as a mandatory component.[17]

INDIA

In 2018, India established an assessment body, HTA India (HTAIn), with the aim of evaluating a number of selected medical technologies. Central and state health ministries, or any government healthcare provider or agency directly or indirectly involved in the health sector in India can submit their topic(s) to the HTAIn for assessment.[18] Another way of taking up topics is through the National Health Innovation Portal.[19] HTAIn seeks to assist in policy-making and clinical decision-making, and empowering the public to make better decisions on healthcare. Topics are prioritized based on population size; disease severity; potential therapeutic and economic impact; availability; and the relevance of evidence and health policy priority.[20]

Table 1: Evidence requirements for HTA in some APAC countries

	Availability of HE guidelines	Clinical evidence consideration			Economic evidence consideration		Other considerations
		SLR/MA	RCT	RWE	BIA	CEA	
AUSTRALIA	✓*	✓	✓	✓	✓	✓	Patient voice is incorporated in the HTA process
SOUTH KOREA	✓*	✓	✓	✓	X	Optional	—
TAIWAN	✓	✓	✓	✓	✓	Optional	Patient voice is incorporated in the HTA process
SINGAPORE	✓*	✓	✓	✓	✓	✓#	Organizational feasibility of MDDs
CHINA	✓†	✓	✓	✓	Optional	Optional	—
JAPAN	✓	✓	✓	✓	✓	✓¥	—
THAILAND	✓*	✓	✓	✓	✓	✓^	—
INDIA	✓	✓	✓	✓	✓	✓	—

HE; health economic, RCT; randomized-controlled trial, RWE; Real World Evidence, SLR; systematic literature review, MA; meta-analysis, BIA; budget impact analysis, CEA; cost-effectiveness analysis

* MDD-specific HTA guideline/process is available
† Academia-led health economic guidelines
# Only if full evaluation is initiated
^ Only for selected MDDs
¥ Only applicable for MDDs that are expecting a peak annual revenue in excess of 10 billion JPY. If the MDD manufacturer can justify otherwise, MHLW does not require a CEA submission

Value assessment of MDDs

The ultimate goal in assessing the value of MDDs is to ensure a patient-centric healthcare delivery and timely access to the care that the patients need, when they need it. At the same time, the objective is to also ensure that high-quality care is affordable, sustainable, and improves patient outcomes.

There are a number of unique considerations when it comes to assessing the value of MDDs, such as the differences in the usage of a device in various medical contexts, differences in the available evidence, and discrepancies in assessment criteria across APAC countries. Transparency and collaboration between healthcare stakeholders, however, remains the consistent and crucial consideration in bringing innovative and important healthcare products to patients.

SPECIFIC CHALLENGES IN THE EVALUATION PROCESS AND IMPLICATIONS

Successful HTA requires the assembly of relevant evidence, which differs from one technology to another. Historically, value assessment frameworks that have been developed to evaluate a healthcare technology have often been used to assess new medicines as compared with medical devices. Over time, researchers and HTA officials have started to recognize that characteristic differences between medicines and devices lead to differences in the available data and evidence.[21,22,23,24] These inherent differences arise from factors such as the administration and function; clinical evidence generation processes, study conduct and requirements; and product lifecycles of medicines as compared with those of MDDs. In addition, specifically for MDDs and as opposed to the case of medicines, pre- and post-operative care play significant roles, making it important to account for both phases when considering the value assessment of MDDs.

Within MDDs there are further differences, such as those between therapeutic devices and diagnostic devices, which are worth noting when considering their value assessment. While certain assessment methods developed for medicines are sometimes also applied to therapeutic medical technologies, the assessment of diagnostic devices may be more complex.[4] Most diagnostic devices are embedded within the complex process of care delivery, spanning across different disease areas, and are often assessed as part of an intervention or within a group of similar technologies, making the evaluation and comparison process challenging.

Given these differences a separate HTA process is recommended, one that recognizes the key differences between MDDs and medicines as described in Table 2. It is also suggested to evaluate and consider the validity of enriching the currently available data with other data sources such as Real World Evidence (RWE), comparative cohorts, and Patient-Reported Outcome Measures (PROMs) registries as alternative sources of evidence, especially in cases where a particular device is limited by its study size and or representative patient population. The use of standardized approaches such as PROMs for prospective collection of data, such as in the case of registries, is also suggested in order to ensure that the information collected is consistent and comparable across geographies for use in the value assessment of MDDs.

