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Webinar Summary

Health Technology Assessment (HTA) for Medical Devices in Asia Pacific

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With inputs from:
APACMed, INTAGE Healthcare

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1. Introduction

The healthcare landscape in Asia Pacific (APAC) is evolving and patient access to medical devices is impacted by policy changes, reimbursement practices and rising healthcare costs. Governments take a multidisciplinary approach and are turning to various methodologies to determine the value of medical technologies to inform policy, pricing and reimbursement decisions.

Health Technology Assessment (HTA) is one of the methodologies used to inform decision-making and promote an equitable, efficient, and high-quality health system. While the use of, or interest in HTA has been increasing in APAC, the HTA landscape in APAC remains dynamic with frameworks and application differing among countries.

At present, Australia, South Korea, and Japan stand out as large medical technology markets in the region with well-established and constantly evolving HTA systems for evaluating medical devices. It is, however, important to note that the methods, processes and the intended use of HTA for medical devices vary in these markets and there is currently no single HTA framework that can be applied across markets.

The HTA for Medical Devices in Asia Pacific webinar, hosted by APACMed on 29 February, zoomed in on the HTA landscape in Australia, South Korea, and Japan, with expert speakers from Avalere Health and INTAGE Healthcare discussing variations in methods, processes, and the intended use for medical devices across these countries.

2. Contextualising HTA for Medical Devices in APAC

Presented by Jeff Weisel (Senior Strategic Advisor) from Avalere Health

While HTA is used by payers to achieve the objectives of determining whether products and procedures provide a differentiated value to incumbent technologies, these objectives are in turn set within a broader context of a country's healthcare policy environment. Governments in the region are taking different paths to balancing equitable access with the value of innovation, based on the level of population coverage, as well as the range of covered products and procedures.

For example, middle-income countries often limit covered products and focus only on costs, resulting in patient access to fewer new innovations. In contrast, higher-income countries such as South Korea, Australia, and Japan use HTA to optimize the cost and usage of a product, and generally include coverage of new innovative technologies that meet their clinical and economic criteria.

