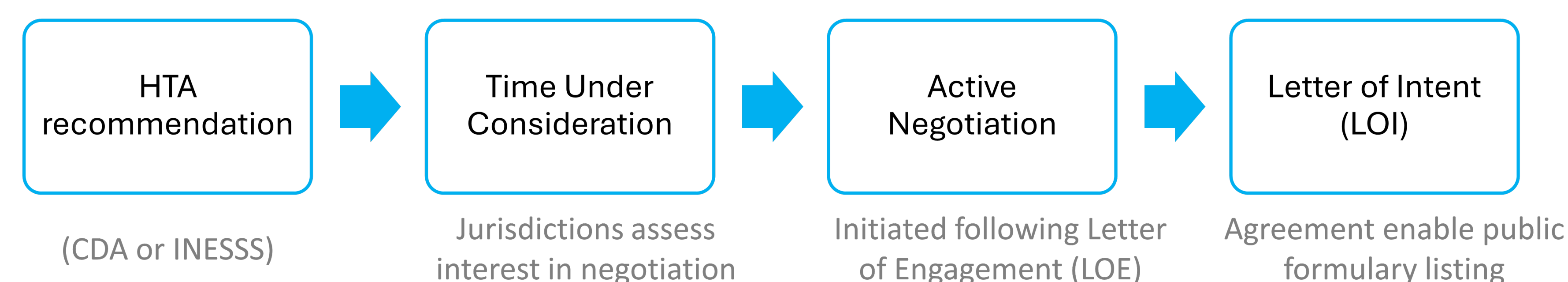


## BACKGROUND

- In Canada, public reimbursement for new medicines follows a sequential process beginning with a Health Technology Assessment (HTA) and, where applicable, subsequent price negotiations through the pan-Canadian Pharmaceutical Alliance (pCPA).
- HTA recommendations are issued by Canada's Drug Agency (CDA) for all provinces and territories outside Quebec, and by the Institut national d'excellence en santé et en services sociaux (INESSS) for Quebec.
- Following an HTA recommendation, products may enter the pCPA negotiation process, which includes a Time Under Consideration phase, followed by active negotiations, and concludes with a Letter of Intent (LOI) enabling public formulary listing (Figure 1).<sup>1</sup>
- Timely and predictable progression through HTA and pCPA negotiations is critical for manufacturers to support market access planning and resource allocation.
- pCPA dashboard metrics (June 2025) suggest improved timelines between 2020 and 2025; however, real-world alignment with these estimates has not been formally assessed.

**Figure 1. pCPA negotiation process following an HTA recommendation**



## OBJECTIVES

- This study aimed to evaluate the duration of the pCPA negotiation process for non-oncology drugs, specifically from HTA recommendation to Letter of Intent (LOI), and assess alignment with pCPA-reported estimates.

## METHODS

Component	Description
<b>Study design</b>	Retrospective review of publicly available data (CDA and pCPA websites) <sup>2,3</sup>
<b>Study period</b>	January 1, 2023 – May 31, 2025
<b>Study population</b>	Branded non-oncology drugs with positive HTA recommendation and pCPA LOE
<b>Exclusion criteria</b>	Oncology drugs, biosimilars, generics, and products not concluding with a LOI
<b>Data sources</b>	Canada's Drug Agency (CDA), INESSS, and pCPA public information
<b>Time intervals evaluated</b>	<ul style="list-style-type: none"> <li>Time Under Consideration: CDA recommendation → LOE</li> <li>Active Negotiation: LOE → LOI</li> <li>Total Time: CDA recommendation → LOI</li> </ul>
<b>Outcome measure</b>	Median duration of each interval (in months, using calendar dates)
<b>Analysis approach</b>	Products grouped by LOE year; results reported as medians