Incorporating HTA methods early in the lifecycle of a technology, prior to widespread dissemination, is also proposed. Early scientific dialogue between the manufacturer and HTA agency may help to identify the optimal time to undertake HTA, considering the availability of evidence needed to inform decisions on adoption. This is particularly relevant and important for devices associated with a “learning curve,” whereby their effectiveness can only be properly evaluated once healthcare professionals have adjusted their practice to incorporate the new technology. It is encouraging to see that some HTA agencies in APAC have already started developing approaches specific to the assessment and appraisal of MDDs.

Table 2: Inherent differences between medicines and MDDs

CHARACTERISTICS	MEDICINES	MDDs	CONSIDERATIONS
INTEGRATION INTO MEDICAL PROCEDURE	• Patient outcome is dependent on adherence and correct dosage administration	• Patient outcome is dependent on skill of physician and occurrence of "learning curve," in which users are less skilled at the start of adoption of the device and get more experienced with time	• For physicians – Ergonomics and experience of physicians using the medical device • For patients – Adherence to medicines
CLINICAL EVIDENCE	• Most new medicines must have evidence from RCTs for regulatory approval (with some exception of oncology products due to feasibility) • Where differences in endpoints are small, large trials are required to prove statistical significance • Randomized controlled trials are feasible in most cases	• Fit-for-purpose evidence that is designed to meet the needs of regulatory bodies • Double-blinded, randomized controlled trials may be feasible in some, but not all cases. For example, sham procedures may be unethical	• Be open and flexible to all forms of evidence that address the scientific questions • More patients might not necessarily mean better evidence
AVAILABILITY OF PHYSICIANS AND QUALIFIED CLINICAL SITES FOR CLINICAL STUDIES	• In general, drug trials have fewer issues when compared to MDD trials in relation to qualified site and physician availability	• Limited, as it usually requires established infrastructure (e.g. suitable facility for a high-tech device) or certified trained personnel	• Ensure infrastructure and capability building by the time of implementation
PRODUCT LIFECYCLES	• Long development and patent life	• Shorter development cycle and rapid incremental changes • Regulatory systems do not always require patient-level evidence	• Update HTA processes for MDDs, when appropriate, with new comparators with similar technology and similar benefits

Considerations for developing robust value assessment frameworks for MDDs

The evaluation process for medical technologies needs to encompass a diverse range of technologies, including dressings, sutures, orthopedic implants, drug-eluting stents, hand-held glucose meters, scanners, and implantable cardiac defibrillators. The evidence requirements for class of devices may differ,[25,26] thus, a one-size-fits-all approach may not be suitable or flexible enough to assess multiple types of MDDs.

HTA is certainly an important tool when considering value assessment frameworks for any healthcare technology but should not be the only criteria considered for decision-making. Other considerations such as clinical need and equity should also be taken into account for a thorough evaluation of value of medical technology.

The rising trend in adoption of HTA-based decision-making in APAC demonstrates the shifting mindset towards value-based healthcare, which is encouraging for all healthcare stakeholders. When it comes to applying the principles of HTA to MDDs, however, there needs to be some criteria in place that addresses the uniqueness of MDDs as compared with medicines. Based on the expertise of a number of

industry stakeholders, and their experience working with various HTA organizations and processes globally, the following principles have been proposed for consideration to aid in establishing a well-designed and effective health technology assessment system for MDDs:

CLEAR CRITERIA FOR ASSESSMENT	Clear, transparent, public criteria to determine which devices require evaluation, allowing interested stakeholders to plan for budgets, workforce training, and appropriate healthcare infrastructure.
CLEARLY DEFINED ROLES	Clear purpose of HTA ensuring effective, efficient, and well-understood processes.
TRANSPARENCY OF PROCESSES AND DECISION-MAKING	Transparent assessment methodologies and data requirements to facilitate planning (e.g. when to submit a request for assessment or input) increasing the confidence of all involved stakeholders in the assessments (e.g. patients, healthcare providers, manufacturers, decision-makers).
MULTIPLE OPPORTUNITIES FOR PUBLIC INPUT	Structured mechanism to receive inputs from patients, manufacturers and the clinical community through written submissions and in-person meetings at various stages of the assessments.
INCORPORATE CLINICAL AND EXPERT ADVICE IN THE DECISION-MAKING PROCESS	Decisions to involve input from specialists in the disease area on the benefits delivered by the technology. Experts' opinion on the available evidence, current treatment options, patient mix that would benefit from the technology in a real world setting to be considered.
CONSIDER ALL TYPES OF EVIDENCE	Clinical evidence from RCTs, single-arm studies, as well as real world studies (registries, post-marketing studies, claims databases, etc.).
CLEAR EVALUATION METHODS AND SUBMISSION GUIDELINES	HTA guidelines for MDD evaluations need to be distinct to those for medicines, taking into account the inherent differences between the two. HTA guidance should be transparently developed incorporating feedback from all important stakeholders in the MDD HTA pathway. Guidance should be updated regularly to reflect the evolution in HTA evaluation methods.
RECOGNIZE DISTINCTIONS BETWEEN MEDICINES AND DEVICES, AND AMONGST THE WIDE RANGE OF DEVICES AND DIAGNOSTICS	HTA should appropriately recognize the differences between medicines and devices, improving the quality of assessments and ensuring timely market access.
REASONABLE AND PREDICTABLE TIMELINES	Reasonable and predictable timelines for public input, assessment and decision facilitating planning.
OPPORTUNITY TO "APPEAL" DECISION OF HTA AGENCY	Formal or informal mechanism to appeal decisions of HTA agencies providing an opportunity for manufacturers to share relevant data and information to the HTA agencies.
CONFIDENTIALITY OF COMPANY DATA	Example of such data include sales data and strategic partnerships.
RAPID OR SHORTER REVIEW PROCESSES	Given the short lifecycle and ongoing incremental improvement of medical devices, the review process should be reasonable and not prolonged.
ALLOW COVERAGE/FUNDING WITH EVIDENCE OR CONSIDER ALTERNATIVE APPROACHES IN CASES WHERE LIMITED EVIDENCE IS AVAILABLE	Coverage with evidence development could be a mechanism for providing access to innovative technologies for patients, while addressing concerns about uncertainty in the evidence related to the use of that technology in routine clinical practice.
IMPLEMENTATION POST EVALUATION	In order for HTA to impact patient outcomes and optimize costs, the HTA findings, positive or negative, need to be implemented and monitored effectively, in order to ensure that the original investment in conducting HTAs is valuable as well as to ensure that findings are being implemented in a fair and even-handed manner.[27]
CONSIDER MULTIPLE CRITERIA FOR DECISION-MAKING	In addition, considerations such as unmet clinical need, equity, and budget impact should also be taken into account while assessing the value of MDDs.

Case study: Singapore – expanded access[28]

In Singapore, Unilateral Cochlear Implant (UCI) is currently subsidized for children (<18 years old) with severe-to-profound sensorineural hearing loss in both ears. Children with UCI would typically use a hearing aid (HA) in the contralateral ear (UCI-HA), which may not provide optimal functional hearing benefits. In the evaluation process, evidence was provided to show that Bilateral Cochlear Implant (BCI) demonstrated similar short-term safety and low device failure rate, and was associated with improved sound localization, and similar or improved speech perception and language development. Information from additional sources also demonstrated that the benefits of BCI exceed its costs. The local cost-effectiveness model showed that usage of BCI would be higher, but the quality-adjusted life years (QALYs) gains versus the comparator likely made it an acceptable use of healthcare resources.

The way forward

The Asia Pacific MedTech industry is undergoing a period of exciting growth and rapid innovation. There is great opportunity for new and emerging medical technologies to transform the ways in which healthcare is conceptualized and delivered, improving patient outcomes, quality of life, and supporting the enhancement of health systems.

Furthermore, the growing trend in the adoption of HTA-based decision-making frameworks in APAC demonstrates the shift in mindset towards value-based healthcare, which can improve patient access to innovation and encourage manufacturers to continue to develop innovative technologies that improve lives.

Well-designed, value-driven medical technology assessments can speed up the availability of new technologies for patients, lead to better care and optimal outcomes for patients, increase treatment choices, reduce financial waste for patients and healthcare systems, and spur innovation.

