# Advancing Health Technology Assessment for Sustainable Universal Health Coverage

## Project Final Report

APEC Health Working Group

May 2025

Asia-Pacific Economic Cooperation

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# 1. Introduction

To achieve universal health coverage, it was essential for governments to ensure all individuals had access to necessary services and care without facing financial difficulties. However, the rising costs of health has become a crucial challenge for governments. To address this challenge, Health Technology Assessment (HTA) had been conducted to assist governments in making informed decisions and determining reimbursement processes for new medicines, innovative healthcare services, and policies as well as enhancing the overall efficiency and sustainability of healthcare systems.

Furthermore, to cope with these challenges, Chinese Taipei proposed the "Advancing Health Technology Assessment for Sustainable Universal Health Coverage" project to provide a platform where member economies could exchange experiences and learn from each other. The focus was on three topics: (1) Towards Universal Health Coverage: the Vital Role of HTA (2) The Impact Stories of HTA (3) Advancing HTA: Navigating Challenges, Building Opportunities, and Fostering Collaboration. The workshop comprised of speeches, panel discussions, and a site visit to a smart hospital (Chang Gung Memorial Hospital).

## I. Organizing the APEC workshop

The "APEC Workshop on Advancing Health Technology Assessment for Sustainable Universal Health Coverage" was organized by the Ministry of Health and Welfare, Chinese Taipei. This workshop was held in Taipei on 3-4 September, 2024 (GMT+8). The event engaged 16 speakers/experts and attracted around 100 participants from 13 APEC economies, including Australia; Canada; Indonesia; Japan; Republic of Korea; Malaysia; Peru; the Philippines; Singapore; Chinese Taipei; Thailand; United States; and Viet Nam.

**Day 1** consisted of 3 plenary sessions including panel discussions. The topics were as follows,

(1) Plenary 1: Towards Universal Health Coverage: the Vital Role of HTA
(2) Plenary 2: The Impact Stories of HTA
(3) Plenary 3: Advancing HTA: Navigating Challenges, Building Opportunities, and Fostering Collaboration

**Day 2** consisted of a half-day workshop and a site visit to Linkou Chang Gung Memorial Hospital

## 2. Presentation Summary

### I. Plenary 1: Towards Universal Health Coverage: the Vital Role of HTA

**(a) The Speaker from Chinese Taipei shared the vital role that the HTA shaping the universal health coverage. The key points were as follows:**

- As cancer had been the leading cause of death in Chinese Taipei for the past 42 years, the rapidly increasing spending on cancer drugs has become a significant challenge for the universal healthcare coverage. In 2023, the expenditure on cancer drugs reached USD1.27 billion, with targeted drugs accounting for the largest share, representing 61.9% of total spending.
- HTA had been used to support decision-making in the universal health coverage for approximately 16 years. Chinese Taipei introduced HTA for new drugs in 2008. In 2011 and 2013, HTA was further applied to innovative medical devices and services, respectively. In 2020, a horizon scanning platform for budget estimation of new drugs and benefit packages was launched. In 2021, to ensure the effectiveness of existing drugs in the reimbursement package, Health Technology Reassessment (HTR) was implemented.
- Taking HTA for new drugs as an example, manufacturers were first required to submit relevant documents through the horizon scanning platform. Following this, Chinese Taipei commissioned the Center for Drug Evaluation (CDE) to conduct the HTA. Based on the clinical data and the HTA report, an expert meeting was then convened to make the relevant decisions.
- HTA reports must contain relative efficacy and safety, cost-effectiveness, budget impact, and other ethical, legal, or social implications.
- Continuous monitoring and surveillance were conducted on the approved drugs and medical services. If necessary, HTR will be conducted to reevaluate the reimbursement decision and adjust health insurance coverage using real-world evidence (RWE).
- For medical services, a comprehensive HTA was conducted for items that were very expensive or had a significant impact on the overall budget, had

unclear comparative effectiveness compared to current treatments, or required further information.

- For new drugs and medical devices, the specific criteria for conducting HTA are new drugs with financial impacts exceeding USD3.14 million and new medical devices with financial impacts exceeding USD942,000.
- Currently, HTR in Chinese Taipei was divided into two processes: the Conditional Listing HTR process and the General HTR process. A registration system was established to collect RWE, which was used to adjust health insurance coverage. If the evidence proves a drug to be effective, a price markup will be applied. Conversely, if a drug is proven ineffective, refund measures such as suspension of reimbursement, price adjustment, or performance-based Managed Entry Agreements (MEA) will be implemented.
- The challenges Chinese Taipei has faced include applying traditional HTA, which primarily focuses on evaluating new drugs, to medical technologies and devices. For technologies with uncertainty in HTA but that address unmet medical needs, innovative approaches should be combined with RWE to implement HTR. The development of talent for HTA and the establishment of an independent agency are essential for the long-term advancement of HTA.
- There were four reforms that Chinese Taipei were taking to advance HTA: Committing to standardized data formats (e.g., FHIR) to improve the efficiency of data collection; establishing a dedicated unit for health policy and medical technology assessment; establishing a comprehensive database of HTA; and implementing an evidence-based payment system to enhance cost-effectiveness.

(b) **The speaker from Australia shared perspectives on HTA and high-cost technologies applied in Australia. The summary was as follows:**

- Australia has a long history of relying on HTA to inform initial subsidy and investment decisions.