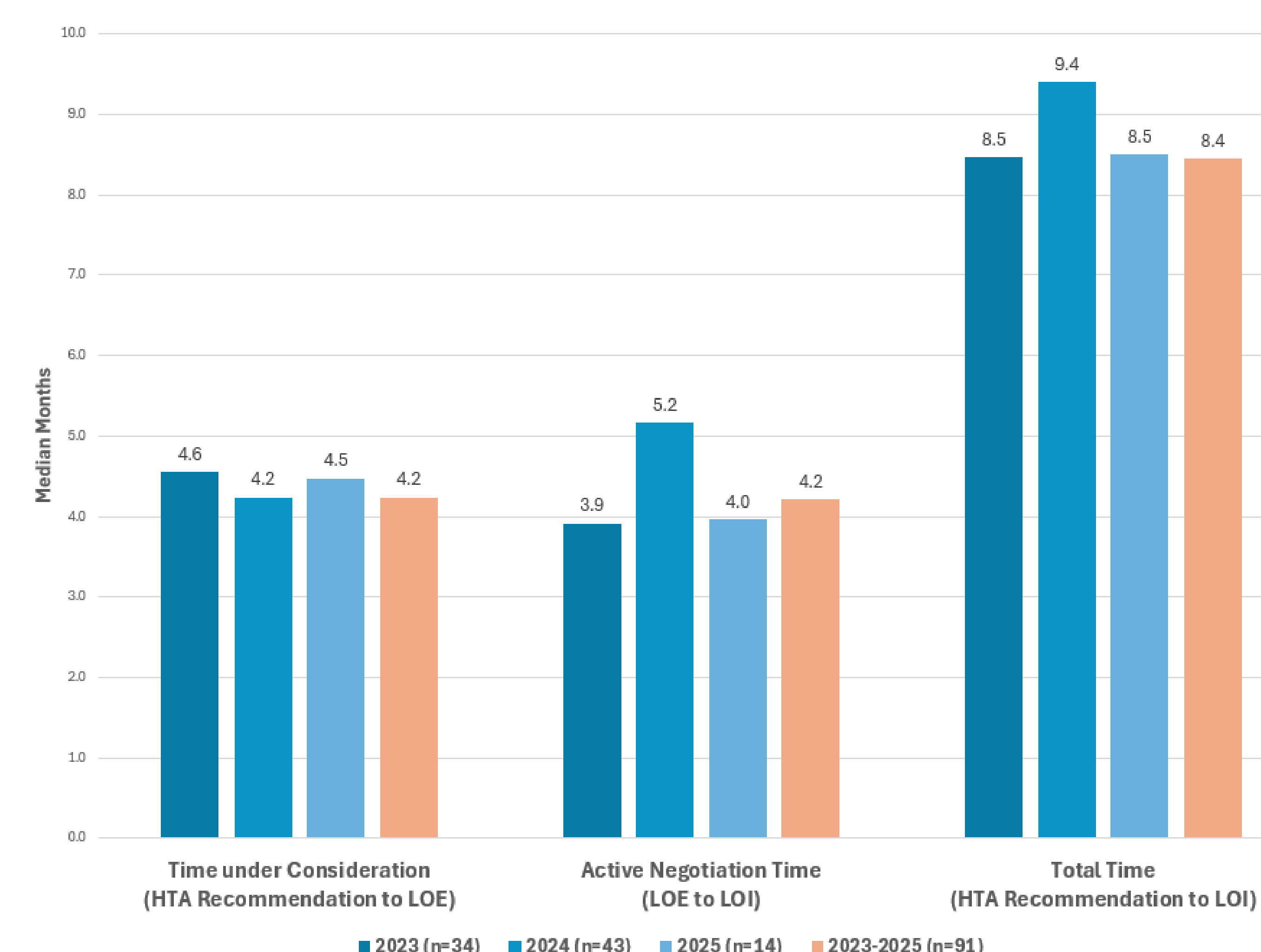
## RESULTS

- N = 91 branded non-oncology drugs included across 2023–2025, categorized by year of pCPA Letter of Engagement (LOE).
- Median time from HTA recommendation to LOE was consistent across years (4.2–4.6 months).
- Median active negotiation time (LOE to LOI) ranged from 3.9 to 5.2 months, accounting for most observed variability.
- Total median time from HTA recommendation to LOI ranged from 8.5 to 9.4 months, with an overall median of 8.4 months.

