

# The value vocabulary: An analysis of societal terms in CDA-AMC and INESSS Health Technology Assessment decision-making



HTA54

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## Background

- In Canada, CDA-AMC and INESSS are the two major HTA bodies. While INESSS has always taken a societal approach to reviews, CDA-AMC only accepted a drug plan perspective. In 2024, CDA-AMC launched a societal co-base pilot that allows manufacturers to include both societal and healthcare payer perspectives in complex reviews (e.g., first-in-class therapies, gene therapies).<sup>1</sup>
- Prior to 2025, CDA-AMC's deliberative framework considered overall clinical benefit, alignment with patient values, cost-effectiveness, and feasibility of adoption into the health system. Reimbursement recommendations summarized the expert committee deliberation, as well as input from patients and clinicians.
- In October 2025, CDA-AMC implemented a new deliberative framework; one aspect of which was to introduce a new domain of "social and ethical considerations" to inform deliberations regarding funding on pharmacotherapies.

## Objectives

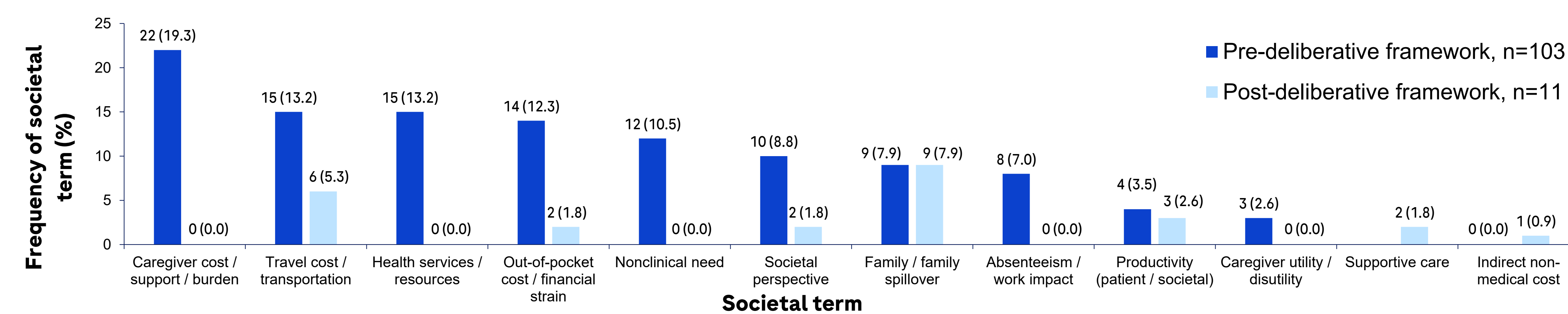
- Examine the impact of formal inclusion of social and ethical considerations in CDA-AMC reimbursement recommendations following the implementation of the new deliberative framework.
- Examine the inclusion of a societal perspective in complex reviews and the impact on reimbursement recommendations.
- Compare the outcomes of CDA-AMC's complex reviews with those of corresponding INESSS reviews.

## Results

### Impact of formal inclusion of societal and ethical considerations following the new CDA-AMC deliberative framework

- Pre-deliberative framework (n/N=103/114), concepts such as caregiver burden (22 mentions) and travel costs (15 mentions) were primarily found in patient input but not discussed in the reimbursement recommendations (Figure 2).
- As of December 1, 2025, post-deliberative framework recommendations (n/N=11/114) show a shift toward acknowledging societal needs as a formal value domain in deliberations (e.g., home-based administration reducing out-of-pocket costs), in addition to patient input, although this has not yet been translated into the pricing or funding criteria.
  - None of the reimbursement recommendations explicitly state that the sponsor submitted a societal perspective as their base-case.

Figure 2. Frequency of specified societal terms across CDA-AMC reimbursement recommendations (N=114)



## Conclusions

- The integration of social and ethical considerations enable a structured deliberative pillar.
- Early results show increased mentions of societal needs; however, the practical impact of these considerations (including nonclinical needs, reimbursement recommendations, and impact of economic evaluations) is yet to be clear.

## Limitations and future steps

- The study was limited by a small sample size of post-deliberative framework recommendations and complex reviews.
- Full clinical and economic data in reimbursement recommendations were not reviewed.
- AI was used for data analysis, limiting the interpretation of qualitative data, although results were validated by human reviewers.
- Future steps include continuing to monitor reimbursement reviews under the new deliberative framework.

## Abbreviations

AI, artificial intelligence; CDA-AMC, Canada's Drug Agency / l'Agence des médicaments du Canada; CDEC, Canadian Drug Expert Committee; HTA, Health Technology Assessment; ICER, incremental cost-effectiveness ratio; INESSS, Institut national d'excellence en santé et en services sociaux.

