

BACKGROUND

In France, several funding methods are possible for individual medical devices. The most innovative and often more expensive medical devices are mainly funded by a positive reimbursement list (LPPR) set up in 2001. The price of medical devices on the LPPR is negotiated with the Healthcare Products Pricing Committee (CEPS). French law provides criteria for setting and reviewing the price. **The objective of this study is to establish the effective impact of these criteria in the latest negotiations between CEPS and manufacturers.**

The medical devices whose price was negotiated with CEPS between January 2018 and May 2019 were selected. For each, the relative difference between the device list price and the comparator list price one year after registration and the price requested was calculated. Discount mechanisms (price-volume, risk sharing, etc.) have not been accounted for.

For the qualitative variables, an **univariate analysis** was performed using the Wilcoxon and Kruskal-Wallis tests based on the number of possible modalities that the variable could take. Kendall correlation was used for quantitative variables. The **multivariate analysis** was performed using a generalized linear model with a Log Normal distribution on the variables from the univariate analysis that had a p-value of less than 0.05. Analysis were done using the R software.

METHODS

RESULTS

A total of 140 medical devices were included in the analysis.

French law provides for different criteria for revising or setting a price during negotiations. These criteria include incremental added benefit (IAB score from French HTA), budgetary impact, age of registration, price of the comparator and the presence of a European price (Germany, Spain, UK, Italy).

Table 1: Characteristics of medical devices included in the study

PARAMETERS	VARIABLES
Incremental Added Benefit	II-III (11) ; IV (8) ; V (121)
Number of CEPS meeting	Mean (sd): 2.14 (1.8) ; median: 1 [1-2]
Comparator	No alternative (4) ; Surgery (7) ; Device - no LPP (6) ; Device - brand (67) ; Device - generic (54)
Negotiation time (d)	Mean (sd): 128.8 (130.8) ; median: 62 [44-108]
Budget Impact (M€)	Mean (sd): 5,53 M€ (8,43) ; median: 1,69 M€ [0,40-4]
External Reference Pricing	0 country cheaper (52) ; 1 (20) ; 2 (7) ; 3 (5) ; 4 (2)
Managed Entry Agreements	None (98) ; Performance-based (4) ; Volume (34) ; other (4)
Dispensing sector	Inpatient (99) ; Outpatient (41)
Therapeutic area	Cardiovascular (30) ; Eye Nose and Throat (10) ; Orthopaedics (62) ; Other (38)
Target Population	Mean (sd): 184 021 (322 092) ; median: 15 500 [1,150-30,000]

Table 1 shows that 86.4% of the devices have not demonstrated clinical improvement (IAB V) and only 7.9% are considered truly innovative (IAB I to III).

The price in Germany, UK, Italy and Spain were only available for 86 devices (61%). Of these 86 devices, 60.5% had no lower price than in France and 23.3% had only one country with a lower price.

The negotiations required an average of 2.14 CEPS sessions with an average duration of 128.8 days (dossier processing time, negotiations and administrative).

