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Company-led Submission For Cancer Medicines: The Singapore Experience

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Introduction

- The Agency for Care Effectiveness (ACE) conducts Health Technology Assessments (HTAs) to inform funding decisions by the Ministry of Health Drug Advisory Committee (MOH DAC) in Singapore.
- Since 2021, ACE introduced the company-led submission (CLS) process for cancer medicines, allowing pharmaceutical companies to request evaluation of their products alongside regulatory reviews.
- This review reports key findings in the first year of CLS implementation.

Methods

- We conducted a retrospective review of 10 CLS topics in the first year of implementation. We reviewed the status and outcomes of the DAC's recommendations.
- We also evaluated the time from (i) HTA submission to first HTA recommendation and (ii) regulatory approval to the first HTA recommendation using descriptive statistical methods.
- The rollout times were further analyzed by whether submissions were parallel submissions (in tandem with regulatory review) or sequential submissions (HTA submission after regulatory approval). These statistics were compared with overseas reference countries.

Results

- At time of review, 3 topics were pending discussion. Of the remaining 7 topics, 3 (43%) received a positive recommendation for inclusion on the MOH Cancer Drug List and 3 (43%) received negative recommendations. The DAC was unable to make a recommendation on 1 topic.

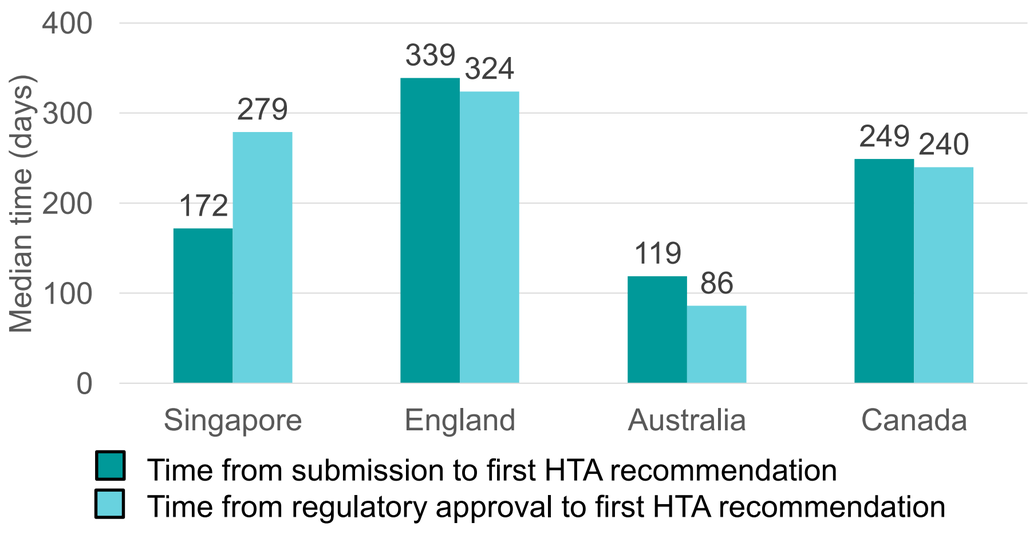

Figure 1: Rollout times across countries

Results

- Median times from HTA submission and regulatory approval to first HTA recommendation were 172 days (169-263 days) and 279 days (53-374 days), respectively (Figure 1).
- Notably, parallel submissions (n=2) had considerably shorter time from regulatory approval to first HTA recommendation compared with sequential submissions (n=4; Figure 2). These timelines were within range of overseas countries.

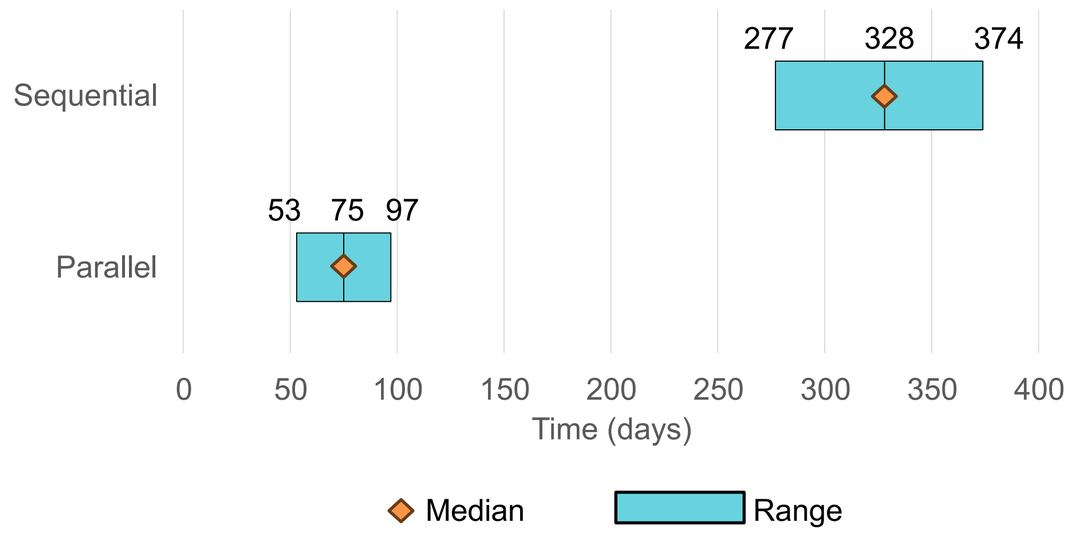

Figure 2: Time from regulatory approval to first HTA recommendation by submission type

Conclusion

- Parallel submissions under the CLS process allow HTAs to be conducted in tandem with regulatory reviews, moving funding decisions upstream, therefore expediting patient access to clinically effective and cost-effective medicines.
- Efforts will be made to further evolve the CLS process for timely reimbursement reviews and expand this process to non-cancer medicines.

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Reference: Further information on rollout times is available in "Sola B, Wang T, McAuslane N. 2023. R&D Briefing 89 Review of HTA outcomes and timelines in Australia, Canada and Europe 2018 – 2022. Centre for Innovation in Regulatory Science London, UK"