- The Pharmaceutical Advisory Committee (PBAC) assessed drugs, and the Medical Services Advisory Committee (MSAC) assessed tests, services, and other technologies.
- PBS (Pharmaceutical Benefits Scheme) was an economy-wide subsidy scheme for pharmaceuticals, its working process was as follows: The regulator received and approved registrations of a drug or medical device; then, the independent Pharmaceutical Benefits Advisory Committee (PBAC) reviewed the registrations and consider reimbursement for such drugs; the recommendations made by PBAC would go to the Minister of Health who could either accepted or paused the recommendation, but could not add anything that was not on the recommendation.
- The Australian framework was very similar to those of other economies in that it relied heavily on evidence, particularly on the cost-effectiveness and safety of a drug or device. The PBAC was very careful with its recommendations because it was aware that reimbursement came from taxpayers' money.
- Consumer advocacy groups and patient advocacy groups also had high expectations on HTA.
- It was difficult to balance the push for early reimbursement of new drugs and novel medical technologies without compromising the assessment of safety, quality, efficacy, or cost-effectiveness.
- Nowadays, high-cost technologies were coming from multiple sectors including biotech (produced new products from extraction or manipulation of living organism), medtech (produced new products services, or solutions using medical technology), and pharma (produced new products primarily from artificial sources).
- In 2021 and 2024, the Australian government conducted a survey and a review regarding HTA and the relevant approval process and revealed the following key points: precision/tailored medicine was an approach not envisaged when the current regulatory and reimbursement system was designed; patient involvement was needed in the approvals decision-making

process; approval processes for new drugs and technologies were very complex; and novel value-based pricing strategies incorporating broad HTA were needed.

- Challenges of HTA in the face of high-cost medical technologies: for example, cell and gene therapies (CGTs). Theoretically, such therapies may serve as a potential one-time treatment. With one or two very expensive treatments may avoid a lot more other treatments needed in the future, thereby actually saving more money in the long run. However, these were very expensive therapies that may serve relatively few people. Therefore, reimbursement approval decision-making for these therapies was a big challenge.
- Australia has long focused on equity over equality, but this idea is now being challenged as debates arise around the financial costs of therapies.
- It was believed that when facing reimbursement decisions for high-cost medical technologies, actively listening to people's opinions was crucial, as was ensuring sustainability.
- It was not about equality but about equity of access. Proactively developing a dynamic HTA system that serves Australians without compromising the sustainability of the healthcare system is very important

**(c) The speaker from the Republic of Korea shared the current status and future perspectives on HTA in Korea. The key points were as follows:**

- Korea's National Health Insurance Service (NHIS) which started in 1977, established the current system by 1989. NHIS provided compulsory coverage for all citizens on the single insurance model. The NHIS managed enrollment and payment while the Health Insurance Review and Assessment Service (HIRA), decided on coverage and review claims.
- In Korea, 9.7% of GDP was spent on healthcare, surpassing the OECD average of 9.2%. However, advances the health technology brought forth financial burdens for the health insurance system. Moreover, as many new technologies were not covered by the health insurance, patients' out-of-pocket expenses had increased.

- NECA was established in 2009 under the Ministry of Health to provide trustworthy data for policy and decision-making.
- In Korea, medical devices and pharmaceuticals went through reviews for reimbursement via different pathways. For pharmaceuticals, HIRA was in charge of the coverage decision and NHIS was in charge of the cost decision; for medical devices, the review process (HTA) would be conducted by NECA, and coverage and cost decisions made by HIRA.
- In 2023, Of the approximately 7,000 devices approved by the Ministry of Food and Drug Safety (MFDS), only 2%, 130 in number, required a new HTA annually. Since 2007, about 3,000 technologies had been reviewed in New Health Technology Assessment (nHTA), and 62% of them had been integrated into the NHIS system. For the final step, Health Technology Re-assessment (HTR) would be conducted to ensure continuous relevancy and necessity of NHI investment in different medical services and drugs.
- The regular pathway of nHTA involved four steps: (1) obtaining approval from the MFDS for medical devices, (2) HIRA reviewing if the product is already listed in insurance, (3) NECA conducting an in-depth assessment of the device's clinical evidence and value, and (4) HIRA making the final coverage decision based on NECA's report.
- To expedite the inclusion of new technologies in the NHI system, three new pathways had been established: (1) The Value-Based Assessment System, which allows technologies with potential value to enter a conditional listing while collecting real-world data for further evaluation, (2)Temporary Exemption of nHTA, which permits immediate market entry after MFDS approval while gathering real-world evidence for later assessment made by the industrial side, and (3) The Integrated Review, which shortens the review process by allowing simultaneous evaluations by MFDS, NECA, and HIRA, reducing the time from 390 to 80 days.
- By June 2024, 28 innovative technologies had been selected under these new pathways, including robots, 3D printing, and AI-based and digital therapeutics.

- Key issues and future directions for HTA in Korea included: balancing innovation with patient safety, ensuring product coverage decisions align with social values and gaining public consensus, prioritizing patient safety and equity, especially in digital health, developing HTA frameworks tailored to the innovation cycle, promoting evidence generation to support patient-centered care, and improving health literacy and information transparency for patients.

**(d) The speaker from Singapore shared insights on the role of Health Technology Assessment in policy making. The key points were as follows:**

- Key objectives of the healthcare financing philosophy were to maintain affordability and accessibility, to instill individual and collective responsibility, and to allow markets to work.
- In Singapore, the healthcare financing comprised S+3Ms, which were, government **S**ubsidies, **M**ediShield Life (universal basic health insurance), **M**ediSave (compulsory individual healthcare savings), and **M**ediFund (medical endowment fund).
- Healthcare affordability has improved, but healthcare expenditure is also rising rapidly. With the introduction of new technologies, health technology costs had reached unprecedented levels.
- Given limited resources, proper allocation was both essential and challenging. HTA served as a bridge to guide these difficult decisions, helping determine which populations, technologies, and drugs to subsidize.
- HTA informed stakeholders about the clinical evidence, cost-effectiveness, and appropriate use of health technologies and could be used in price negotiations to secure better prices.
- The Agency for Care Effectiveness (ACE) was established in August 2015 as the HTA and clinical guidance agency in Singapore. Its vision was to deliver the best health outcomes sustainably and work with stakeholders, providers, payers and patients to provide better-informed decision-making.
- A key factor for effective implementation and application of HTA was a clear,

transparent, and robust structure, processes, and methods that aligned with international best practices.