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## Disclosures

JSM, LY and SY are employees of F. Hoffmann-La Roche Ltd. JET did not receive any honoraria for this work.

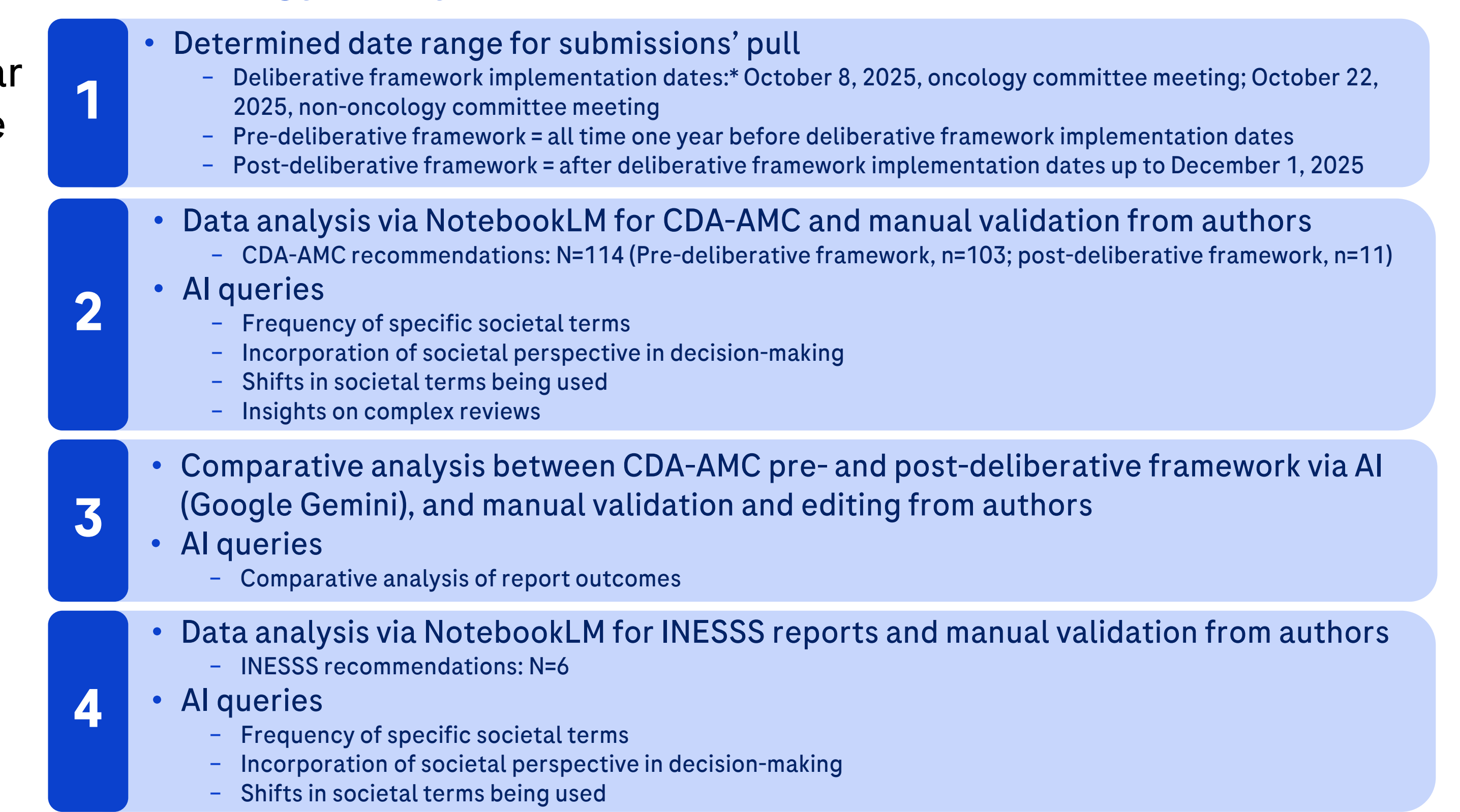
## References

- Piloting the Addition of New Perspectives to Economic Evaluations of Drugs. CDA-AMC. (March 2024). <https://www.cda-amc.ca/news/piloting-addition-new-perspectives-economic-evaluations-drugs>. (Accessed April 2026).

## Methods

- A comparative analysis was conducted on CDA-AMC patient input reports and reimbursement recommendations issued one year pre-deliberative framework and post-deliberative framework, using manual review and AI (NotebookLM)-generated summaries (Figure 1).
  - Reimbursement recommendations were evaluated for frequency and context of societal keywords (e.g., productivity, caregiver burden, travel costs, family spillover, etc.).
- Complex submissions explicitly incorporating societal perspective economic analyses were further analyzed, and the corresponding INESSS reviews were analyzed to compare across HTA bodies.

