Submission Processes and Requirements for Health Technology Assessment in Australia, Canada, England and Spain

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INTRODUCTION

- Health technology assessment (HTA) is a multidisciplinary and systematic process that evaluates the value of health technologies and can inform decision making and reimbursement.
- In general, HTA agencies can be grouped into two basic HTA archetypes based on the type of value assessment that is prioritised: clinical effectiveness or cost effectiveness. Regardless of the type of value assessment prioritised, the submission process can still be remarkably diverse between countries.
- New European Union (EU) legislation [1] was adopted in January 2022 and aims to harmonise HTA processes across Europe, reducing duplication of HTA efforts. However, this EU HTA Regulation (EU HTAR) will be applied in a staggered manner until January 2030. Until this time, the standard HTA processes will be applicable for certain technologies.

Objective: This study assesses the HTA requirements in Australia, Canada, England and Spain: four countries where pharmacoeconomic evidence forms an integral part of the value assessment. Technology developers can use these insights to identify where efficiencies can be made in the global market access strategy for new technologies, such as when to submit HTA dossiers.

METHODS

A pragmatic review and desk-based research were conducted in May 2024. Published articles, HTA guidelines, process documents, conference abstracts, and white papers were reviewed to identify country-specific processes. Where available, data were extracted about the general submission process and stakeholders involved (including regulatory, HTA and pricing authorities), as well as the clinical and pharmacoeconomic evidence requirements for HTA submission. Comparisons of the median time from marketing authorisation to HTA decision within each country were also conducted. The key findings and between-country differences were synthesised in a narrative summary.

RESULTS

The review identified several areas with implications for market access strategy:

- All countries – with the exception of Spain – use a parallel regulatory/HTA process; instead, Spain uses a sequential process (Table 1).
- The median HTA review time between 2014 and 2018 was shortest in Australia (125 days) and longest in England (266 days) (Figure 1). Australia demonstrated general consistency in HTA review time between submissions (interquartile range = 9 days), and England had the most variation in the duration of HTA reviews (interquartile range = 216 days).
- All countries require comparative pharmacoeconomic and clinical evidence within the indication (Table 1). A cost-utility analysis is the preferred analytical tool across countries. However, Spain also places a key focus on budget impact.

Figure 1: HTA timelines

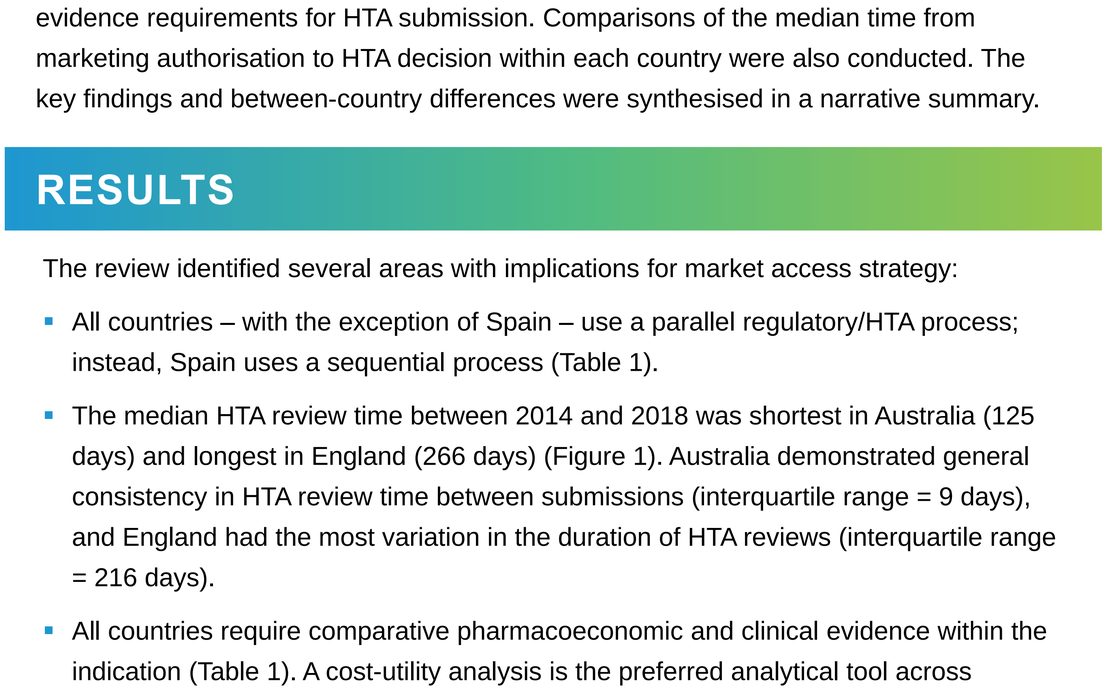

Table 1: Responsible authorities and submission requirements in each country

	Australia	Canada	England	Spain
Responsible authorities				
Regulatory body	TGA	Health Canada	MHRA	AEMPS
National HTA agency	PBAC	CADTH	NICE	AEMPS
Payer	PBS	Publicly-funded federal drug plans	NHS	Autonomous health authorities
General submission process				
Regulatory / HTA submission	Parallel*	Parallel*	Parallel*	Sequential^
Earliest possible HTA submission	When the regulatory review is accepted	180 days before the expected NOC	60 days following invitation	After EMA is accepted
Additional information after submission	Can be requested	Can be requested	Can be requested	Can be requested
Main HTA criteria	Clinical, cost effectiveness	Clinical, cost effectiveness	Clinical, cost effectiveness	Clinical, budget impact
Evaluation of clinical and economic evidence				
Comparator(s)	Any technologies that may be displaced	Any technologies that may be displaced	Any relevant technologies in the indication	None specified
Economic assessment tools	CEA, CMA, CUA	CUA	CUA	CUA and BIM
Threshold per QALY gained	n/a	n/a ($CA 50,000 is often used)	£20,000 to £30,000	n/a
Disease modifiers	Severity of illness	n/a	Severity of illness	n/a
Confidential data	Can be used and redacted	Can be used and redacted	Can be used and redacted	Not specified

*** Not all health technologies or pharmaceuticals are assessed using the parallel process**[2,3]
^ It is possible for the process to be started before CHMP opinion, but this it not the usual or preferred option
Abbreviations: AEMPS, Spanish Agency of Medicines and Medical Devices; CADTH, Canadian Agency for Drugs and Technologies in Health; CEA, cost-effectiveness analysis; CMA, cost-minimisation analysis; CUA, cost-utility analysis; ICER, incremental cost-effectiveness ratio; MHRA, Medicines and Healthcare products Regulatory Agency; n/a, not applicable; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; NOC, Notice of Compliance; PBAC, Pharmaceutical Benefits Advisory Committee; PBS, Pharmaceutical Benefits Scheme; TGA, Therapeutic Goods Administration; QALY, quality-adjusted life year

CONCLUSIONS

The different submission processes and requirements in Australia, Canada, England and Spain are likely to affect the market access strategy for health technology developers. Similar requirements in Australia, England and Canada will allow for efficiencies in submission planning. However, different strategies will be required for Spain, which places a key focus on budget impact. It is likely that the upcoming EU HTAR will make the HTA processes more similar in all EU countries, including Spain. Future research should also investigate how this could affect strategic decision making.

REFERENCES

1. European Commission. *Regulation on Health Technology Assessment* [online]. **2.** Wang T et al. 2019. R&D Briefing 86. Center for Innovation in Regulatory Science [online] **3.** Wang T et al. Front Pharmacol. 2020 Dec 3;11:594549.

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