The design of transparent and collaborative HTA systems (including early scientific dialogue between relevant stakeholders) is instrumental to expanding patient access to care. There are several vital stakeholders informing the design and implementation of successful HTA systems, including government, industry, researchers, providers, and crucially, patients. Early collaboration between industry and academia or hospitals (e.g. centers of excellence for MDDs), including vital stakeholders, can be leveraged to produce local, specific, and meaningful evidence to inform HTA and decision-making processes. This collaboration can also be expanded to a more formalized ecosystem that supports the HTA assessment process.

Transparent and collaborative HTA system design is instrumental in expanding patient access to care.

While guidelines and dedicated processes are not yet available for HTA in MDDs in certain APAC economies, the principles for an ideal HTA system outlined in this paper can be used as the starting point for discussions

when developing an optimal system design. Training and education sessions with experts from across the region and the globe may be useful for capacity building and sharing best practices. Collaboration between multiple stakeholders such as government, payers, healthcare providers, patients and the industry is key to realizing the goal of an affordable and sustainable healthcare system.

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About the authors

SIRINTHIP PETCHARAPIRUCH
Principal, Real World Insights, IQVIA Asia Pacific

Sirinthip leads and manages the Health Economics and Outcomes Research (HEOR), Real World Evidence, HTA, and market access business for IQVIA, Asia Pacific with a focus on regional Asia Pacific and South East Asia markets.

With over 12 years of extensive experience in roles generating HEOR and Real World Evidence to support product strategy and HTA submissions, her areas of expertise lie in developing pricing and market access strategies, aligning data to evidence requirements in the HTA market, and usage of Real World Evidence to support health care decision making.

Sirinthip is a pharmacist by training and she holds a Master's degree in Healthcare Research from Queen Mary, University of London, and a Postgraduate Certificate in International HTA, Pricing and Reimbursement from the University of Sheffield.

CALLIX WONG
Consultant, Real World Insights, IQVIA Asia Pacific

Callix is a consultant with IQVIA's Health Economics and Outcomes Research (HEOR) team in Asia Pacific.

In her current role, Callix manages and delivers various projects related to HEOR, HTA and market access within the APAC region. She has a diverse background in healthcare and over 11 years of experience spanning from clinical to commercial setting in both public and private sectors, with deep expertise in market access and health economics. Prior to joining IQVIA, she held marketing and market access roles in several pharmaceutical MNCs, with proven track record in pricing and reimbursement.

Callix holds a Bachelor of Pharmacy from The University of Science Malaysia and an MSc in Health Economics and Decision Modelling from The University of Sheffield, U.K.

Primary contributors

VIRGINIA PRIEST, Head of Health Economics and Market Access, Asia Pacific, Boston Scientific

DR. VIVA MA, Outcomes Research Lead, Health Economics and Outcomes Research Centre of Excellence, Great Asia, Becton Dickinson

DR. ANH BOURCET, Director, ASPAC Health Economics and Market Access, Health Outcomes, Global Orthopedics and Biosurgery, Johnson & Johnson

MARIANNE HUYNH, Healthcare Economics, Health Policy and Reimbursement Partner, ANZ, Medtronic

DR. PINAKI GHOSH, Manager, Market Access and Health Economics, B. Braun

ELIZA CHONG, Former Head of MedTech Consulting, Asia Pacific, IQVIA MedTech

EVANTHIA ACHILLA, Former Senior Consultant, Real-world Insights, IQVIA Asia Pacific

Other contributors

CAITLIN ASJES, Director, Public Affairs, Greater Asia, Becton Dickinson

DR. SANG-SOO LEE, Senior Healthcare Economics and Government Affairs Director, North Asia (Korea and Japan), Medtronic

DR. LIESL STRACHAN, Director, Global Health Policy, Reimbursement and Health Economics, Medtronic

JEGATHESWARAN PANDERENGEN, Health Economics and Market Access Manager, Asia Pacific, Boston Scientific

GEORGIA SWAN, Manager, Government Affairs and Market Access, APACMed

AVIK SARKAR, Associate Consultant, Strategic Marketing, IQVIA Asia Pacific

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CONTACT US

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