- Health technology subsidy process in Singapore was: After the selection of topics, evidence-based evaluation, value-based pricing, and economic modelling would be conducted to produce the HTA report; then, the report would be adopted in the decision-making by the advisory committees of the Ministry of Health.
- Introduced in 2016, Value-Based Pricing (VBP) has become a crucial mechanism to ensure that the prices of health technologies align with their value. Under VBP, pricing negotiations with manufacturers ensure that only the most cost-effective treatments are provided. Once the price is determined, a maximum selling price is established for public healthcare institutions to follow, ensuring that savings from negotiations with manufacturers are passed on to patients.
- Risk-share arrangements (RSAs) helped mitigate uncertainty in cost-effectiveness and budget impact, and where if the expenditure of that health technology has exceeded a certain grid cap, the company is supposed to provide some rebates.
- To address the issue of increasing cancer drug expenditure, Singapore extended HTA to inform insurance coverage of cancer drugs, to ensure costs & premiums sustainability and achieve a lower price with broad coverage. As a result, cancer drug prices had been lowered by 30% on average and about 90% of all cancer drug treatments registered in Singapore were covered.
- The MOH Implant Subsidy List (ISL) was established in 2023, about 22,000 implants were listed and prices for some commonly-used implants had been reduced by 20 to 30%.
- Patient involvement was critical in the work. In 2021, the Consumer Engagement and Education initiative was launched to help citizens understand ACE's work by enhancing their health literacy.
- Since ACE's establishment, it has achieved SGD690 million of cost savings and improved access and affordability of selected medicines and medical

technologies for over 600,000 patients.

**Panel Discussion:**

**Q1. Do you have a unique and independent HTA agency? How many full-time employees do you have in those agencies?**

**The speaker from Chinese Taipei**: Chinese Taipei was trying to establish an independent HTA unit separated from Center for Drug Evaluation (CDE). Currently, the number of full-time employees working on HTA is around 70, but Chinese Taipei is hoping to expand the number to up to 200 or 300 in the long term.

**The speaker from Australia**: In Australia, members of the HTA agency were employees of the government, so they all had other responsibilities other than HTA. And some HTA projects were outsourced to other agencies like universities. Therefore, Australia did not have a clear idea about how many people were in the team.

**The speaker from Korea**: The HTA agency founded by the government shall celebrate its 15th anniversary this year. In NECA, there were 160 to 180 full-time employees.

**The speaker from Singapore**: In Singapore, the agency ACE was established as part of the division of the Ministry of Health. The agency will celebrate its 10th anniversary next year. ACE had over 100 employees but was also in charge of creating some clinical guidance. Therefore, the number of employees on the designated HTA team was around 60 plus.

**Q2. Have you started looking into additional sets of skills, like computer experts or mathematicians, for HTA to help us with future challenges?**

**The speaker from Chinese Taipei**: Chinese Taipei currently had two main groups of people in the HTA process, which were HTA methodology experts and Pharmaceutical Benefits and Reimbursement Scheme (PBRS) joint committee members. Chinese Taipei did face a shortage of relevant experts and professional workers, so education was a critical part at the moment. In addition,

patient participation was critical and I personally was curious to know some key points in selecting patient representatives.

**The speaker from Australia:** It was important to embrace a broader expert pool, AI technologies, or even language models. It was best to have these experts remain in their respective fields and participate in HTA as consultants. In this way, they can still be in contact with the latest technology trends in their respective fields.

**The speaker from Korea**: Korea believed consumer groups and patient groups were also very important in the HTA process. The most important thing was to obtain support from partners and colleagues. Throughout the 15 years of HTA and NECA experiences, obtaining university and societal support was important for us.

**The speaker from Singapore**: Singapore needed to bring more talents into the HTA field as consultants and building networks was a good way to start.

**Q3. 1) How to establish relevant training for patient groups and train patient experts? 2) How to avoid involving more stakeholders in the process becomes extra hurdles and prolongs the process? 3) What's the recommended ICER threshold of review time?**

**The speaker from Singapore**: The first thing was to map out the stakeholders, including patient groups and expert groups. Then, Singapore conducted training on HTA literacy for these stakeholders to facilitate their participation in the discussion. Also, there was a consumer panel that helped us to understand consumers' perspectives. A guideline was established for patients to help them generate input for the HTA process. Singapore did not have such ICER threshold established.

**The speaker from Korea**: To obtain societal recognition and real-world evidence, all stakeholders must be able to participate in the process.

**The speaker from Australia**: Consumers' participation was important. A proactive and ongoing consultation on more generic topics would be a good idea to obtain opinions from a broader expert group without delaying any

particular HTA process. There was no ICER threshold has been established in Australia.

**The speaker from Chinese Taipei**: HTA helped determine cost-effective options and valuable items; however, these two criteria did not always align. In Chinese Taipei, 1% of GDP was established as an acceptable ICER for standard drugs, but this did not apply to certain items, such as drugs for rare diseases. Therefore, more time was needed to reach a consensus on ICER.

**The Moderator**: Threshold for review time differs from item to item and it was hard to come up with a universal standard.

## II. Plenary 2: The Impact Stories of HTA

**(a) The speaker from Malaysia shared insights on how Health Technology Assessment is advancing in Malaysia. The key points were as follows:**

- HTA was established in Malaysia in 1995, starting as a one-person unit before expanding into a section under the Medical Development Division of the Ministry of Health in 2001. In 2006, the Evidence-Based Medicine Unit from the Institute for Medical Research was merged with the HTA section. Horizon scanning was introduced in 2014, followed by the initiation of value-based medicine in 2015. In 2020, due to the COVID-19 pandemic, a rapid review system was established separately from other reviews. In 2022, the Health Technology Division (interim) was formed, serving as the MOH's single entry point for the health industry with additional functions.
- MaHTAS (Malaysian Health Technology Assessment Section) functions in the technology lifecycle by conducting horizon scanning to identify, prioritize, and assess the potential impact of innovative technologies.
- The purpose of HTA was mainly for the procurement and adoption of new technologies. In addition, HTA reports had impacts on private insurance service provision, clinical practice, and private insurance reimbursement. HTA reports also served as a reference for regulatory approval and investment decisions.
- The HTA agency had 32 (+ 5) reviewers, 6 information specialists, and 6 administrative staff, which made Malaysia one of the smallest HTA agencies. In addition to HTA, Malaysia also conducted clinical practice guideline creation, health industry conversations, economic evaluation and value-based evaluation, horizon scanning, and public health interventions.
- The HTA process in Malaysia included assessment (by MaHTAS and expert committee), appraisal (by technical advisory committee), and decision (by HTA and Clinical Practice Guideline (CPG) council).
- In 2000, a mandate by the Director General specified that "HTA is encouraged for all health technologies, but mandatory for medical devices worth more than MYR200,000 per unit before decisions for procurement.",

so in 2023, an updated mandate by the Director General specified that “all health technologies that have potential to be introduced in Malaysia health facilities should undergo HTA by MaHTAS”. Currently, only policy makers and health professionals from the public sector could request HTA.