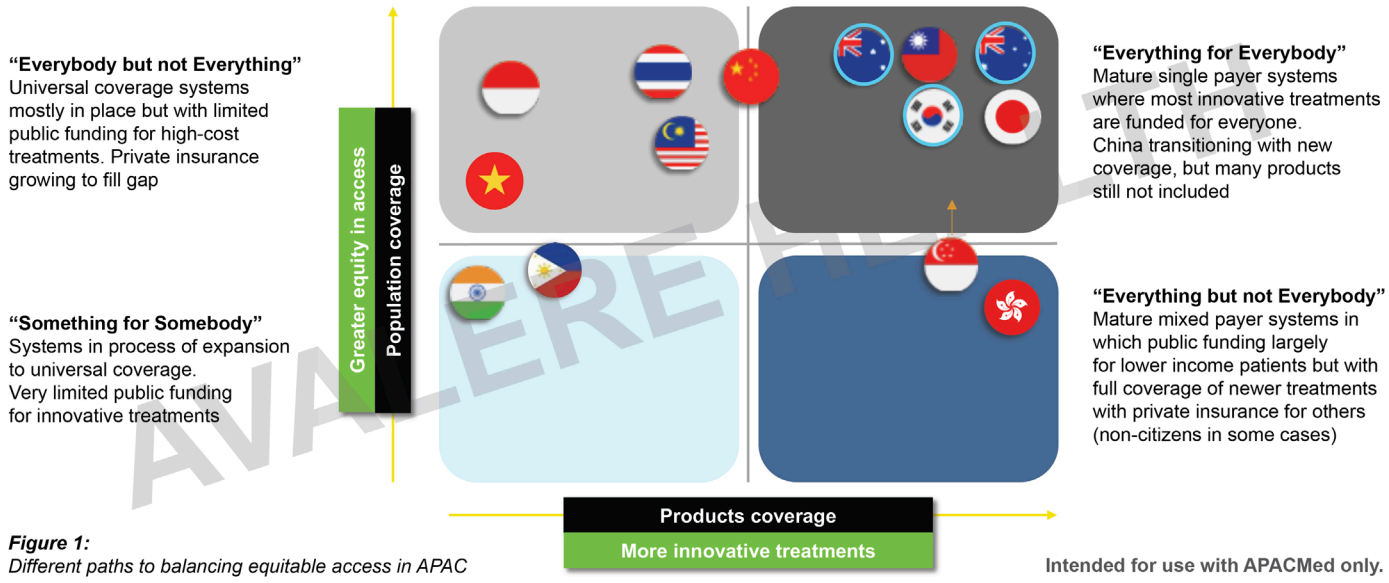


Figure 1:
Different paths to balancing equitable access in APAC

3. Deep Dive into HTA Practices for Medical Devices

3.1 South Korea and Australia

Presented by Dr Smarth Lakhanpal (Associate Director) from Avalere Health

3.1.1 The role of HTA in medical device reimbursement in South Korea

In South Korea, new medical technologies gain regulatory approval from the Ministry of Food and Drug Safety (MFDS) before reaching the market. Two HTA agencies, the National Evidence-based Healthcare Collaborating Agency (NECA) and Health Insurance Review and Assessment Service (HIRA), play a crucial role in determining adoption. The New Health Technology Assessment (nHTA) conducted by NECA categorizes technologies to determine whether they are eligible for health insurance review / reimbursement coverage determination by HIRA. NECA performs nHTA by conducting a systematic review of the safety and effectiveness of new non-pharmaceutical technology (including associated clinical procedures). HIRA, more specifically the Medical Device Expert Evaluation Committee within HIRA, plays a central role by reviewing evidence (submitted by manufacturers, institutions, or societies) to assess the device's value for reimbursement by the Ministry of Health and Welfare (MoHW). Based on this HTA (and reference pricing), HIRA recommends a reimbursement price to the MoHW. For decision making on premium pricing for new products, HIRA performs a multi-criteria decision analysis which considers a variety of evidence, including clinical and pharmacoeconomic evidence, real-world evidence, and improvement in patients' quality of life.

Notably, all medical technologies, regardless of their intended market (private or public reimbursement), require HTA evaluation by HIRA.

Furthermore, South Korea has introduced special pathways to accelerate patient access to new medical technologies, including parallel review pathways, conditional approval for evidence development, and rapid assessment for in vitro diagnostics/genetic tests. These initiatives demonstrate South Korea's commitment to facilitating timely access to cutting-edge medical technologies while ensuring thorough evaluation and evidence-based decision-making.

3.1.2 The role of HTA in medical device reimbursement in Australia

In Australia, medical devices are funded within a diagnosis-related groups payment system which applies to public hospitals and often covers the cost of technologies associated with specific diagnoses or procedures. If a new medical device or service is not covered by the Medicare Benefits Schedule (MBS), an evaluation by the Medical Services Advisory Committee (MSAC) is required that evaluates both the technology and the services associated with the technology. Following MSAC's recommendation, and prior to MBS listing, schedule prices of medical devices are recommended based on MSAC assessment results.

MSAC conducts a comprehensive HTA review primarily relying on pharmacoeconomic evidence for establishing technology benefit. With regard to pharmacoeconomic evidence, particularly for establishing superiority, a cost-effectiveness analysis is needed. In other cases, a cost minimization approach is followed. A budget impact assessment is needed for all assessments. Similar to South Korea, Australia applies strict HTA evidence requirements, with a systemic literature review of randomized controlled trials considered the highest level of evidence. However, MSAC recognizes the challenges of producing such evidence across different diagnostics and devices, and has defined other approaches to evaluating clinical evidence, such as a direct from test to health outcome evidence approach or a linked evidence approach for investigative technologies. Importantly, ethical and equity issues are also key considerations during the evaluation process.