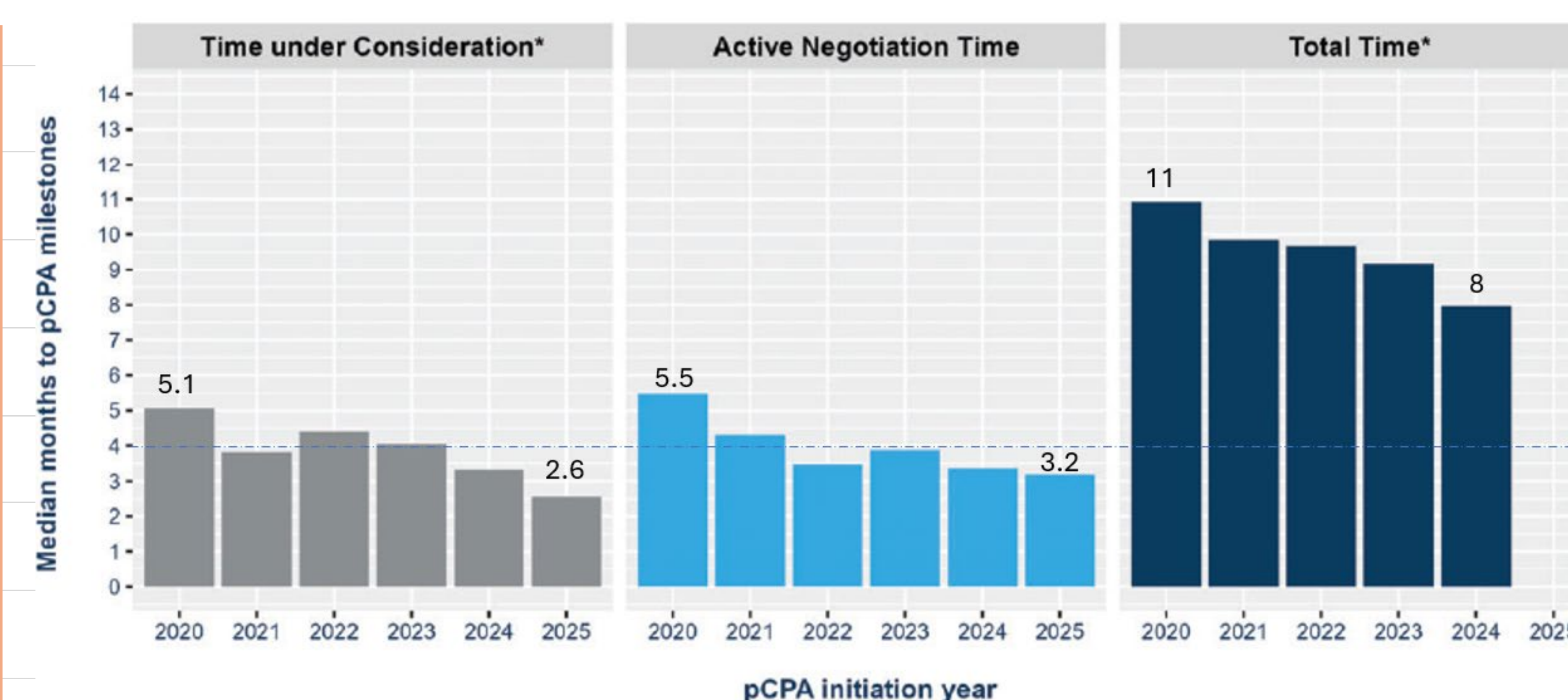
**Table 1. Internal analysis- Median number of Months (By year of LOE)**

	Time under Consideration (HTA Recommendation to LOE)	Active Negotiation Time (LOE to LOI)	Total Time (HTA Recommendation to LOI)
<b>2023 (n=34)</b>	4.6	3.9	8.5
<b>2024 (n=43)</b>	4.2	5.2	9.4
<b>2025 (n=14)</b>	4.5	4.0	8.5
<b>2023-2025 (n=91)</b>	<b>4.2</b>	<b>4.2</b>	<b>8.4</b>

**Figure 2. Internal Analysis on pCPA timelines (in months)**



**Figure 3. pCPA Dashboard timelines (June 2025)**



## CONCLUSION

- Observed timelines from the internal analysis were longer than pCPA dashboard-reported timelines.
- In pCPA dashboard reporting, median Time Under Consideration and Active Negotiation durations did not exceed 4 months between 2023 and 2025.
- In contrast, internal analyses showed longer durations, with the greatest divergence observed during the Time Under Consideration phase.
- Inclusion of biosimilars in pCPA reporting likely contributes to shorter reported timelines.
- These findings provide manufacturers with more realistic planning assumptions for branded non-oncology products.

## REFERENCES

- pCPA website. The negotiation process. <https://www.pcpacanada.ca/negotiation-process>. Accessed May 2026
- Canada's Drug Agency (CDA). Find reports. Accessed April 2026.
- pCPA Website. Brand Name Drug Negotiations Status. Accessed April 2026.