- Patient involvement was important, all reviews must include patient groups and expert committees. Patient representatives were presented in all HTA and CPG councils. Relevant reports must be available to the public.
- Currently, Malaysia has produced 84 HTA reports, 430 technology reviews, 270 information briefs, 155 clinical practice guidelines, and 136 tech brief reports.
- In terms of recommendation of HTA, 44% were recommended, 23% were recommended for research purposes, and 32% were not recommended. However, a positive recommendation did not automatically lead to inclusion; it was based on specific applications and funding requests.
- Impact Story: Bone-targeting agents in prevention of skeletal-related events (SREs) in metastatic. Bone-targeting agents were used as a treatment, but it was not provided earlier for prevention purposes. After conducting HTA, it showed that bone-targeting agents, if introduced to prevent SREs, would actually result in 200% cost saving for the government.
- Advance HTA in Malaysia: Reposition its role as a key shaper in the healthcare system. A proactive approach could inform innovators and industries about the technologies needed for the healthcare. Prioritizing topics based on healthcare needs and conducting value assessments before including them in clinical practice guidelines and care pathways was essential for improvement. Additionally, strengthening capacity, identifying low-value health technologies for disinvestment, and fostering collaboration were also important.

**(b) The speaker from the United Kingdom shared the HTA impact stories from NICE. The summary was as follows:**

- Established in 1999, The National Institute for Health and Care Excellence (NICE) did HTA and produces medical guidelines. NICE helped practitioners

and commissioners got the best care to people, fast, while ensuring value for the taxpayer. NICE produced useful and usable guidance and provided rigorous and independent assessments of complex evidence for new health technologies.

- At the beginning, HTA was seen as a cost containment mechanism. However, with a lot of effort put in by NICE, HTA was now seen as a tool to ensure the sustainability of the health system.
- In response to health service pressures, shared decision-making, rapid innovation, and vast amounts of data, NICE embarked on a five-year transformation journey to remain relevant. While upholding its core principles of transparency, rigor, and independence, it focused on providing timely and practical guidance. NICE aimed to enhance its relevance by prioritizing what matters most and sought to achieve a greater demonstrable impact by leveraging data and implementation insights.
- Over the past year, NICE has made significant progress. Technology appraisals become 45% faster, with guidance for two medicines published within 24 hours of marketing authorization. Enquiries to NICE advice had increased by 82%, and the uptake of recommendations was measured across 19 priority topics.
- Impact Stories:
  - ✓ NICE produced guidance for a new medicine to treat Pompe disease, a rare condition, ahead of its marketing authorization by the UK regulator. This was the first time guidance was published before regulatory approval, made possible through collaboration with regulators on the Innovative Licensing and Access Pathway (ILAP). The close cooperation between NICE, the regulator, and the manufacturer played a crucial role. During the process, the manufacturer sought scientific advice from NICE, which helped streamline their economic model. This collaborative approach resulted in the exceptionally early publication of the guidance, ensuring faster access to treatment.

- ✓ NICE was dedicated to reducing health inequalities and had recently approved a groundbreaking gene therapy for beta thalassemia, known as Exa-cel. This condition primarily impacted individuals from disadvantaged backgrounds who often encountered socioeconomic challenges and limited access to healthcare. Acknowledging these disparities, NICE prioritized the successful approval of Exa-cel, which would be accessible through the Innovative Medicines Fund—a managed access fund tailored for non-cancer drugs, similar to the Cancer Drugs Fund. This initiative allowed for the collection of evidence on the long-term effects of the therapy while patients received treatment. It remained uncertain whether Exa-cel could restore full quality of life or offered lifelong benefits. The overarching goal of this approach was to facilitate early access to the therapy while simultaneously gathering vital data on its effectiveness.
- ✓ NICE was actively supporting commissioners in the field of health technologies and MedTech by evaluating interventions like transcatheter aortic valve implantation (TAVI). By analyzing the cost-effectiveness of TAVI, NICE discovered that commissioners could save money compared to their current expenditures. Typically, NICE guidance resulted in increased costs for commissioners, but in this instance, it offered a financial benefit. This finding had been positively received by commissioners, highlighting NICE's commitment to help improving efficiency within the healthcare system while ensuring effective treatment options were available.

(c) **The speaker from the United States shared how ICER works on HTA within the U.S. health system. The key points were as follows:**

- The United States, unlike nearly all economies of similar wealth, had no governmental health technology assessment organization. There was also no central negotiation for drug pricing in the US, and payers were generally required to cover any drug that was medically necessary.
- In the absence of a governmental HTA body, Institute for Clinical and

Economic Review (ICER) was created as an independent non-profit in 2006 with the intent of using evidence about comparative effectiveness to guide cost-effectiveness analyses to suggest fair prices in the US market. Since 2013, ICER has become an independent HTA agency that developed publicly available value assessment reports.

- There was no similar governmental agency in the US and ICER had no authority to apply assessment results.
- Value assessment framework that assessed long-term value for money. In addition to the cost-effectiveness factors, ICER considered benefits beyond health, such as patients' education development, and special social or ethical priorities.
- In the early stage of an ICER review, called the scoping period, ICER engaged with various stakeholders, including clinical experts, patients, and manufacturers, to gather comprehensive information about a disorder. This helped define the scope of the review. ICER then published a draft scope for public comments, revised it based on feedback, and shared the updated scope. A preliminary model concept was also presented to stakeholders and made available on an open science framework.
- In the middle stage of an ICER review, ICER finalized the economic model, often with the help of outside contractors, and graded the evidence using its own rating matrix. ICER then published a draft evidence report, which included these ratings and threshold prices, and opened it for public comment. ICER shared its model with manufacturers but did not receive dossiers or models from them. In the late stage, ICER published a revised report with suggested prices, responded publicly to comments, and held a public meeting. Finally, it released a final report that included its recommendations.
- ICER calculated the cost per QALY (quality-adjusted life year) and cost per equal value life year (evLY) to determine suggested prices. U.S. federal regulations limited the use of QALYs and similar measures in cost-effectiveness analyses, as these may discriminate against individuals with

disabilities by not treating life extension equally. An evLY was similar to a QALY until life extension, where it assumed all patients were in good health, which may produce skewed results in certain conditions.

