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

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INTRODUCTION

Health technology assessment (HTA) describes the multidisciplinary systematic process by which the value of health technologies is assessed and is used to inform healthcare decision making. As HTA bodies introduce more rigorous requirements, the submission process is becomingly increasingly complex and diverse between countries; for example, with the introduction of disease modifiers or the incorporation of health equity.

Key global healthcare markets include Australia, Canada, England, France and Germany. This study aimed to assess and compare the HTA submission processes and requirements in these five countries, and it can be used to identify where efficiencies could be made when developing global market access strategy.

METHODS

Pragmatic desk-based research was undertaken in November 2023. Published articles, HTA guidelines, process documents, conference abstracts, and white papers were reviewed. Where available, information was extracted about the general HTA submission process, key stakeholders, clinical evidence requirements, and pharmacoeconomic evidence requirements. The median time from regulatory approval to HTA decision within each country was also identified and extracted.

Table 1: Responsible authorities and submission requirements in each country

	Australia	Canada	England	France	Germany
Responsible authorities					
Regulatory body	TGA	Health Canada	MHRA	ANSM	BfArM and PEI
National HTA agency	PBAC	CADTH	NICE	HAS	IQWiG
Payer	PBS	Publicly-funded federal drug plans	NHS	Social Security System	Statutory Health Insurance
General submission process					
Regulatory / HTA submission	Parallel*	Parallel*	Parallel*	Sequential	Sequential
Earliest possible submission	When the regulatory review is accepted	180 days before the expected NOC	60 days following invitation	Time of regulatory approval	Time of regulatory approval
Additional information after submission	Can be requested	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	Clinical
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	All competing technologies (inclusions / exclusions must be justified)	All relevant technologies in the indication
Economic assessment tools	CEA, CMA, CUA	CUA	CUA	CEA, CUA	No requirement for CEA
Threshold per QALY gained	n/a	n/a ($CA 50,000 is often used)	£20,000 to £30,000	Value according to Actual Benefit Level	n/a
Disease modifiers	Severity of illness	n/a	Severity of illness	SMR and ASMR	Added benefit
Confidential data	Can be used and redacted	Can be used and redacted	Can be used and redacted	Can be used and redacted	Cannot be redacted

*** Not all health technologies or pharmaceuticals are assessed using the parallel process[1,2]**

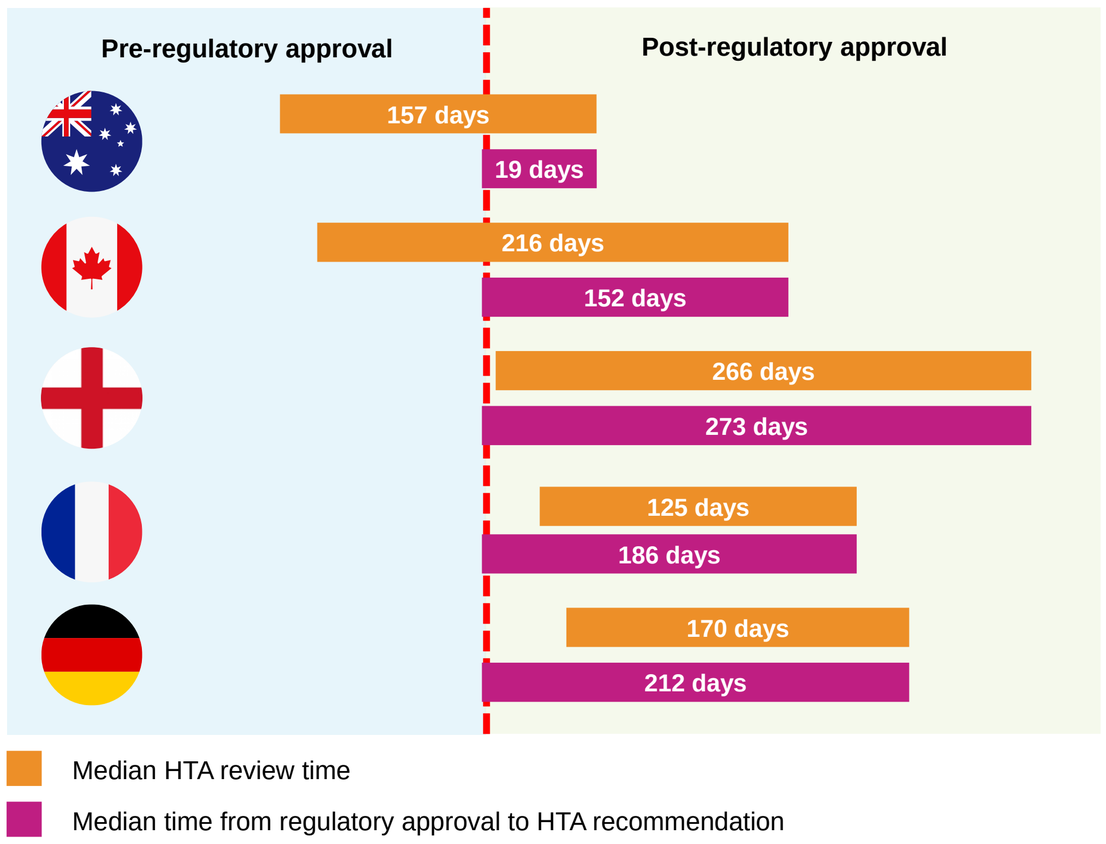
Abbreviations: ANSM, French Agency for the Safety of Medicines and Health Products; ASMR, amelioration du service médical rendu; BfArM, Federal Institute for Drugs and Devices; CADTH, Canadian Agency for Drugs and Technologies in Health; CEA, cost-effectiveness analysis; CMA, cost-minimisation analysis; CUA, cost-utility analysis; HAS, French National Health Authority; ICER, incremental cost-effectiveness ratio; IQWiG, Institute for Quality and Efficiency in Health Care; 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; PEI, Federal Institute for Vaccines and Biomedicines; SMR, service médical rendu; TGA, Therapeutic Goods Administration; QALY, quality-adjusted life year

RESULTS

Information about the responsible regulatory, HTA and pricing authorities as well as the HTA requirements in each of the five countries is presented in Table 1. All countries require comparative clinical evidence within the relevant indication(s). Head-to-head data are preferred but indirect evidence is accepted. Confidential data can be redacted in company submissions in all countries, excluding Germany. Economic evidence requirements are similar across three of the five countries: Australia, Canada and England. Economic evaluation may be requested in France based on risk assessment; however, it is yet to play a real role in Germany.

The median HTA review time is shortest in Australia and longest in England. Companies take advantage of the available parallel processes in Australia and Canada, with the median time from regulatory approval to HTA recommendation faster in these countries. Company-HTA interactions during assessment contribute to a longer review time; the highest frequency of requesting additional evidence from the company was in England, which also had the longest median HTA review time. Timelines are shown in Figure 1.

Figure 1: HTA timelines



CONCLUSIONS

The different submission processes and requirements in Australia, Canada, England, France and Germany are likely to affect the market access strategy for health technology developers. Similar requirements in Australia, England and Canada allow for efficiencies in submission planning. However, different strategies will be required for non-cost-effectiveness markets, such as France and Germany. It is likely that the recent EU HTA Regulation[3] will make the HTA process more similar in all EU countries, including France and Germany. The impact of the EU HTA Regulation on market access should be investigated as the Regulation is rolled out over the coming years.

REFERENCES

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