

The impact of the Clinical Added Value labels on price negotiation duration

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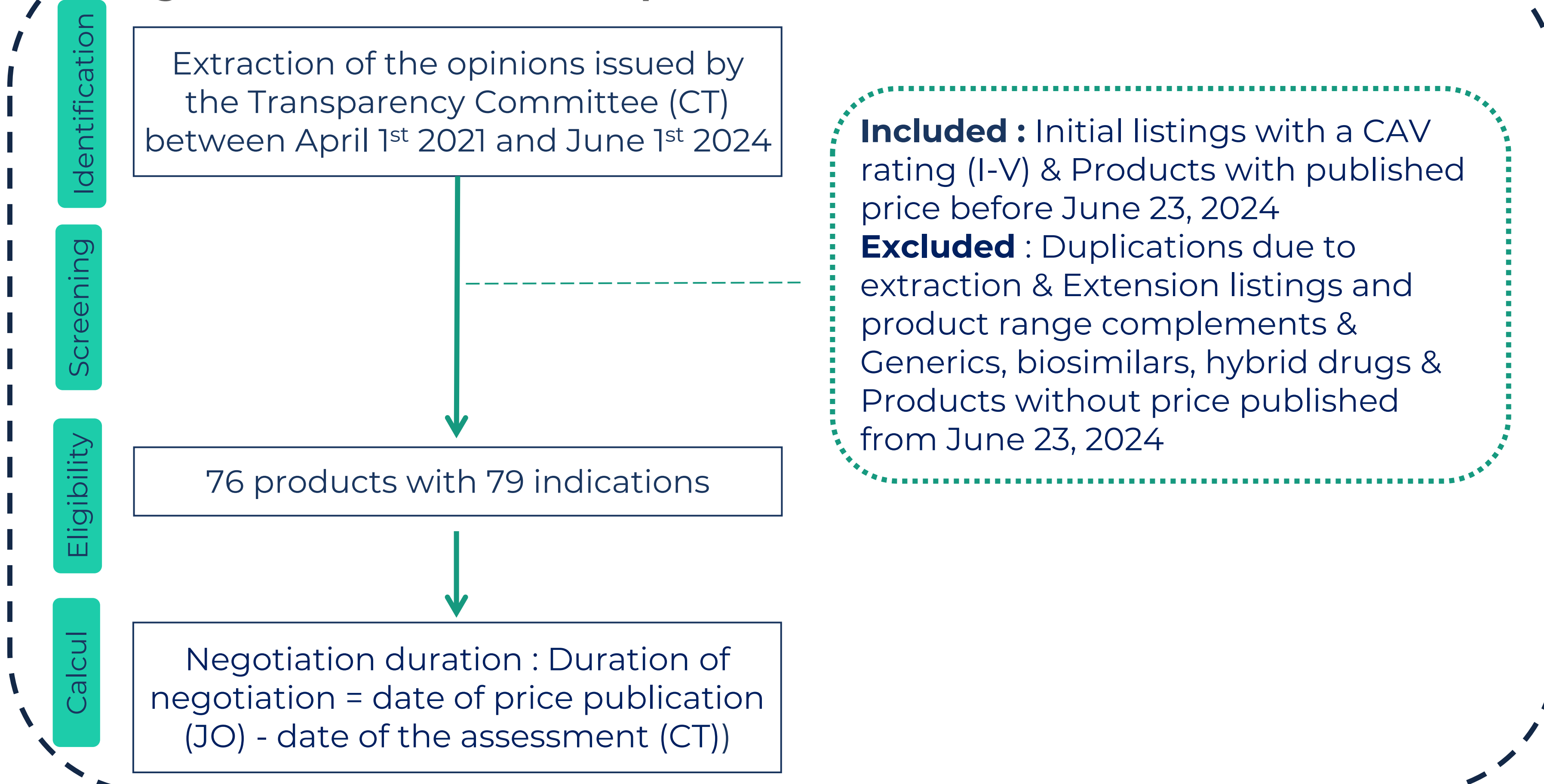
Background and objective

The Clinical Added Value (CAV) of healthcare products is assessed by the French Health Technology Assessment Agency (HAS) to determine eligibility for reimbursement and price publication. CAV is categorized into five levels, from major (CAV I) to insufficient (CAV V), and plays a crucial role in price negotiations with the French Healthcare Products Pricing Committee (CEPS). According to the framework agreement between pharmaceutical companies and the CEPS, a higher CAV rating generally corresponds to more favorable pricing conditions. Beyond the CAV level, the specific label assigned in the CAV assessment can vary across products, potentially influencing negotiation outcomes.

This study examines the impact of CAV labels on the duration of price negotiations with the CEPS.

Method

Figure 1. Flowchart of the opinion selection



Results

A total of 76 products with 79 indications met the criteria. The distribution of products and CAV labels is presented in Table 1: more than three quarters of the products are classified under the "Therapeutic strategy" label (76%, or 60 out of 76 products). Distribution of CAV labels for the 76 products identified is shown in Figure 2 below. Half of the products have a CAV V rating (54.4%), while CAV I-III ratings are more challenging to obtain, appearing in only 1 out of 5 cases (19.0%). The majority of products are listed on the retail list (59.2%).

