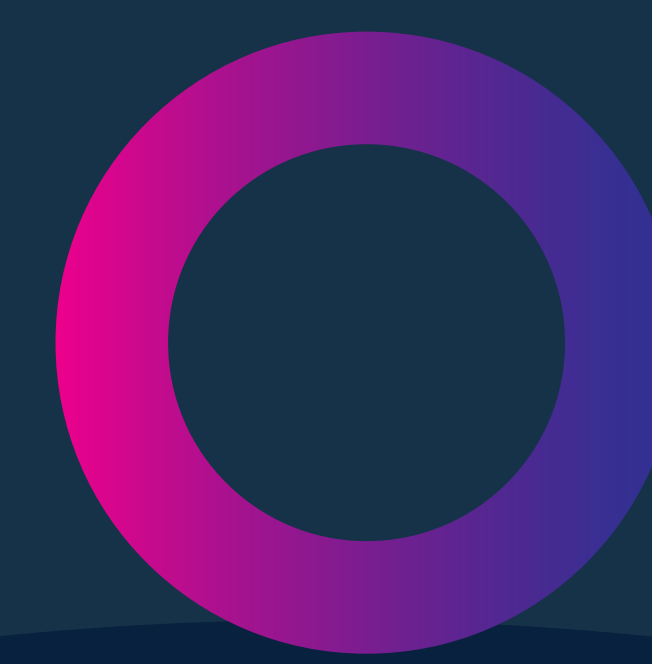


Self-sustainability in HTA: Is a proportionate approach really proportionate?

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INTRODUCTION

- Increasing demand for health technology assessment (HTA) in recent years has highlighted the need for efficiencies within appraisal processes to ensure patients continue to have fast access to new and innovative treatments.
- HTA bodies are modifying their approach to ensure that they can continue to, independently, and continuously, conduct and fund evaluations of treatments, ensuring efficient, evidence-based decision-making and long-term viability.¹⁻⁴
- One such approach is proportionate review, which enables process adaptations to carry out a streamlined, 'light-touch' HTA evaluation process for simpler, low-risk treatments.¹

OBJECTIVES

- To review key healthcare policies across healthcare markets and explore the level of integration of a proportionate approach to HTA in the EU5, Australia, and Canada.
- To evaluate the proportionate approach to HTA in the identified healthcare markets and understand the potential future impact this approach may have on self-sustainability of these healthcare systems.

METHODS

Selection of markets and documents for inclusion

- HTA policies and methodology documents were identified via country government organisation websites, and through review of HTA-specific news and communications released by healthcare agencies in the EU5, Australia and Canada.
- Markets were considered for inclusion if any HTA policy, methodology documents or reports included "proportionate approach" considerations and goals.
- Healthcare policies relating to HTA methodology were reviewed and analysed to assess the level of inclusion and approach to proportionate HTA, particularly focusing on process stream-lining and self-sustainability.
- In addition, web-crawling was used to determine the impact of proportionate review on HTA timelines.

Proportionate approach considerations

The policies and any HTA methodology documents were reviewed to determine the level of integration of a proportionate approach (i.e., how many mentions), targets and anticipated implementation dates.

RESULTS

Availability of policies mentioning proportionate approach

- HTA methodology documents which include considerations for a proportionate approach were identified in the United Kingdom (UK), Canada, and Australia. Relevant policy documents identified from the National Institute of Health and Care Excellence (NICE) in the UK, the Australian Government Department of Health and Aged Care (DoHAC), and Canada's Drug Agency (CAD), are shown in Table 1.
- All three identified markets included policies which set out specific requirements or goals for a proportionate approach in HTA methodology, including potential implementation timelines.
- In contrast, the inclusion of specific proportionate approach methodologies and self-sustainability considerations in HTA methodologies of other markets in the EU5 (Germany, France, Spain and Italy), was either limited or absent.
- These countries are investigating methodology adjustments aimed at streamlining HTAs and improving access pathways, particularly for innovative therapies such as advanced therapy medicinal products.

Table 1. Included markets and documents reviewed per market

MARKET	HTA METHODOLOGY DOCUMENTS INCLUDED	DATE OF POLICY
	Proportionate approach to technology appraisals: final report 2022-23 ²	April 2023
	NICE consultation on the first modular update of the Guide to Health Technology Evaluation (PMG36) ⁵	October 2023
	Upcoming Improvements to the Reimbursement Review Process ³	June 2023
	CADTH Pharmaceutical Reviews Update — Issue 38 ⁶	June 2023
	CADTH Pharmaceutical Reviews Update — Issue 39 ⁷	June 2023
	CADTH Pharmaceutical Reviews Update — Issue 43 ⁸	January 2024
	CADTH Pharmaceutical Reviews Update — Issue 44 ⁹	February 2024
	HTA Policy and Methods Review – Final report <i>Accelerating Access to the Best Medicines for Australians Now and into the Future</i> ⁴	September 2024

Variation in proportionate approach initiatives across markets

- Progress and timelines for implementing a proportionate HTA approach differ significantly across markets, reflecting varying levels of integration and outcomes.
- The considerations and implementations of a proportionate approach to HTA is relatively recent, with the UK as the first market announcing a proportionate approach to HTA in 2022, followed by Canada in 2023, and Australia in 2024.
- Among these markets, only the UK has detailed methodologies with clear targets and implementation timelines, with Australia as the latest market to announce upcoming changes to its HTA methodology in-line with a proportionate approach.

