Streamlined Success or Missed Opportunity: Evaluating the Impact of Simplified Economic Approaches on HTA Recommendations Across CDA-AMC, INESSS and NICE

Jessica S Moreira[1], Lori Yin[1], Simon Yunger[1]

1. Hoffmann-La Roche Limited; Mississauga, Ontario

Background

- Health Technology Assessment (HTA) bodies have taken ongoing measures to streamline the process of bringing effective drugs to patients, including simplified economic approaches (SEA) (defined as cost-minimization analysis [CMA] and cost comparison [CC]*).
- Canada's Drug Agency (CDA-AMC) revised its *Procedures for Reimbursement Reviews* in 2020 to accept CMA under certain clinical and cost criteria**[1].
  - These *Procedures* became effective on October 20, 2020 for oncology drugs and October 26, 2020 for non-oncology drugs[1].
  - In 2024, CDA-AMC removed the requirement that CMA must show cost savings relative to appropriate comparators[2].
  - In 2025, CDA-AMC introduced the Pharmaceuticals with Anticipated Comparable Efficacy and Safety (PACES) proportionate approach pathway with a mandatory CMA for simpler low-risk assessments as an expansion to their 'Tailored Review' stream***[3].
- In 2022, National Institute for Health and Care Excellence (NICE) introduced a proportionate approach to technology appraisals that included CC[4,5].
- As of 2023, Institut National D'excellence en Santé et Services Sociaux (INESSS) does not conduct a reanalysis of the budget impact for products submitted with a CMA or where the 3-year budget impact is below $10M[6,7].

*CMA and CC both evaluate the costs of interventions with comparable health outcomes. However, CMA goes a step further by providing a deeper analysis to identify the most cost-effective option. Cost-utility analyses (CUA) and cost-effectiveness analyses (CEA) compare the costs of different interventions with their respective benefits or outcomes.

**1. The drug represents an additional drug in a therapeutic class. 2. The drug under review demonstrates similar clinical effects. 3. The drug under review is anticipated to result in equivalent or lesser costs.

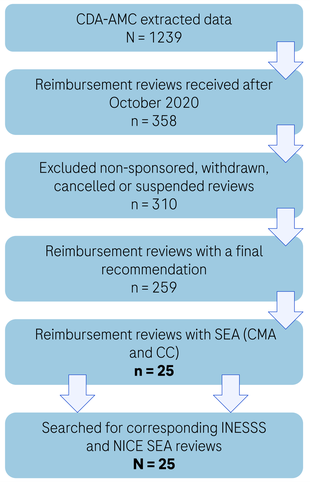
***CDA-AMC employs a proportionate approach to drug reviews, consisting of three levels: tailored, standard, and complex. Each level aligns the resources to the effort required for a comprehensive evaluation. The Tailored Review stream focuses on new combination products, new formulations of existing drugs, and PACES.

Objective

This analysis examined the usage of SEA in CDA-AMC, INESSS and NICE submissions and their associated recommendations.

Methods

- CDA-AMC reviews were extracted, as of December 31, 2024[8].
  - CDA-AMC reimbursement reviews with a final recommendation issued to sponsor and drug plans that were received after October 20, 2020 for oncology drugs and October 26, 2020 for non-oncology drugs were included for analysis.
  - Non-sponsored review types, such as Formulary Management Expert Committee (FMEC) and request for advice (RFA), and withdrawn, cancelled or suspended reimbursement reviews were excluded.
- Reimbursement reviews were stratified by type of economic analysis submitted (CMA, CC, or CUA/CEA).
- The corresponding SEA reviews were searched for INESSS and NICE[9,10].
- Data analysis was conducted using Google Sheets.



Figures and Tables

Figure 1. Overall volume of CDA-AMC submissions by pharmacoeconomic analysis type (n = 259 subs).

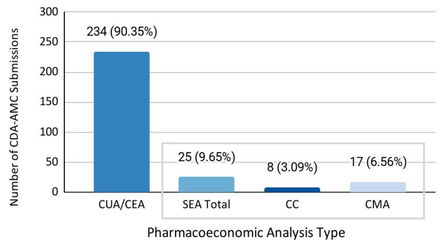
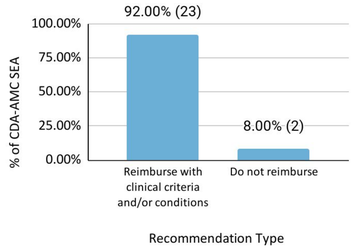


Figure 2. CDA-AMC outcomes for SEA submissions (n = 25 subs).



Figures 3. Proportion of CDA-AMC pharmacoeconomic analysis type. A. In non-oncology (n = 138 subs). B. In oncology (n = 104 subs).

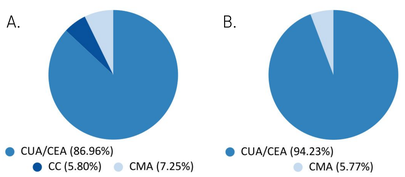


Figure 4. Overall volume of SEA submitted to CDA-AMC over time (n = 25 subs in 2024).