- In terms of the cost-effectiveness threshold, ICER looked at the "opportunity cost," which meant ICER thought about "how much can be paid before the cost causes more health **loss** than gain?"
- ICER reviews took about nine months, so ICER could accomplish 7 or 8 reviews per year. ICER usually picked topics where there was concern and uncertainty, or where it might have a chance to influence pricing decisions.
- In terms of evidence for ICER influence, studies comparing the ICER Health Benefit Price Benchmark (HBPB) published before and after the price approval by the FDA had shown that the net price tended to be substantially close to the suggested price made by ICER if the ICER report was issued before the final price was set.

**(d) The speaker from Thailand shared the concept of HTA implementation in Thailand. The summary was as follows:**

- The implementation of HTA was also based on three major factors: evidence synthesis, economic evaluation, and Ethical, Legal, and Social Implications (ELSI). HTA was not used to make decisions, but to help to make well-informed decisions.
- HTA was a part of the policy-making process (topic nomination, topic selection, assessment, decision-making) in Thailand. Subcommittees would consider whether technology or intervention should be included in the universal coverage benefits package (UCBP) using the following criteria: cost-effectiveness, availability of clinical practice guidelines, health system readiness, budget impact on the universal coverage scheme (UCS), and ethical and social issues.
- HTA was used to support reimbursement decisions for the National List of Essential Vaccines (NLEM) and UCBP. For example, it provided evidence for the inclusion of cost-ineffective drugs for rare diseases (including high-cost interventions) and supported price negotiations, processes, and other

reimbursement models (e.g., Managed Entry Agreements, Coverage with Evidence Development programs). Special consideration was given to life-saving drugs with no alternative treatments.

- Following were the decision criteria for UCBP: Cost-effectiveness, Clinical practice guideline, Health system readiness, budget impact and ethical and social issues.
- Thailand currently had a cost-effectiveness threshold of USD5,000. While interventions under this threshold were generally recommended, cost-effectiveness was not the only factor in decision-making. Other important criteria, such as whether the condition was life-threatening or whether alternative treatments were available and also considered when deciding if interventions above the threshold should be recommended.
- Thailand was working to incorporate health equity into existing methods and policy-making processes, adding “equity” to the traditional metrics of cost and efficiency.
- Green HTA was a concept that aimed to evaluate and identify care that could deliver co-benefits, which aimed to redefine the concept of “value” by adding environmentally friendly factors in the assessment process.

**Panel Discussion**

**Q1. Do you think more societal perspectives should be incorporated into the HTA process?**

**The speaker from US**: When people focused too much on the societal perspective and not the healthcare perspective, they might question the value of providing certain care for patients beyond their productive years or patients who wouldn’t be able to live until their productive years.

**The speaker from Thailand**: In Thailand, the primary perspective was the societal perspective. However, for pricing decisions, the payer's perspective must also be considered. Therefore, most of the time, both the payer's perspective and the societal perspective were considered.

**Q2.** From the outside, experts in HTA often first look at how NICE would proceed before taking any action, so thank you for the talk. One of the new measures is the implementation of 'proportionate review.' I wonder what the early results or thoughts are regarding this?

**The speaker from the UK**: It was truly a work in progress. The thinking was that NICE had reached the peak of highly technical evaluations and was now trying to understand where it could flex the mechanism to become more pragmatic. Additionally, a key focus was identifying the topics that truly matter and finding ways to improve the healthcare system.

**Q3. Is there any possibility of information and resource sharing early on in the HTA process?**

**The speaker from Malaysia**: Currently, Malaysia had HTA harmonization that could be expanded to other organizations. Guidelines had developed to conduct relevant work.

**The speaker from US**: ICER's reports were all freely available online to anyone who wanted to look at them, and there was a modeling product available called ICER Analytics, which generally had been made available to other HTA who had wanted to use it to put their own numbers into the models that had been developed.

## III. Plenary 3: Advancing HTA: Navigating Challenges, Building Opportunities, and Fostering Collaboration

**(a) The speaker from Canada shared his insights on reimagining Health Technology Assessment to support Universal Health Coverage. The Key points were as follows:**

- Mega trends in HTA such as emerging blockbuster drugs that generate billions of USD of profits annually, limited evidence at launch, public health and health equity, accelerated development and approval, the need for speed (Rapid HTA), non-traditional technologies (Digital health, AI), patient centricity, affordability, and sustainability were forcing traditional HTA to evolve and revolution in order to make good recommendations.
- Canada identified three key trends that it believed would have the most significant impact on the science and practice of health economics, outcomes research, and related areas like HTA. These trends were affordability, the science of well-being and whole health, and the digitalization of healthcare. Building on these insights, Canada developed a new strategic plan, which it had defined as ISPOR's strategy to 2030.
- Factors contributing to an HTA agency's success: identify the client, anticipate healthcare system and technologies, engage with stakeholders, conduct life cycle HTA, and focus on impacts.
- HTA was not traditional science research, it required relevance, timeliness, quality, and impact. HTA reports and recommendations must be implementable and implemented to make the evidence contextualized to consider and support the particular needs but not make it a barrier to change.
- While reimaging HTA, obtaining better technologies, better health, better patient experience, and better value were necessary and it was so-called the new definition of HTA, which had gained consensus from multiple organizations around the world: "HTA is 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."