DISCUSSION

NICE, UK ^{2,5}	
START DATE	• NICE introduced and piloted a proportionate approach in 2022.
KEY ACTIONS	• Simplified, removed, or reconfigured parts of the appraisal process.
PROGRESS AND RESULTS	<ul style="list-style-type: none"> During Phase 1 of the project (pilot), NICE recommended 6 treatments which benefitted around 175,000 patients and sped up the process by up to 20 weeks (45%).¹ In Phase 2, the pathways approach will shift towards using reference models within the current Single Technology Appraisal framework. Process improvements, proportionate reviews, and rapid entry to managed access development were explored, but some initiatives were paused pending further reviews and consultations.⁵ Exploring proportionate processes for topic reviews, including biosimilars and generics continues into 2024/25.⁵
NEXT STEPS	<ul style="list-style-type: none"> Following interim implementation of proportionate approaches, NICE will formally incorporate them into the manual for health technology evaluations through modular updates. The first modular update was announced in October 2023, covering several aspects, including its cost comparison process and streamlined committee decision-making.⁵
Implementation of a proportionate approach to HTA has contributed to producing timely guidance and supported more patients receiving faster access to new treatments. NICE is continuing to explore further ideas and proportionate approaches to HTA.	

CAD, CANADA ³	
START DATE	• Updates announced in June 2023.
KEY ACTIONS	• Improve the pathway that provides access of effective drugs to patients.
PROGRESS AND RESULTS	<ul style="list-style-type: none"> Introduced the Family Medicine Education Consortium (FMEC) in June 2023 to create a controlled test-and-learn environment to introduce innovative approaches to reviews, methods, deliberative processes, stakeholder inputs, and the communication of outputs.^{6,9} From June 2023 – February 2024, FMEC has assessed and provided reimbursement recommendations for 8 single drugs, 2 drug classes, and 1 therapeutic area. Their reviews have focused on: <ul style="list-style-type: none"> Streamlined Drug Class Reviews⁷ Streamlined Economic Reports⁸ Revision of criteria for submission of a Cost Minimization Analysis⁸
NEXT STEPS	• FMEC pilot phase has been extended, although there is limited mention as to next steps. ⁹
CAD has outlined key updates aimed at reducing the burden associated with HTA, and continue to expand their program. Whilst detailed outcomes from the introduction of a proportionate approach are not yet available, an increase in FMEC suggest positive outputs.	

DOHAC, AUSTRALIA ⁴	
START DATE	• Recommendations published in September 2024.
KEY ACTIONS	<ul style="list-style-type: none"> Streamline and simplify health technology funding by removing unnecessary complexity and redundancy. Restructure health technology funding and assessment processes so they are fit-for-purpose and proportionate to the level of risk, complexity and potential benefit of a therapy. Create consistency and clarity by developing a unified HTA pathway process.
DoHAC has recently announced potential updates to its processes as part of a shift towards proportionate HTA, with these plans still in the early stages of development. There is an opportunity for Australia to utilise the work conducted by NICE in the UK and CAD in Canada to understand opportunities for effectively introducing a proportionate approach and adapting these to the needs of the Australian healthcare system.	

Abbreviations: CADTH, Canadian Agency for Drugs and Technologies in Health; HTA, health technology assessment; NICE, National Institute of Health and Care Excellence

CONCLUSIONS

- A sustainable HTA approach can streamline the assessment process, reduce the time needed to evaluate new treatments and ensure long-term efficiency in decision-making.
- The UK, Canada and Australia are introducing self-sustainability to their appraisal processes through a proportionate approach to HTAs to meet the growing demand for appraisals.
- As further outcomes from HTA methodology revisions are released, it is anticipated that HTA bodies may reduce their reliance on demonstrating plausible cost-effectiveness in cases of limited data. This shift aims to expedite market access and uptake of innovative treatments, especially in response to the growing need for rapid assessment of new therapies.
- While the use of a proportionate approach to HTA is limited in some markets, other HTA bodies may make methodological changes without explicitly referring to them as such.

By simplifying and reconfiguring parts of existing HTA processes, a proportionate approach results in a faster technology evaluation process and subsequently rapid guidance development, allowing HTA bodies to re-invest time to evaluate other, more complex appraisals.

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