# Evolving national health technology assessment (HTA) frameworks in theory versus practice in the Asia-Pacific region: a targeted literature & HTA review focusing on Australia, Japan, and Taiwan

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## Introduction

Value-based assessment of therapies is centric to optimal resource allocation and health system sustainability. In recent years, multiple theoretical definitions of value expanding beyond cost-effectiveness–centric views, incorporating multistakeholder perspectives have emerged globally.[1-3] This includes the ISPOR value flower that considers 12 elements of value, of which ten are considered non-traditional value elements that are included in the societal perspective. These 12 elements of value include traditional elements such as quality adjusted life-years (QALY) gained and net costs, and non-traditional elements such as productivity, family spillovers, value of knowing, insurance value, fear of contagion and disease, severity of disease, value of hope, real option value, equity, and scientific spillovers. Pharmacoeconomics and health technology assessment (HTA) guidelines across Asia-Pacific (APAC) markets have published guidance for HTA evaluations to consider traditional and non-traditional value elements to varying degrees, including novel elements of value outlined in the ISPOR value flower. However, the extent of use of these elements in reimbursement decision-making is still unclear.

## Objectives

Key objectives of this research include:

- Identifying and comparing novel elements of value in published national HTA guidelines across 11 APAC markets
- Conducting a deep dive on HTA conducted in three APAC markets (Australia, Taiwan, and Japan) to compare use of determinants in theory versus in practice for select therapies

## Methods

- A targeted review of published national pharmacoeconomic guidelines and academic literature from 11 APAC markets was conducted to identify theoretical value elements mentioned or included in the guidelines.[4,5]
- A deep-dive into guidelines for Australia, Japan, and Taiwan evaluated these in practice using 10 asset-indication examples from post-2018 HTA reports, selected based on inclusion in UK's NHS high-cost list or for having novel value elements cited as important in global evaluations.[6,7]
- Details on the consideration of value elements and the use of financial or risk-sharing agreements in HTA were analyzed.

## Results

Productivity (11/11), equity (10/11), family spillover (10/11), severity of disease (7/11), and value of knowing (1/11) were non-traditional elements of value from the ISPOR value flower considered in APAC guidelines (Table 1). Notably, other non-traditional value elements such as real option value, scientific spillovers, value of hope, insurance value, and fear of contagion and disease were not present in any of the APAC guidelines reviewed.

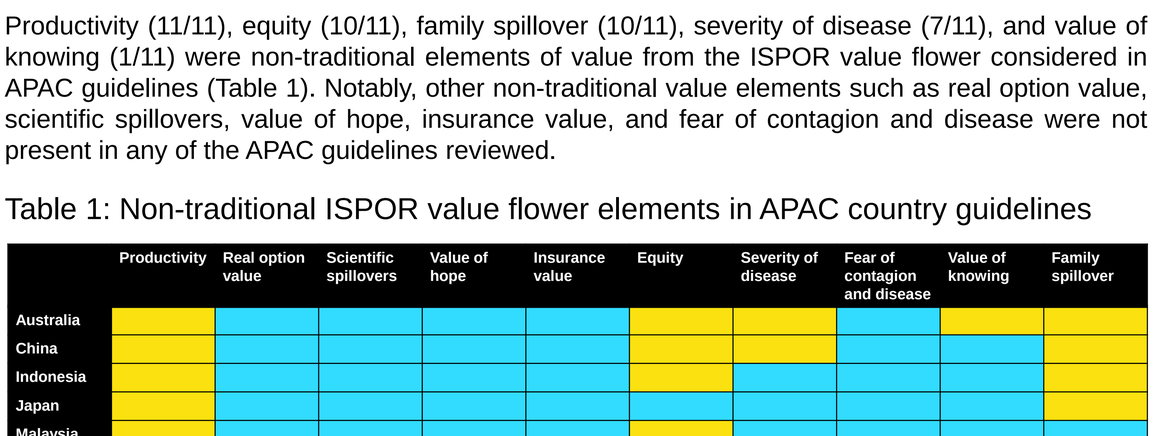
Table 1: Non-traditional ISPOR value flower elements in APAC country guidelines

| | Productivity | Real option value | Scientific spillovers | Value of hope | Insurance value | Equity | Severity of disease | Fear of contagion and disease | Value of knowing | Family spillover |
|---|---|---|---|---|---|---|---|---|---|---|
| Australia | | | | | | | | | | |
| China | | | | | | | | | | |
| Indonesia | | | | | | | | | | |
| Japan | | | | | | | | | | |
| Malaysia | | | | | | | | | | |
| New Zealand | | | | | | | | | | |
| Philippines | | | | | | | | | | |
| Singapore | | | | | | | | | | |
| South Korea | | | | | | | | | | |
| Taiwan | | | | | | | | | | |
| Thailand | | | | | | | | | | |

Not included  Included

Overall, the HTA reports deep dives showed that while the guidelines included a broader range of value elements, in practice, not all of these were necessarily considered as critical in decision-making. Traditional elements of costs (24/25) and QALYs (18/25) were used most often along with disease severity (24/25), a non-traditional element. Other non-traditional value elements like productivity (8/25), value of hope (6/25), family spillover (5/25), and equity (3/25) were considered less often (Figure 1).