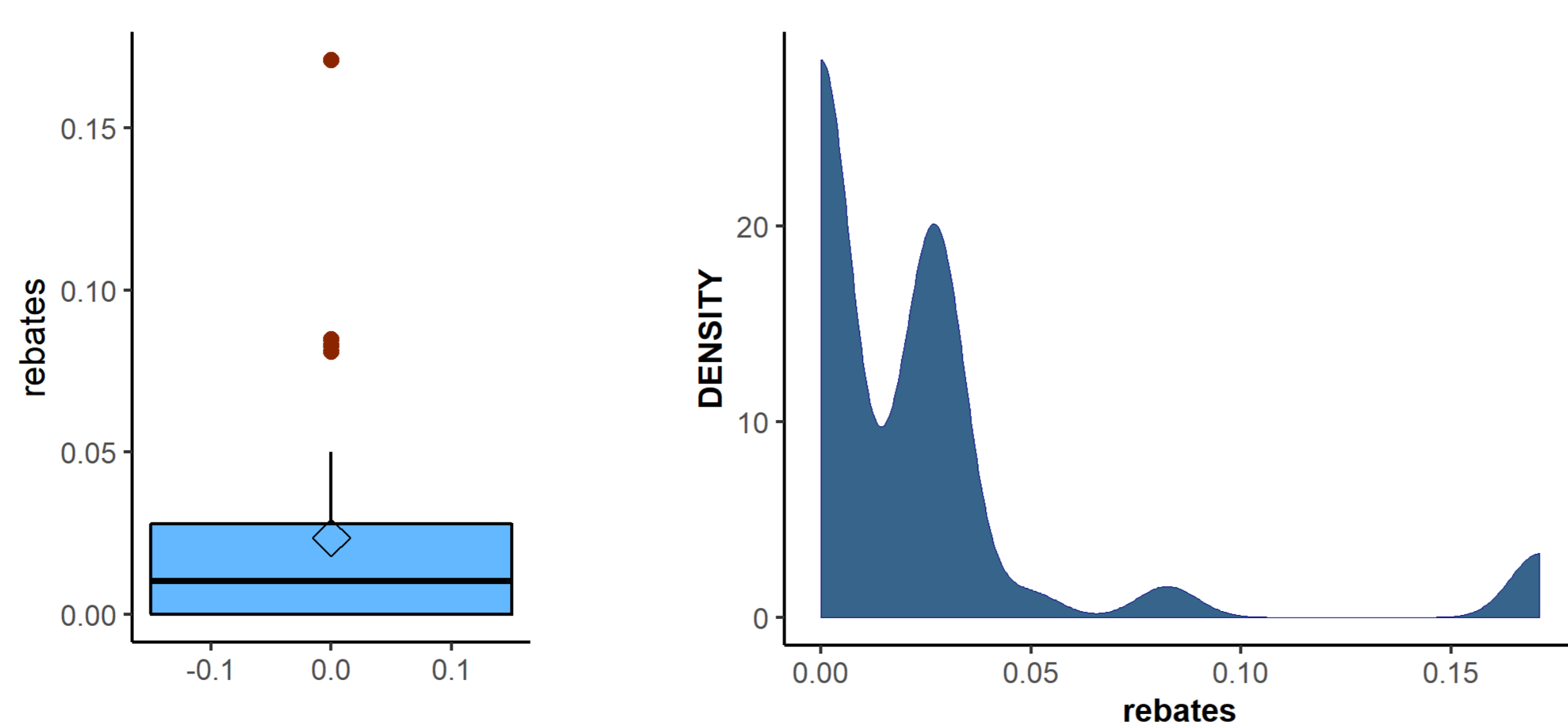


Figure 1: Distribution of rebates (at 12 months after assessment by CEPS)

Figure 1 shows that the distribution of the variable of interest in this study, the percentage of discount compared to the comparator (at 12 months) is mainly less than 5%. The average is 2.36% [0.00%-2.80%].

Moreover, the statistical distribution does not follow a normal distribution.

Table 2: Univariate analysis between percentage of rebates and different variables of interest

VARIABLES	P-VALUE	TEST
Incremental Added Benefit	0.0006	Kruskal-Wallis
Number of CEPS meeting	< 0.0001	Kendall correlation
Comparator	< 0.001	Kruskal-Wallis
Negotiation time (d)	0.004	Kendall correlation
Budgetary Impact (M€)	0.05	Kendall correlation
External Reference Pricing	NS (0.3)	Kruskal-Wallis
Managed Entry Agreements	< 0.0001	Kruskal-Wallis
Dispensing sector	< 0.0001	Wilcoxon
Therapeutic area	< 0.0001	Kruskal-Wallis
Target Population	0.002	Kendall correlation

With the exception of the External Reference Pricing, all the parameters tested were significantly different in the univariate analysis.

These parameters were used for the multivariate analysis (**Table 3**). The type of comparator and the therapeutic area had to be removed because of excessive collinearity (GVIF score > 7).

Table 3: Multivariate analysis between percentage of rebates and different variables of interest

PARAMETER	OR	2.5%	97.5%	WALD TEST
CEPS sessions	0.99	0.995	1.002	NS 0.16
Incremental Added Benefit				NS 0.31
I-II-III	-	-	-	
IV	1.019	0.98	1.05	
V	1.020	0.99	1.05	
Negotiation duration	1.00	0.99	1.00	NS 0.16
Budget Impact	1.00	1.00	1.00	0.017
Managed Entry Agreements				0.0063
No	-	-	-	
Performance-based	0.98	0.94	1.00	
Volume-based	0.98	0.97	1.00	
Other	0.97	0.92	1.00	
Sector				0.00022
Inpatient	-	-	-	
outpatient	0.97	0.95	0.98	
Target population	1.00	1.00	1.00	0.025

Table 3 shows that there would be a correlation between a product's discount compared to its comparator and the **budget impact**, the **type of discounts**, the **sector** and the **size of the target population**.

