

Are global trials good enough to support the reimbursement of a new technology in Asia? A review of Asian HTA submissions

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Background

- An increasing number of Asian countries are implementing structured health technology assessment (HTA) models for reimbursement of new technologies.¹
- Previous literature showed that Asian origin is a potential effect modifier in relative treatment effect estimates.²
- Correspondingly, some Asian HTA bodies seem to prefer analyses based on local trials, or on international trials with considerable participation of Asian patients.
- Local Asian trials are not always feasible and limiting to Asian subpopulations from global trials might result in small sample sizes.

Objective

- The aim of this study was to conduct a review of recent Asian technology appraisals (TA) to understand HTA acceptance and considerations in using global trials to support Asian submissions.

Methods

- A comprehensive review was conducted in June 2022 on the public summary documents of drug TAs published on Asian HTA websites since 2017.
- Data were extracted on the availability of submitted cost-utility analyses (CUA), the usage of local efficacy/safety trial data to reflect local populations, critiques, and the final HTA recommendations.

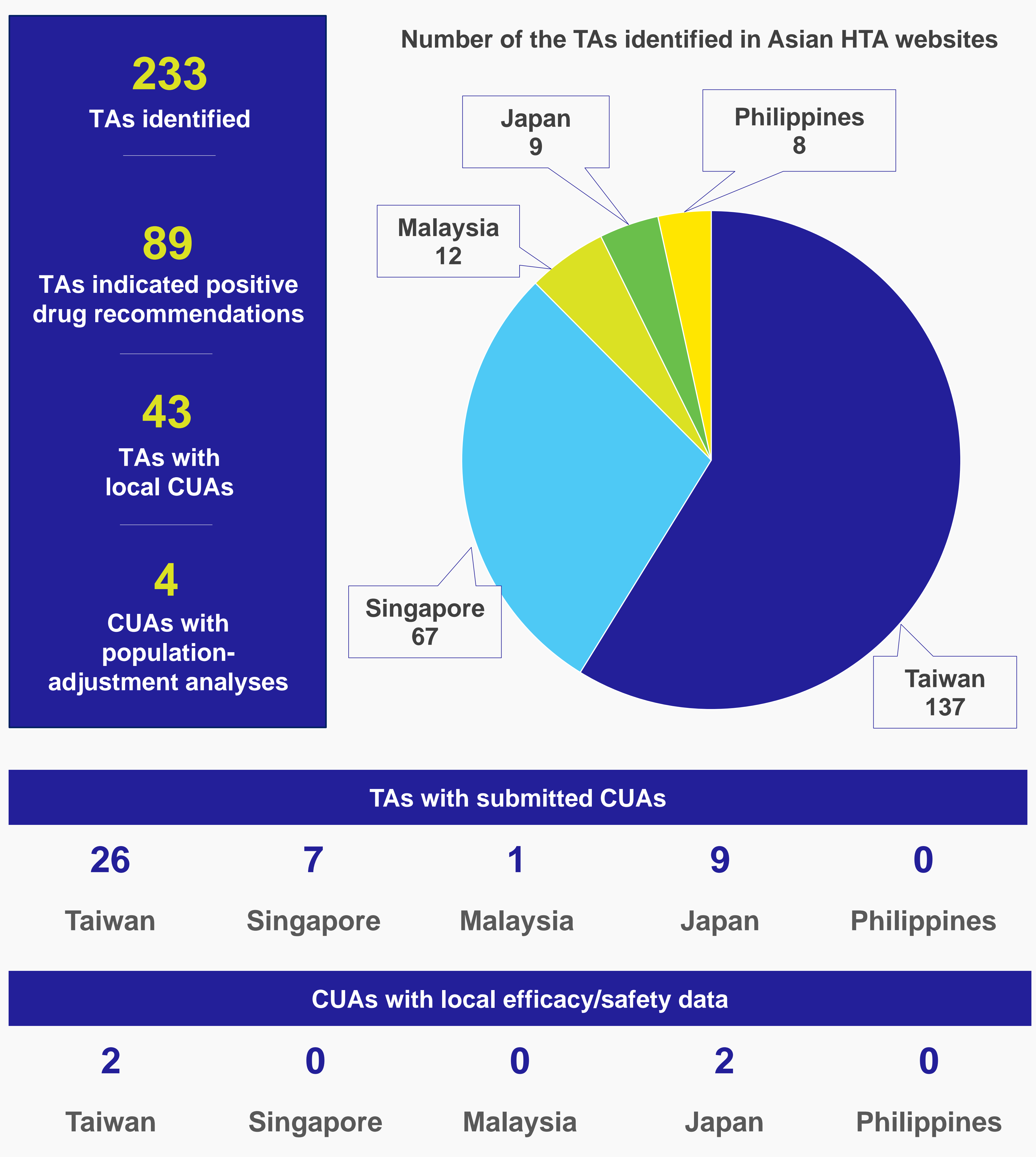
Conclusions

- Asian HTA submissions based on international trials remain the primary source of evidence to support Asian HTA decision-making.
- Not all submissions included CUAs; those submitted with CUAs rarely included local efficacy/safety data.
- This HTA review demonstrated that relying on international trials or local data was not a decisive driver in reaching the final recommendation.

Results

- A total of 233 TAs were identified and reviewed, among which 137 TAs were from Taiwan, followed by Singapore (67), Malaysia (12), Japan (nine), and Philippines (eight).³⁻⁷
- Eighty-nine (38%) TAs indicated explicitly positive drug recommendations.
- Submissions which relied on previously published CUAs, or CUAs submitted to other HTA bodies based on evidence from international trials, received no major critiques from the Asian HTA bodies regarding this topic.
- Only two submissions each in Taiwan and Japan used local Asian model data in their CUAs.
- Among all TAs identified, the suitability of using international trial data instead of local data is only discussed by the Taiwan HTA body. Among 22 out of 137 TAs from Taiwan, the HTA agency criticised the low proportion of Asian patients in the international trials and the lack of transferability of model inputs to a local setting. For the submissions in which the suitability of using data from foreign populations was not discussed by the sponsor, the TAs were usually criticised for that reason.
- In Taiwan, 26 out of 137 TAs included submitted CUAs. In two of those submissions, population-adjustment analyses were performed by using local efficacy/safety data to simulate patient-level data or generate parameters for modelling.
- All nine TAs submitted to Japan agencies included submitted CUAs, in which population-adjustment analyses were conducted in two submissions by using local epidemiological data, such as standardised mortality rates from Japan, or results of network meta-analysis on local trials.
- One submission from Malaysia and seven submissions from Singapore reported the inclusion of CUAs. No adjustment using local data on efficacy/safety was made in the submissions from these countries. No submissions were identified from Philippines.
- Across the Asian markets, and for the submissions without CUAs, the submitted evidence was mainly derived from published literature on economic evaluations or overseas HTA submissions.

Figure 1. Overview of Identified TAs



Abbreviations: CUA, cost-utility analysis; HTA, health technology assessment; TA, technology appraisal

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Disclosures

- The authors declare no conflict of interest.