Figure 1. Methodological framework for HTA societal terminology analysis



\*Not equal to submission dates.

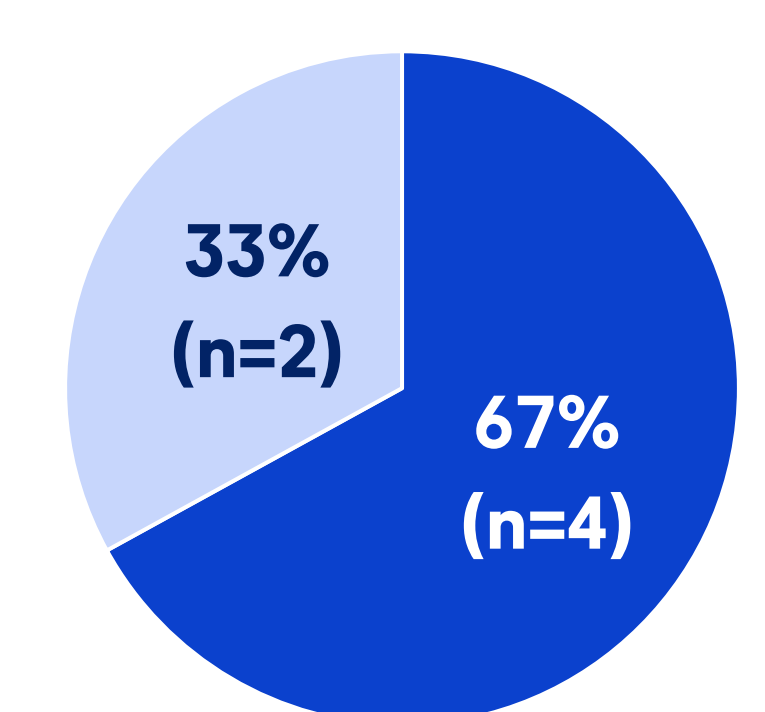
## CDA-AMC complex reviews – Societal perspective pilot

- Explicit evaluation of societal perspective by CDA-AMC allowed committees to consider reimbursement based on unmet clinical needs for drugs targeting ultra-rare diseases (e.g., omaveloxolone and tofersen; Table 1).
- Among the six complex reviews with a manufacturer submitted societal analysis co-base case, CDA-AMC conducted a base-case societal perspective reanalysis in 33% (n/N=2/6) of the reviews (Figure 3).
- In the two CDA-AMC reanalyses considering the societal perspective, committee deliberations deemed the societal perspective evaluations to be too uncertain for decision-making, resulting in prioritization of the payer perspective.

Table 1. Summary of complex reviews with societal perspective evaluations

Product	Indication	Recommendation	Societal analysis co-base submitted by manufacturer	Societal analysis co-base accepted by CDA-AMC	Societal perspective implication on deliberative framework
Omaveloxolone	Friedreich's ataxia	Reimburse with conditions	Yes	Yes	CDEC deemed the indirect cost and outcome model inputs highly uncertain due to a lack of evidence; therefore, the societal analysis was deemed too uncertain to inform decision-making
Fecal microbiota	Clostridioides difficile infection	Reimburse with conditions	Yes	Yes	CDEC considered the results of the societal analysis too uncertain to inform decision-making
Trofinetide	Rett syndrome	Do not reimburse	Yes	Yes	The societal perspective analysis was not mentioned in the summary of the CDEC deliberation
Teprotumumab	Thyroid eye disease	Do not reimburse (Draft)	Yes	No	The societal perspective analysis was dismissed by the CDA economic reviewers due to concerns about flawed long-term cost and efficacy assumptions, and therefore was not considered in the CDEC deliberation
Tofersen	Amyotrophic lateral sclerosis	Reimburse with conditions	Yes	No	The societal perspective analysis was dismissed by the CDA-AMC economic reviewers due to lack of robust methodology, and therefore was not considered in the CDEC deliberation
Teplizumab	Type 1 diabetes	Do not reimburse (Draft)	Yes	Yes	The societal perspective analysis was not mentioned in the summary of the expert committee deliberation

Figure 3. Proportion of post-deliberative framework complex reviews with societal perspective reanalysis (N=6)



- Co-base case societal perspective reanalysis not conducted
- Co-base case societal perspective reanalysis conducted

## INESSS reports

- Five out of the six submissions reviewed by CDA-AMC had available recommendations from INESSS (one out of the six submissions was still under review as of December 1, 2025).
- INESSS reports indicated stronger emphasis on societal values (e.g., family spillover, 30+ mentions in four reports) but found marginal practical impact on outcomes, with 80% (n/N=4/5) of the drugs receiving negative recommendations; however, the impact of societal perspective relative to clinical and economic data on recommendations remains unclear.



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