- HTA was not a method, it was a policy tool, a tool to support policy. At this moment, Canada had a lot of boards of international organizations participating in this and it was called a milestone in international collaboration.
- 4 Big ideas for HTA to support sustainable universal coverage:
  (1) Harmonization: Potentially developing HTA “recognition” and “reliance” model where smaller regulatory bodies could choose to either “recognize” the decisions bigger economies or entities made or “rely” on the evidence these economies obtained to make their own decisions.
  (2) Life Cycle Management: Centralizing a global horizon scanning initiative and engaging with venture capital and investor communities, while encouraging parallel regulatory and HTA reviews. A key aspect was coordinating the collection and use of real-world evidence (RWE), along with developing a harmonized approach for reassessing health technologies. Additionally, there was a focus on disinvestment, phasing out technologies that no longer provided sufficient value.
  (3) Process innovation: Employing AI in HTA, and developing a global methods manual with a regular update process. It also included validating rapid evidence review processes, integrating patient-generated evidence, and researching QALY and other value frameworks, with a stronger focused on qualitative evidence and value modifiers.
  (4) Risk mitigation: Implementing performance-based contracting, promoting innovative reimbursement models, and exploring third-party platforms for price negotiation, contract management, adjudication, and deal cataloging.

**(b) The speaker from the Philippines shared the current status, barriers, and future direction of HTA in the Philippines. The key points were as follows:**

- HTA was first introduced in the Philippines in 1993. However, the minimum elements to make it spark and viable were not there until 20 years later, when the Philippines passed the Universal Healthcare Act of the Philippines and

institutionalized HTA.

- Under the PHL UHC Act 2019, HTA was a priority-setting mechanism recommendatory to provide guidance on financing and coverage decisions for the Department of Health (DOH) and the National Health Insurance Corporation (PhilHealth).
- The HTA council was the governing body of HTA in the Philippines. It was first created in October 2018, under the DOH. The main function of the council was to produce coverage recommendations on health technologies to be financed by DOH and PhilHealth.
- The HTA council must be transparent and apart from the usual clinical and economic evidence and council was required to look at ethical, social, legal, and health system impacts. The stakeholders included the FDA, PhilHealth, patient groups, clinical experts and voting citizen representative in the core committee of the HTA council.
- The HTA division, which supported the functioning of the HTA council, started as a one-person unit in 2019 under the Department of Health and had expanded to a 30-employee division now.
- All HTA results were made into recommendation reports which were submitted to the minister of health who made the final decision. Pursuant to the law, the minister could not make a positive decision for coverage without a positive recommendation from the HTA council.
- In 2023, the HTA Division moved from the Department of Health to the Department of Science and Technology to maintain its integrity away from the politics of the healthcare sector.
- Normative Guidance on HTA (including the process guide and the methods guide) was created and published during the pandemics (2019-2020) and the second edition was expected to be published at the end of 2024.
- The Philippines' vision was to conduct HTA in a way that was not only credible but also validated and well-supported by stakeholders. Therefore, it rigorously followed these core principles: ethics, availability, enforceability, inclusiveness, evidence-based and scientific defensibility, transparency and

accountability, and efficiency. At the core was meaningful and effective stakeholder engagement.

- With the last five years of efforts, the worth of HTA in the Philippines was proven. So, the Philippines's current direction was to fully realize the potential of HTA and scale up its implementation.
- However, the Philippines still faced several challenges in scaling up HTA, including technical challenges such as a limited number of HTA practitioners, poor health information infrastructure, and limited awareness of HTA; operational and process challenges, such as transitioning responsibilities between ministries, a lack of efficient mechanisms, budget constraints, and the absence of a formal process to measure the impact on universal health coverage; and organizational challenges, such as human resources disproportionate to the workload and a high turnover rate due to the lack of permanent positions.
- To cope with the challenges, the Philippines' current direction focuses on strengthening HTA capacity, including the establishment of an HTA research network, an efficient commissioning process, piloting nominator-led assessments, and the development of a local HTA postgraduate program. Additionally, it is ramping up stakeholder engagement, enhancing efficiency, and establishing an HTA monitoring and evaluation (M&E) framework to measure impact.

**(c) The speaker from Japan shared how the new Health Technology Assessment system is working in Japan. The key points were as follows:**

- Japan's National Health Insurance Program had been implemented since 1961 for over 60 years now. Although such insurance programs were not operated by a single insurer, the drug or medical service prices were set by the government to ensure accessibility for all Japanese people.
- As relevant expenses grow, the Japanese government decided to implement the "Cost Effectiveness Evaluation System" in 2019.

- HTA principles: accessibility to new technologies, financial impacts of the new technologies, and transparency.
- The new evaluation system implemented in 2019 was mainly applied for drugs, cell and gene therapies, and medical devices. Results of the evaluation were used for reimbursement price adjustment and not coverage decisions.
- Generally, when the incremental cost-effectiveness ratio (ICER) exceeds JPY5 million per quality-adjusted life year (QALY), the price was adjusted. However, for certain rare diseases, pediatric diseases, and cancer, the threshold was set at JPY7.5 million.
- On principle, the price of new drugs should be the same as similar existing drugs. However, if the new drug was proven more effective or safer for the patient, a 5 to 120% premium may be applied to encourage innovation.
- Japan's Ministry of Health, Labor, and Welfare would request manufacturers to submit details of the cost structure and data for evaluation and price determination. The product for which the manufacturer refused to submit its cost structure, or whose annual sales exceed JPY5 billion, would be subject to a cost-effectiveness analysis.
- In the past five years, the Central Social Insurance Medical Council (Chuikyo) has selected 50 products for cost-effectiveness evaluations. The evaluation process for each product could take up to 1.5 to 2 years to complete, during which time the products remained clinically available. To date, 27 evaluations had been completed.
- The evaluation process started with requesting data and cost-effectiveness analysis from the manufacturer. The manufacturer should submit these documents within 9 months of product launch.
    (1) Center for Outcomes Research and Economic Evaluation for Health(C2H) conducted the evaluation and analysis of the product, which would take 3 to 9 months.
    (2) C2H submitted the evaluation report to the Chuikyo, which would then make the final decision.