Products with a Managed Entry Agreement have a lower percentage of rebates, as do devices used in outpatient sector.

Although the GLM model determines a positive correlation between the Budget Impact and the size of the target population, its effect is very small (estimate < 10⁻⁸).

When setting a price, the Incremental Added Benefit is a crucial element. The multivariate analysis did not reveal a statistical correlation, the small sample and the small difference in effect may be the cause. **Figure 2** presents in a descriptive manner the average decreases observed at 12 months compared to the comparator.

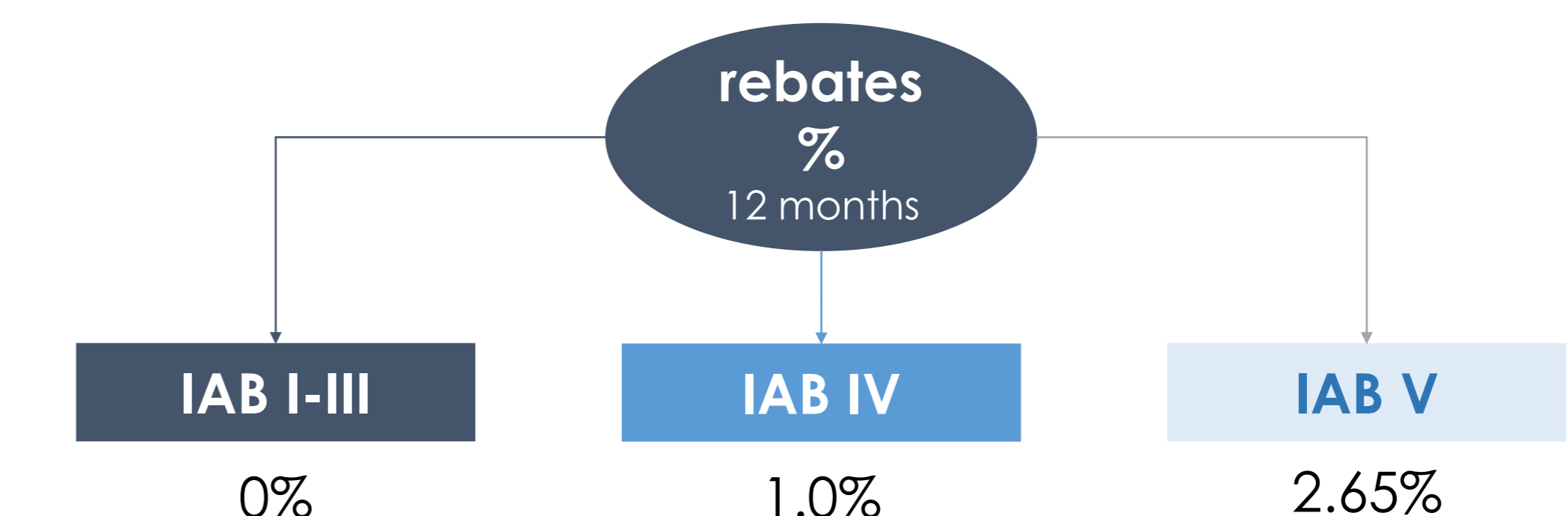


Figure 2: rebates means according to Incremental Added Benefit (IAB)

CONCLUSION

The multivariate analysis revealed different correlations between the percentage decrease in relation to the comparator and different variables :

- The **Budget Impact** has a positive correlation: when the expected budget impact is significant, there is a greater decrease within 12 months.
- The **outpatient sector** seems to be negatively correlated, only the analysis does not take into account the decreases that occurred before the product was listed (with a so-called category price). If the price of a category has just been decreased, a further decrease within 12 months is not necessarily realized. This is the case with outpatient devices where many reductions had been made upstream.
- Finally, the presence of a **Managed-Entry Agreements** also appears to be negatively correlated. Thus, the price would be less likely to be reduced when a discount mechanism exists.