3.1.3 Recent and upcoming HTA reforms, key learnings, and opportunities for improvement

Across South Korea and Australia, HTA guidelines for medical devices are evolving for medical technologies such as digital therapeutics and AI-based diagnostics. For example, in 2023, South Korea introduced changes in the coverage of advanced medical technologies, where health insurance will include advanced medical technologies such as digital therapeutics and AI-based diagnostics.

In Australia, the Protheses List reforms are underway, and the independent HTA Review conducted by Medicines Australia may not only impact the HTA of pharmaceutical products but may also have downstream implications on medical devices.

The HTA processes for medical devices in both South Korea and Australia share the following key themes, providing key learnings for other markets:

- Pivotal role of HTA assessment in determining device coverage in both public and private settings
- Consideration of factors beyond clinical and economic implications
- Acceptance of real-world evidence (RWE) under strict conditions
- Parallel regulatory and HTA processes to expedite patient access

Each country also offers unique key learnings. For example, South Korea allows for coverage with evidence development for certain cases (e.g. IVD), and Australia remains open to active stakeholder engagement in the HTA process.

Opportunities for future improvement have been identified for each country. For South Korea, the HTA process may benefit from enhanced involvement of patient advocacy groups. For Australia, there has been a call for better coordination between HTA bodies, as well as more formal pre-submission meetings to clarify evidence submission requirements for manufacturers.

3.2 Japan

Presented by Michael LoPresti (Executive Director and Director, Value & Access) from INTAGE Healthcare Inc.

3.2.1 Medical device reimbursement

In Japan, reimbursement generally applies to non-standard and/or single-patient use devices, while other standard products are paid through procedure (technical) fees. The reimbursement process for medical devices involves a submission to the Ministry of Health, Labour, and Welfare (MHLW) after marketing approval, with the Central Social Medical Insurance Council (Chuikyo) serving as an advisory board group designated by the MHLW to consider reimbursement topics. Novel devices that offer a new benefit over existing products are primarily reimbursed using the similar functional category comparison method (SFCM), which uses a similar product in the market as a benchmark for reimbursement calculation.

Reimbursement of the new device is then determined by considering whether it deserves premiums based on the value it contributes or if it targets a more specific indication. In contrast, if there is no comparable product in the market, a Cost Calculation Method (CCM) is used: The manufacturer proposes a baseline cost, and additional factors such as operation profit ratio, distribution costs, and consumption taxes are added. Premiums similar to the SFCM may apply but may be reduced based on disclosure level.

Foreign reference pricing may come into play after determining the device's price, resulting in adjustments either up or down.

3.2.2 The role of HTA in post-listing reimbursement price adjustment

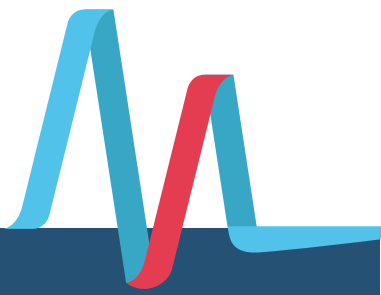
In April 2019, Japan introduced a new HTA process whereby selected reimbursed drugs and devices with a high anticipated market size may face a downward adjustment in the reimbursement price if they cannot demonstrate cost-effectiveness. Drugs and devices that receive an innovation, usefulness, or improvement premium and have an estimated peak sales of JPY 5 billion or more may be asked to submit cost-effectiveness results, and products that are considered expensive may also be asked to submit a cost-effectiveness analysis.

Since the introduction of the new HTA process, newly reimbursed drugs have more commonly been selected for HTA review compared with newly reimbursed devices. Out of about 102 reimbursed devices, only three have been selected: their premiums ranged between 5% to 10%, and the initial reimbursement price was generally at a level similar to or less than the average foreign reference price. All three devices were selected based on the JPY 5 to 10 billion peak annual sales threshold. Based on the analysis of the HTA review completed for two of the selected devices so far, a downward price adjustment was applied due to differences in outcomes between manufacturer-submitted analyses and the public analysis, such as the lack of adjustment for covariance in quality of life data submitted by the manufacturer.