The mean negotiation duration was longest for products with the "Versus generic/biosimilar" label (335.75 days), followed by "Same as" (309.33 days) and "Therapeutic strategy" (278.16 days) (Figure 3). The "Versus innovative product" label had the shortest mean negotiation duration (128.00 days). Medians followed a similar trend, with 258.5 days for "Versus generic/biosimilar," 216.0 days for "Same as," 231.5 days for "Therapeutic strategy," and 129.0 days for "Versus innovative product" (Figure 3). The Kruskal-Wallis H-test indicated no statistically significant difference in negotiation duration across the CAV labels (p = 0.205).

Table 1. Distribution of products and indications

CAV labels	Count (indications)	Percentage
Therapeutic strategy	60	76.0%
Same as	9	11.4%
Versus innovative product	5	6.3%
Versus generic/biosimilar	5	6.3%
Total	79	100%
CAV levels	Count (indications)	Percentage
I-III	15	19.0%
IV	21	26.6%
V	43	54.4%
Total	79	100%
List	Count (products)	Percentage
Retail	45	59.2%
Hospital	21	27.6%
« Liste en sus »	10	13.2%
Total	76	100%

N = 79 indications for 76 products.

Figure 2. Distribution of CAV labels

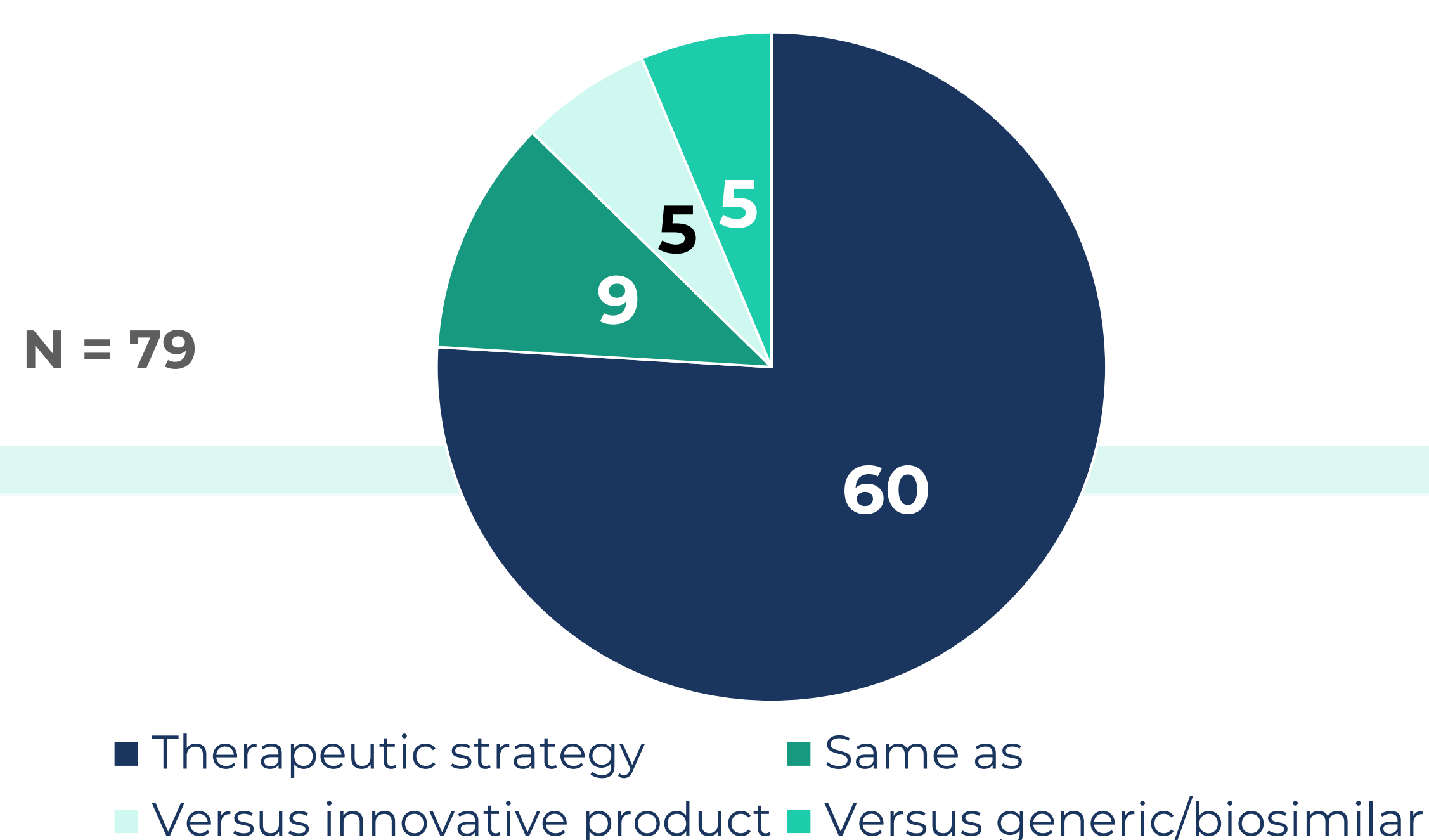
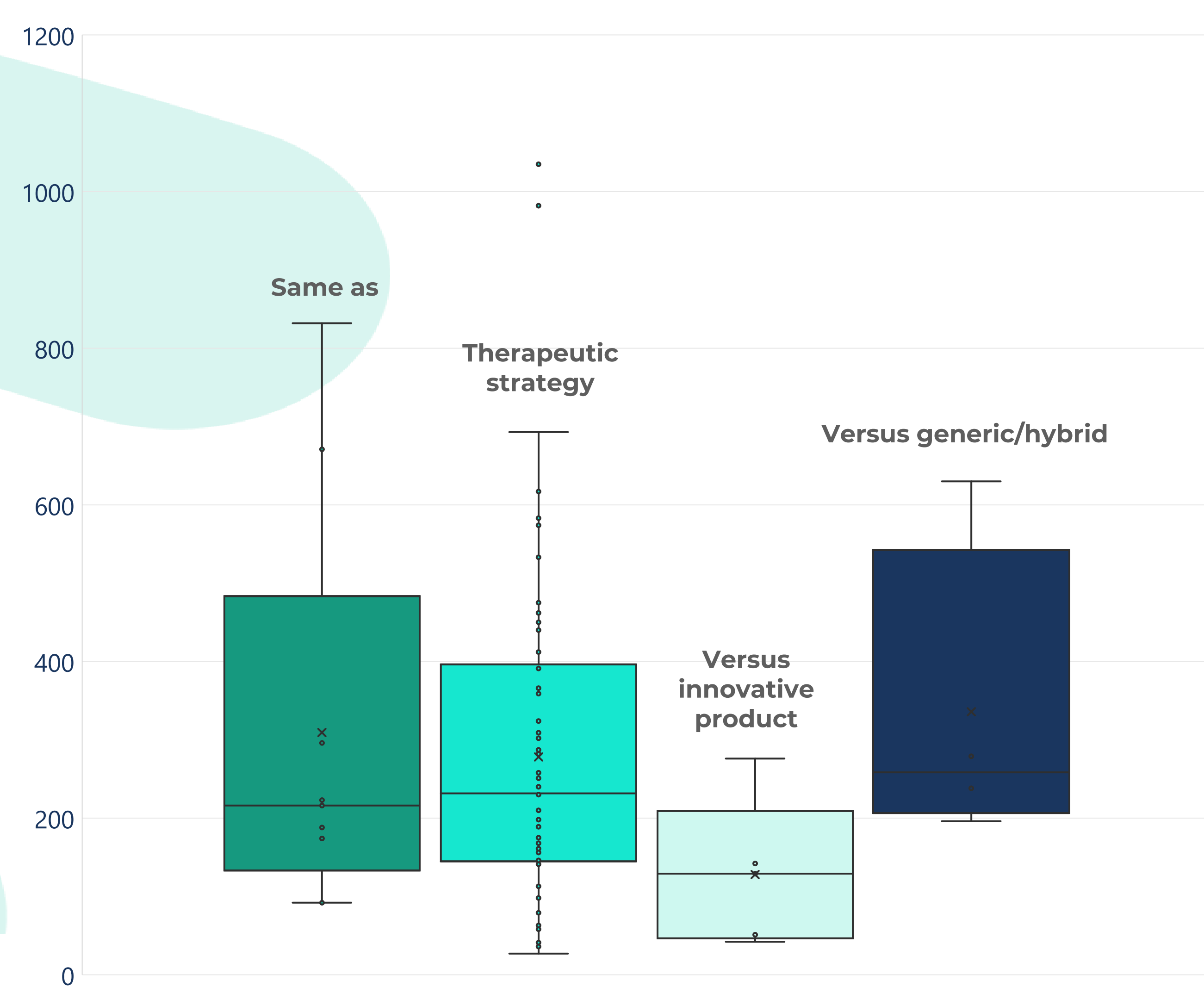


Figure 3. Median negotiation time (in days) in CAV labels groups



Conclusion and Discussion

Although statistical significance was not achieved, the "Versus innovative product" label showed a notable trend toward shorter negotiation timelines. This finding suggests that CAV labels may play a role in influencing the duration of price negotiations with the CEPS. The lack of statistical significance is likely due to the small sample size, which may have limited the power to detect differences. Nevertheless, these results highlight the potential importance of CAV labels in shaping negotiation processes, particularly for labels associated with innovation. Further research with a larger sample size could help confirm these preliminary findings and provide deeper insights into the impact of CAV labels on pricing negotiations.