Understanding differences in pharmaceutical products based on price publication status

Method

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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), which play 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 used in CAV assessments can vary across products, potentially influencing negotiation outcomes.

The objective of this study was to evaluate the effect of Clinical Added Value (CAV) levels and labels on the price publication status (with or without a published price).

Figure 1. Flowchart of the opinion selection Extraction of the opinions issued by the Transparency Committee (CT) between **Included:** Initial listings with a CAV April 1st 2021 and June 1st 2024 rating (I-V) & Products with published price before June 23, 2024 & Products without price published from June 23, 2024 **Excluded**: Duplications due to extraction & Extension listings and product range complements & Generics, biosimilars, hybrid drugs 138 products with 141 indications Negociation time if price published: Duration of negotiation = date of the assessment – date of price publication If no price published: Duration of negotiation = Date of the research (June 23, 2024) – date of price publication

Results

A total of **141 indications (138 products), with 76 having published prices and 65 without** met the criteria. Table 1 compares CAV labels, CAV levels (I to V) and the product listing according to whether the award had been published in the JO or not. The majority of products with CAV labels "versus innovative product" and "versus generic/biosimilar" do not have a published price, whereas "same as" products have a published price (11.4%). Nevertheless, the CAV level does not seem to influence the negotiation time, which is very close to the CAV level. The mean negotiation time for products with published prices was 275.00 days, whereas products without published prices had a significantly longer mean time of 545.58 days (figure 2).

Table 1. Distribution of products and indications

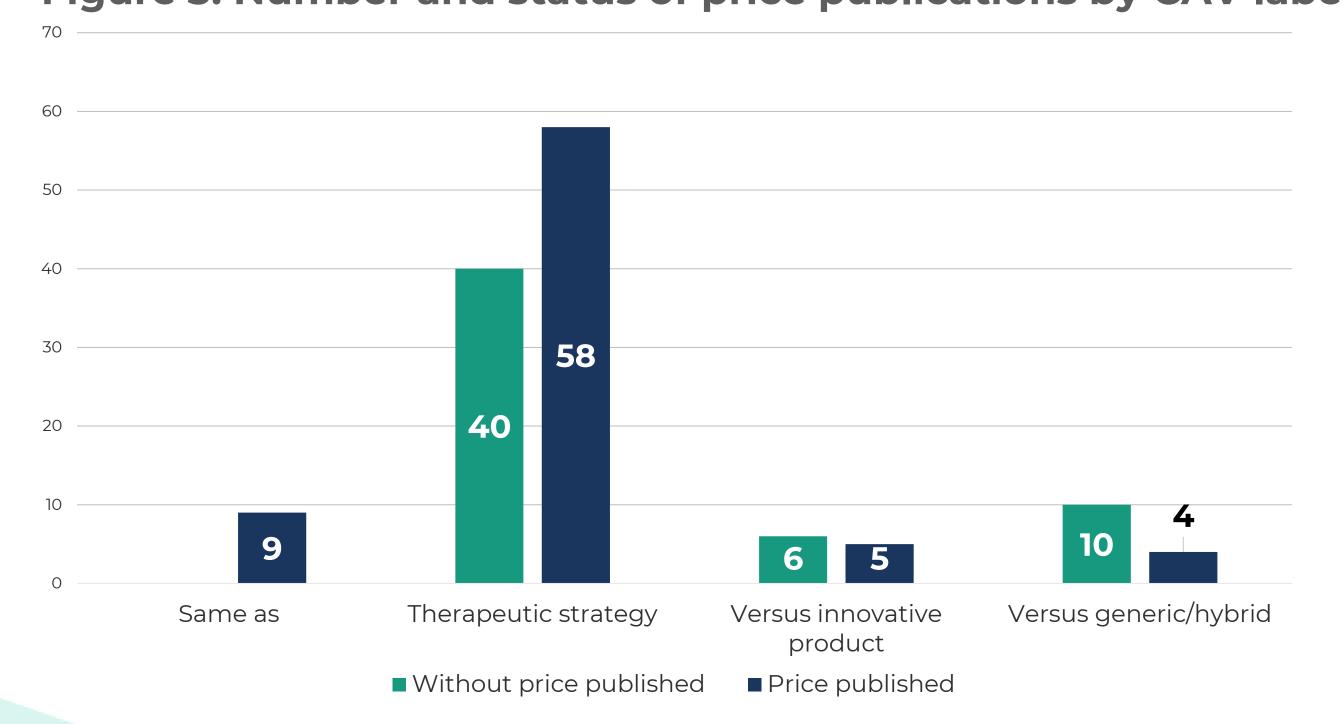
	Price published	No price
CAV labels	Cout of indications (percentage)	Cout of indications (percentage)
Therapeutic strategy	60 (76.0%)	49 (75,4%)
Same as	9 (11.4%)	0 (0%)
Versus innovative product	5 (6.3%)	6 (9,2%)
Versus generic/biosimilar	5 (6.3%)	10 (15,4%)
Total	79	100%
CAV levels	Count of indications (percentage)	Count of indications (percentage)
1-111	15 (19.0%)	15 (23.1 %)
IV	21 (26.6%)	14 (21.5%)
V	43 (54.4%)	36 (55,4%)
Total	79	100%
List	Count of products (percentage)	Count of products (percentage)
Retail	45 (59.2%)	37 (57%)
Hospital	21 (27.6%)	28 (43%)
« Liste en sus »	10 (13.2%)	

Differences in mean negotiation time across CAV labels were assessed using the Kruskal-Wallis H-test for primary analysis.

Figure 2. Mean negociation time (in days) between published price and without published price groups



Figure 3. Number and status of price publications by CAV label



The <u>CAV level</u> did not affect price publication status (similar frequencies and no statistically significant differences between the two groups (p = 0.462)).

However, the Chi-square test for <u>CAV label</u> showed significant differences between the two groups (p = 0.009).

Specifically, the "Same as" label exhibited notable discrepancies, with standardized residuals of -2.04 for products without published prices and 1.88 for those with published prices, suggesting that this category is more frequent among products with published prices.

Conclusion and Discussion

This study highlights that, while CAV levels did not significantly impact price publication status, CAV labels appear to influence whether a price is published. Notably, the "Same as" label was more frequently associated with products that had published prices, suggesting that this label may be linked to a higher likelihood of successful negotiation outcomes. However, it is important to interpret these findings with caution due to the small sample sizes for certain CAV labels and levels, especially for categories like "Same as" and "Versus innovative product." The limited number of indications in these groups may affect the reliability of the observed trends and could partly explain the lack of statistical significance in some comparisons. Future research with larger datasets would be valuable to confirm these initial observations and provide a more robust understanding of the influence of CAV labels on price publication status.