3.2.3 Current challenges and future changes

Current challenges related to the HTA process for medical devices in Japan include:

- Limited time to discuss/debate the design of the study, and no direct communication with the public analysis group reviewing the cost-effectiveness analysis submitted by manufacturers
- Difficulty in fitting cost-effective analysis and HTA principles into the existing reimbursement process, as premiums are allowed for "usefulness" based on limited data which are difficult to validate through a cost-effectiveness process
- Need to consider a broader view of value, including indirect costs and nursing costs. As Japan is facing a shortage of healthcare professionals, how new devices can help alleviate the burden of healthcare professionals could become a consideration in the future
- Uncertainty and lack of clarity about the reimbursement process and the evidence requirements



Looking ahead, the 2024 revisions of the HTA process are anticipated to make allowance for manufacturers with insufficient resource for the HTA process —however, this may lead to a public analysis being conducted without any reference to the manufacturer's analysis. Additionally, the analysis guidelines are anticipated to introduce some updates, such as excluding some patient populations if their exclusion is thought to have a limited impact on the overall results.

4. Role of Industry in Shaping Value Assessment of Medical Technologies and Optimizing Patient Access

Presented by Jeff Weisel (Senior Strategic Advisor) from Avalere Health

Industry can play a key role in engaging with government stakeholders to develop assessment methodologies that better recognize the value of innovative medical technologies. This may include the following:

- Track policy developments at various levels and understand the broader policy landscape
- Develop advocacy based on evidence, particularly highlighting the unique data requirements for medical devices compared to pharmaceuticals
- Advocate for frameworks that recognize the broader societal impact beyond technical aspects
- Understand and highlight the perspective of patients and caregivers as important stakeholders
- Engage with HTA bodies early in discussions to align submissions with their requirements

Our Speakers

Jeff Weisel, Senior Strategic Advisor, APAC, Avalere Health

Jeff has more than 25 years' experience in APAC and other emerging markets, working with leading life science and MedTech organisations on issues of strategic and business innovation, and access to healthcare. His experience has encompassed executive positions in the pharmaceutical industry and leadership of Big 4 consulting practices. In market access leadership roles with AbbVie and Novartis, he helped deliver the success of top global brands and he also played a key role in industry policy engagement with PhRMA. He has extensive experience in the area of innovative financing models with both public and private payers. He has served on the Board of Governors of AmCham Singapore, lectured on market access strategy at ESSEC Business School, been a regular speaker and moderator at APACMed events and contributed to the development of the life sciences sector in Singapore through appointments in government and academia. Jeff holds an MA in Asian Studies and Economics from George Washington University.

Dr Smarth Lakhanpal, Associate Director, Avalere Health

Smarth has more than 5 years of experience in health economic, price forecasting, and market access consulting in Asia Pacific. He has previously supported delivery of successful commercialisation strategies for life science innovations including medical technologies. His range of expertise includes new technology due diligence, early pipeline assessment, P&R assignments and HTA submissions across multiple therapeutic areas including oncology, chronic diseases, medical diagnostics, and rare diseases. He also has experience in leading multiple global strategy projects. Smarth holds a PhD in Biological Sciences from National University of Singapore.

Michael LoPresti, Executive Director and Director, Value & Access, INTAGE Healthcare Inc.

Michael is Director of the Value & Access at INTAGE Healthcare, a leading marketing intelligence provider and CRO based in Japan. He has been working in the healthcare industry for over 20 years with over 10 years dedicated to reimbursement strategy development and HEOR evidence generation for Japan. Michael has published papers on the assessment of novel healthcare technologies in Japan and is an expert in Japanese reimbursement policy – having supported with over 300 reimbursement strategy projects for Japan. Michael has two M.S. degrees (Economics and Demographics) and is fluent in spoken and written Japanese.