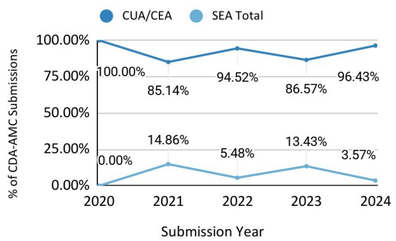


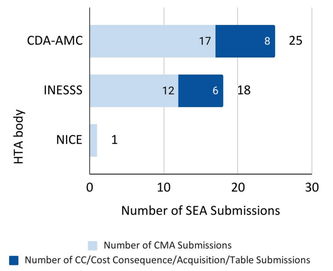
Table 1. INESSS outcomes for corresponding SEA submissions by manufacturer submitted pharmacoeconomic analysis type (n = 23 subs).

INESSS Recommendation Type	CUA	CMA	Cost Consequence /Acquisition Cost	Cost Table	n/a	Total
Inscription: Registration	-	3	1	-	-	17.39% (4)
Inscription - Avec conditions: Conditional Registration	2	8	3	1*	2**	69.57% (16)
Refus d'inscription: Registration Refusal	No economic analysis is conducted when the clinical review is negative					13.04% (3)

*2 submissions combined from CDA-AMC; **Recommended to be on the 'liste des produits du système du sang du Québec', or Economics were previously reviewed by INESSS.

Note: INESSS re-analysis led to changes to pharmacoeconomic analysis type for 4 subs. CUA → Acquisition Cost, CUA → CMA, CMA → Cost Consequence, Cost Consequence → CMA.

Figure 5. Overall volume of HTA body SEA submissions upon reanalysis.



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10. *NICE guidance*. (n.d.). https://www.nice.org.uk/guidance

Disclosures

This work has been produced by Hoffmann-La Roche Ltd.

Results

- Of the 259 CDA-AMC reimbursement reviews analyzed, 234 (90.35%) included CUA/CEA, while 25 (9.65%) included SEA (8 [3.09%] included CC and 17 [6.56%] included CMA).
  - 23/25 (92.00%) SEA submissions received recommendations to reimburse with clinical criteria and/or conditions; of those 100.00% included cost parity/savings criteria.
- Although CDA-AMC performed reanalyses on manufacturer submissions in some cases, there were no changes to pharmacoeconomic analysis type.
- SEA makes up a higher proportion of non-oncology (13.04%) than oncology (5.77%) CDA-AMC submissions.
- Since CDA-AMC SEA acceptability, use of SEA has not increased over time.

Based on the sample 25 SEA reviewed by CDA-AMC,

- INESSS had 2 CUA, 11 CMA, and 4 cost consequence/acquisition cost, and 1 cost table manufacturer submissions where an economic review was published.
  - 3/11 (27.27%) CMA received full recommendations to reimburse and 8/11 (72.73%) had conditions, of which 7/8 (87.50%) included cost criteria.
  - 1/4 (25.00%) cost consequence/acquisition cost received full recommendations to reimburse and 3/4 (75.00%) had conditions, of which 100.00% included cost criteria.
  - The cost table received a recommendation with conditions that included cost criteria.
- INESSS had 12 CMA, 5 cost consequence/acquisition cost, and 1 cost table SEA submissions upon reanalysis.
  - Of the 4 submissions where reanalysis involved changes to pharmacoeconomic analysis type, 1/4 (25.00%) received full recommendations to reimburse and 3/4 (75.00%) had conditions, of which 100.00% included cost criteria.
- The two CDA-AMC SEA submissions that received recommendations to not reimburse had the same outcomes at INESSS, showcasing concordance in the clinical conclusions.
- From the sample 25 examined by NICE, only one drug submission and one reanalysis included a CMA.
  - One drug submitted both CUA and CMA, which was reanalyzed as a CUA only.
  - Another drug was submitted as a CUA but was reanalyzed as a CMA.
- None of the sample 25 underwent the NICE proportionate approach pilot.
  - In the pilot, 9/11 proportionate approach reviews used CC and 2/11 had CUA; none of these were captured in our sample 25.

Conclusions

- Since SEA acceptability within the CDA-AMC *Procedures* in 2020, SEA submissions remain a minority proportion of submissions.
- Where used in CDA-AMC submissions, all SEA recommendations included cost parity/savings criteria.
- Since the streamlined approaches to technology appraisals were introduced, there has been some consistency between the SEA submitted to Canadian HTA bodies (CDA-AMC and INESSS), but not with NICE.
- Greater utilization and consistency in the use of SEA may allow for additional streamlined reviews in the future.

Limitations

- Started with SEA submissions results from CDA-AMC, so it is possible that some SEA submissions from INESSS and NICE might have been missed.
- There was a small sample size for comparison.