- The National Institute of Public Health, established in 1938, had over 80 years of experience in public health research and training. The Center for Outcomes of Research and Economic Preparation for Health, part of the institute, was founded in 2018 to focus on health quality assessment, with its system starting in 2019 for that specific purpose.
- The new system was a two-step evaluation: First, it determined whether a new product had additional benefits. Then, if the results were positive, a cost-effectiveness analysis was conducted to determine the reimbursement price; if the results were negative, a cost-minimization evaluation was conducted.
- Of all the evaluations conducted following the assessments and decisions made by Chuikyo in the past five years, only about one-fourth passed the cost-effectiveness evaluation, while approximately three-fourths were subject to price adjustments (lower reimbursement prices).
- Issues under discussion at Chuikyo, included the length of evaluation process, the need for a re-evaluation process, the choice of comparator, the impacts on long-term care cost, the range of price adjustment, the development of human resources including education programs and the C2H itself, and the application of evaluation results.

**(d) The speaker from Indonesia shared the strategic approach to challenges and collaborative development driving transformation in Indonesia. The summary was as follows:**

- The National Health Insurance Program of Indonesia (JKN) started in 2014, covering 96% of the population. Same year, the Ministry of Health (MOH) conceptualized HTA to support a law that mandated evidence-based resource allocation.
- In 2021, HTA became one of the priority programs when the MOH launched the Health System Transformation in Indonesia. In 2023, a review of the current HTA business process began. Since there were only seven members on the team, the MOH collaborated with universities to carry out evaluation projects as a think tank for HTA.
- The HTA process in Indonesia involved 3 main PICs (HTA committee, HTA

staff from MOH or Agents from University, External stakeholders) and required about 17 months of assessment to produce recommendations: 4 to 6 months for topic selection, 7 to 13 months for assessment, 1 to 2 months for appraisal, and 1 to 2 months for dissemination of results.

- To facilitate topic selection, six criteria were identified for Topic Prioritization: Technological impact on health (26%), conformities with priority policies (22%), potential cost saving (20%), volume (14%), technology cost (11%), and acceptance (7%). Meanwhile, the team was working with a consultation company to develop a refined selection process that could digitalize and accelerate the process. Results had come out of the improvement of the following: standardization of process, strengthened topic identification, and enhanced HTA literacy for stakeholders.
- With support from CGD, IDSI, MTAPS USAID, and the World Bank, Indonesia was applying adaptive methods in two projects in 2023 to streamline the assessment process and provide timely evidence to decision-makers.
- Indonesia promoted active stakeholder engagement in HTA through the Stakeholder-Led Submissions (SLS) mechanism and the Value-Based Pricing (VBP) strategy, making the process more effective and efficient in supporting HTA recommendations and addressing financial aspects. These two mechanisms were learned from ACE Singapore.
- Multi-criteria decision analysis (MCDA) had been introduced to improve HTA appraisal processes, supported by MTAPS USAID. The assessment was organized into four major groups: assessment quality, clinical aspects, economics, and implementation readiness. Pre-meeting surveys were conducted to ensure equal participation. This approach successfully reduced the meeting duration for each HTA appraisal from 3-4 days to half a day, significantly streamlining the process and increasing efficiency.
- To address the challenges of improving HTA literacy, Indonesia planned to use digital platforms (websites) to enhance communication about HTA, promote greater stakeholder engagement, and strengthen collaborations.

- Collaboration and continuous engagement with partners were the key points to enhance HTA efficiency in Indonesia.

**(e) The speaker from the industry shared considerations on utilizing HTA to inform reimbursement. The key points were as follows:**

- Improving patient outcomes was a shared goal, and to achieve this, it was necessary to accelerate patient access to new medicines and technologies. From an industry perspective, it was believed that HTA was a valuable tool in achieving this.
- Optimal patient access was informed by a series of evaluations and decisions, including regulatory approval, HTA assessments, reimbursement, budget allocation, and the healthcare system and infrastructure.
- From an industry perspective, three critical enablers of effective HTA were transparency, evidence-based approaches that incorporated the perspectives of a broad range of stakeholders, and flexibility.
- Transparency contributed to stakeholders' understanding and trust. It should be applied to the HTA process, as well as decision-making.
- Clinicians also played a crucial role in HTA by offering unique insights, particularly in rare diseases, rapidly evolving treatments, and new practices. Their expertise was invaluable for understanding how to implement new technologies into clinical practice.
- Flexibility in process and pathways, methods, evidentiary requirements, decision-making allowed fit-for purpose evaluations across a multitude of situations. For example, clinical data on rare diseases was very limited, and relevant flexibility in HTA would be needed to ensure patient access to new technologies.
- HTA was a valuable tool for effective resource allocation and a critical step toward optimal patient access. It was essential to ensure sufficient budget and investment in the healthcare system to provide the necessary infrastructure and resources for delivering these technologies, allowing HTA results to translate into improved patient outcomes

**Panel Discussion**

**Q1. What are the main challenges of HTA transformations in your respective economies? And how do you overcome these challenges?**

**The speaker from Canada**: Dialogues with stakeholders were most important in initiating any kind of transformation or even just a minor change.

**The speaker from the Philippines**: The greatest challenge stemmed from the fact that this transformation began during the pandemic, a time when timeliness was paramount. At that time, it was necessary to help stakeholders understand that a regular HTA process required time, transparency, and clarity in the methods. It was essential to reach a consensus, recognizing that this was a fair approach.

**The speaker from the Industry**: The industry faced challenges during transformations, particularly in collaborating with local and regional partners in HTA processes. As regional connectors, the goal was to bridge economies within the region and globally. By advocating for methods suited to the Asia-Pacific region, transparency in local HTA systems enabled better information sharing, which was crucial for overcoming these challenges effectively.

**The speaker from Indonesia**: Indeed, communication with stakeholders was often the biggest challenge. However, it was worth pointing out that Indonesia's transformation succeeded because the government was committed to and supported the application of HTA in decision-making, which helped overcome the many challenges it faced.

**The speaker from Japan**: The biggest challenge was the capacity for assessment. The government expected to perform more evaluations but was unable to manage such a high workload. Increasing the number of HTA experts is essential.

**Q2. What's the purpose of harmonization and is it really feasible and useful for economies to solve the complexity problem or people training?**

**The speaker from Canada**: It was possible to harmonize some methods in processing or patient engagement. However, at the time, it was very difficult to

compare HTA institutions because they used different terminology for recommendations—some referred to it as “reimbursement,” while others simply answered “yes” or “no.” Regulators established the International Council on Harmonization to unify their approaches, and it was believed that a similar need existed within the HTA community.