Figure 1: HTA decisions in Australia, Taiwan, and Japan incorporating ISPOR value flower elements




Fifteen reports considered cost-effectiveness analysis (CEA) in their decision-making of which six received a favorable decision despite exceeding informal thresholds. In Australia, a threshold higher than the informal incremental cost-effectiveness ratio (ICER) threshold (>US$60,000/QALY) was considered acceptable conditional to risk-sharing measures in circumstances where high unmet need (Revestive) or transformative clinical benefit (Kymriah, Zolgensma) were observed.

Similarly, in Taiwan, a threshold higher than the informal ICER threshold (NT$2,133,853/QALY) was accepted for Kymriah, but subject to a risk-sharing agreement considering the overall financial impact. In Japan, a higher reference ICER (>JPY7,500,000/QALY) was accepted without financial or risk-sharing agreements, for products requiring special consideration, i.e., rare (Ultomiris) and pediatric (Zolgensma) diseases or cancer (Enhertu, Kymriah).

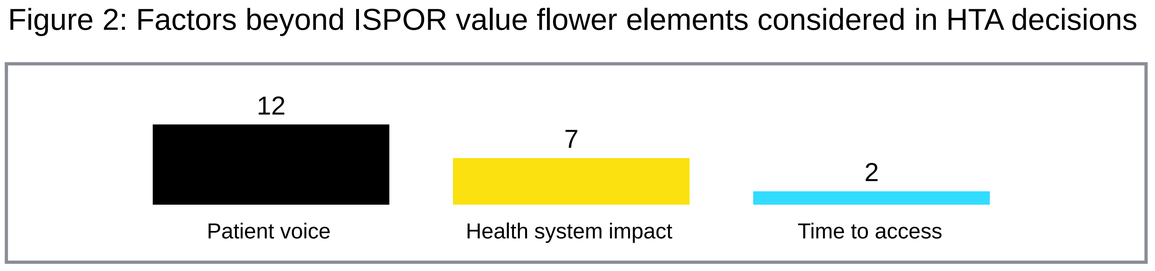
Table 2: Reimbursement status and use of risk-sharing agreements, special pricing arrangements, or financial restrictions

| | Australia | Japan | Taiwan |
|---|---|---|---|
| Kymriah (tisagenlecleucel) | Risk-sharing agreements ▲ | No specific considerations ▲ | Risk-sharing agreements ▲ |
| Emgality (galcanezumab) | Risk-sharing agreements | No specific considerations | Financial restrictions |
| Mayzent (siponimod) | Risk-sharing agreements | | |
| Ultomiris (ravulizumab) | Risk-sharing agreements | No specific considerations ▲ | |
| Trelegy (fluticasone furoate/umeclidinium bromide/vilanterol trifenatate) | Risk-sharing agreements | No specific considerations | No specific considerations |
| Enhertu (trastuzumab deruxtecan) | Not reimbursed in the absence of risk-sharing agreements | No specific considerations ▲ | |
| Revestive (teduglutide) | Risk-sharing agreements | No specific considerations ▲ | No specific considerations |
| Zolgensma (onasemnogene abeparvovec) | Risk-sharing agreements | Coverage with evidence development | No specific considerations |
| Rybelsus/Ozempic (semaglutide) | Special pricing arrangements | No specific considerations | No specific considerations |
| Cosentyx (secukinumab) | Special pricing arrangements | | No specific considerations |

▲ CEA with informal threshold being exceeded

Besides non-traditional elements of value outlined by the ISPOR value flower, additional elements of value have been considered across the 25 HTA reports, including patient voice (12/25), healthcare system impact (7/25), and equity (3/25) (Figure 2).

Figure 2: Factors beyond ISPOR value flower elements considered in HTA decisions




APAC HTA guidelines have also considered societal and novel value elements, beyond those listed in the ISPOR value flower (Table 3). Based on our analysis, these have not played a role in decision-making as of date and remain theoretical in nature. However, implementation of these could be considered by HTA bodies in the future. Additional policy shaping work may be needed in the region to support agencies in recognizing the broader value elements and consequently, the true value of innovative treatments.

Table 3: Factors beyond ISPOR value flower elements considered in APAC country guidelines

| | Adherence improving factors | Consumption | Social services | Legal or criminal justice | Education | Housing | Environment | Transportation | Economic activity | Healthcare system capacity |
|---|---|---|---|---|---|---|---|---|---|---|
| Australia | | | | | | | | | | |
| China | | | | | | | | | | |
| Indonesia | | | | | | | | | | |
| Japan | | | | | | | | | | |
| Malaysia | | | | | | | | | | |
| New Zealand | | | | | | | | | | |
| Philippines | | | | | | | | | | |
| Singapore | | | | | | | | | | |
| South Korea | | | | | | | | | | |
| Taiwan | | | | | | | | | | |
| Thailand | | | | | | | | | | |

Not included  Included

## Conclusion

HTA bodies in APAC markets have incorporated broader value elements into their pharmacoeconomic guidelines, reflecting some similarities with the ISPOR value flower. Additional value elements beyond the value flower have also been recognized, i.e., patient voice, health system impact, and time to access.

In practice, however, value elements have been incorporated to varying degrees, with the disease severity modifier being used the most. There is a need to harmonize the definitions of these value elements across different markets. Additionally, standardization is required, as it remains unclear when, how, and to what extent these elements are being considered in decision-making.

Nevertheless, APAC markets have taken a positive approach towards realizing the true value of treatments in public reimbursement decision-making. Moving forward a systems thinking approach is necessary to ensure that the true value of treatments is recognized.

**Scan here for poster references**

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