**Q3. Some products are cost-effective in one aspect but not all aspects. How to determine whether a product is truly valuable from the perspective of an insurance provider?**

**The speaker from Canada**: Cost-effectiveness wasn’t the main issue, as it was always possible to determine whether a product was cost-effective. The real challenge at the time was affordability and the budget impact of new technologies. It was necessary to explore innovative contracting methods with the industry, such as performance-based contracts or subscription models, to ensure that valuable and impactful technologies remained accessible and affordable for patients.

## IV. HTA institutional Insights and Forward-Looking Perspectives

**(a) The speaker from Chinese Taipei shared experiences on how the HTA institution works with funders and industry to facilitate access to innovative health technologies. The summary was as follows:**

- Chinese Taipei began conducting HTA in 2007 to support drug reimbursement decisions. In 2008, the Division of HTA was established under the Center for Drug Evaluation (CDE), focusing on maximizing health benefits through evidence-based policymaking. Initially, it focused on drug assessments, but it has now expanded to include medical devices, health services, and support for policymaking in various health sectors. Furthermore, since 2015, patients have been involved in the appraisal process, giving them a platform to voice their opinions, though further improvements are needed to fully integrate patient perspectives.
- The HTA process for drug reimbursement involved rapid assessment reports

(within 42 days) and transparent communication with manufacturers and stakeholders. This had enhanced efficiency and trust in the system.

- To improve patient access, Chinese Taipei had introduced 3 major mechanisms, Managed Entry Agreements, Horizon Scanning since 2018 and 2019, respectively, and Reassessment to handle high-cost drugs and plan for new technologies entering the market.
- For the future of HTA in Chinese Taipei, the government aimed to strengthen capacity, foster collaboration with academia, and continue international partnerships through the Center for Health Policy and Technology Assessment (CHPTA)—a non-departmental public body established on December 27, 2023, marking a significant milestone in the HTA process. Additionally, implementing parallel processes for regulatory and reimbursement assessments to streamline access to new therapies.

## 3. Key Findings and Corporation Recommendations

- A well-structured and transparent Health Technology Assessment (HTA) framework was crucial for managing the rising costs and complexities of healthcare systems and it played a vital role in ensuring equitable access to effective treatments, guiding reimbursement decisions, and maintaining sustainability in universal health programs. By evaluating new drugs, medical devices, and innovative technologies based on clinical evidence, cost-effectiveness, and safety, HTA helped allocate resources efficiently while adapting to rapidly evolving medical and technology advancements.
- HTA highlighted its crucial role in ensuring healthcare systems were cost-effective, equitable, and responsive to innovation. Influencing both public and private healthcare decisions through comprehensive evaluations, value of timely, evidence-based guidance to shape policy and pricing decisions, integrating cost-effectiveness with ethical and social concerns, demonstrating that HTA not only guided healthcare decisions but also promoted broader health equity.

- For sustainable UHC, HTA must support by addressing challenges to keep providing an affordable and sustainable, healthcare system and ensure its ability to respond to rapid technology development. To further evolve HTA frameworks, focusing on harmonization, lifecycle management, and strong stakeholder engagement between local and international adaptation and collaboration for effective, timely, and equitable healthcare access were key points.
- In the future, strengthening institutional capacity, training HTA professionals, and fostering harmonization to engage expert organizations and stakeholders would enhance transparency and alignment with public health goals. Leveraging digital health technologies and AI would further improve HTA's precision and impact in efficiently addressing healthcare challenges.

## 4. Site Visit to Chang Gung Memorial Hospital

**(a) The speaker shared the digital health indicator journey and experiences from Chang Gung Memorial Hospital. The summary was as follows.**

- The Chang Gung Memorial Hospital (CGMH) network included nine branches, with around 10,000 beds and 800 million outpatient visits annually, serving approximately one-third of the population.
- Since 2000, the CGMH had undergone a digital transformation in medical records, facing initial resistance from doctors reluctant to type, eventually transitioning to structured data collection and AI-driven automation toward to the future hospital.
- The CGMH utilized AI for clinical assistance, such as diagnostic recommendations and examination suggestions as well as the co-pilots for doctors to improve decision-making efficiency.
- The CGMH had extended healthcare services to remote mountain and island areas through telemedicine, integrating smart devices and specialist support to enhance medical access in these regions.
- Since 2019, the CGMH had implemented a digital pathology system,

scanned over 100 million pathology slides and utilizing AI-assisted diagnostic tools, enhancing efficiency and enabling remote pathology services.

- During the COVID period, to provide telemedicine and enhance patient engagement, structured data and AI technology played important roles.
- The success of digital transformation and AI adoption was attributed to strong leadership, which maintained a long-term vision and commitment to advancing the hospital's technological capabilities despite the time and resce challenges involved.

**(b) The speaker shared the application of medical AI at CGMH. The summary was as follows:**

- The hospital focused on improving the endocrine model, utilizing vast data sets, and integrating metadata management systems to efficiently handle petabytes of medical data for research and diagnostics.
- AI was extensively employed across various medical fields, such as detecting bone fractures, analyzing angiography, and assessing neuron functionality using medical imaging, enhancing diagnostic accuracy and reducing the learning curve for clinicians. In addition, AI models played a pivotal role in orthopedic surgeries, chest X-rays, CT scans, and kidney-related imaging by automatically identifying medical conditions and alerting healthcare professionals, thereby improving clinical workflows.
- The hospital had digitized half of its pathology slides and developed AI models that assisted pathologists in diagnosing diseases like nasopharyngeal carcinoma and breast cancer, contributing to faster and more accurate diagnoses.
- AI was utilized to assist in emergency departments, making quick decisions for patient care, especially in time-sensitive situations. AI helped improve decision-making for clinicians by offering insights based on large datasets.
- The hospital focused on educating clinicians to adopt AI technologies through continuous programs, collaborations with international experts, and integrating AI into the clinical decision-making process.
- The hospital had developed its own multilingual language models to support

communication in clinical settings, particularly for patient education, and to help clinicians with research and consultations using AI-powered solutions.