ARE THE **SALES FORECAST** FOR MEDICAL DEVICES ACCURATE? A RETROSPECTIVE ANALYSIS IN FRANCE (2018-2019)

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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. To be reimbursed through this list, manufacturers must share some clinical and economic data and, among them, sales forecast.

Medical device expected budget impact is a key factor in pricing. In France, this forecast is mainly based on sales forecasts. This study aims to identify whether or not sales forecasts tend to be higher than reimbursement data.

METHODS

All medical devices accepted for a renewal of inscription in 2018 and 2019 with a 5-year history were analyzed. Sales forecasts were based on economic data provided by manufacturers. The reimbursement information was extracted from the French Sniiram exhaustive database. Information on new indication or new comparator entry was collected using data monitoring from the French Healthcare Products Pricing Committee (CEPS).
Devices general characteristics were taken from the French Health Technology Agency (HAS) assessment. For each device and for each year (**n**), an index (**kn**) corresponding to the ratio of the **reimbursement data** to the **sales forecast** data and the absolute difference (**dn**) between these data were calculated. A final index (**kf**) corresponding to the sum of the kn and dn weighted by the dn values is measured. A maximum of 5 years of historic was used. Thereafter, an univariate analysis of kf to assess the correlation with different collected factors was performed.

$$k_f = \frac{\sum_{n=1}^{5} k_n \times d_n}{\sum_{n=1}^{5} d_n} = \frac{\sum_{n=1}^{5} \frac{reimb_n}{sales_n} \times |reimb_n - sales_n|}{\sum_{n=1}^{5} |reimb_n - sales_n|}$$

Equation 1: formula to determine the kf index to measure the accuracy of sales data. Kf less than 1 means that the sales data were overestimated

RESULTS

On more than 300 devices covered by the analysis period, 51 could be included in the analysis. Devices seen by CEPS for registration or renewal on the LPPR but with a too short history to allow the calculation of the kf index were excluded from the analysis.

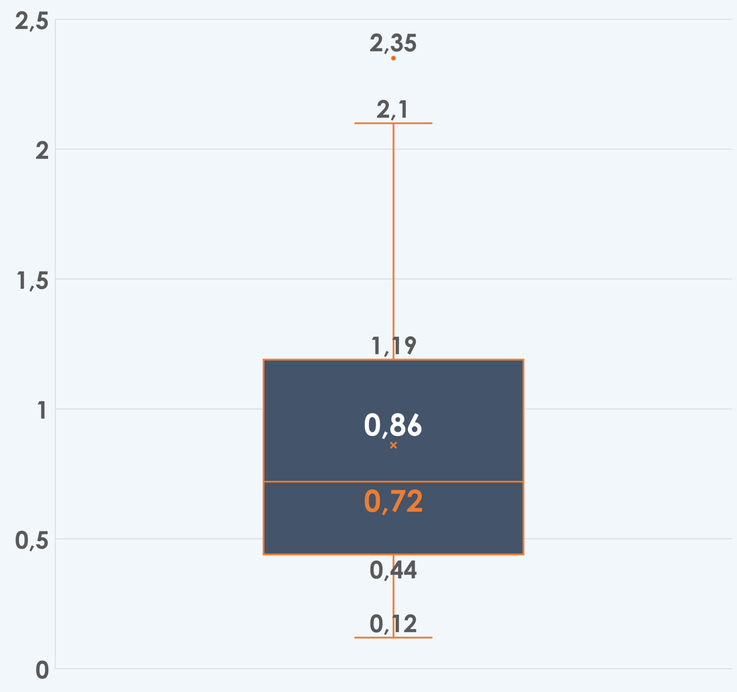

Fig. 1: Boxplot of the **Kf** index for the 51 devices included

Figure 1 shows the distribution of Kf in the analyzed sample. The mean (0.86) and median (0.72) are below 1 meaning that sales forecasts are generally higher than the actual reimbursement data observed. Nevertheless, the values remain very scattered with a Q25 of 0.44 and a Q75 of 1.19

Table 1: Characteristics of medical devices included in the analysis

VARIABLES	MODALITIES
Incremental Added Benefit	III-IV (4) ; V (47)
Therapeutic area	Cardiovascular (17) ; Diabetes (4) ; Neurology (7) ; Eye Nose and Throat (8) ; Orthopaedic (4) ; Wounds (4) ; Other (7)
Price – volume agreements	No (36) ; Yes (15)
Target population	0-500 (3) ; 500-1,000 (9) ; 1,000-9,999 (15) ; > 10,000(18)
Time from reimbursement (y)	7.5 (4.0 – 10.0)
External Reference Pricing	No (28) ; Yes (11)
Annual Budget Impact	5,9 M€ (0,33 – 7,55)
Target population methodology	Estimate (9), Range (4), from medico-administrative data (27)

Table 1: The vast majority of products did not show any clinical improvement compared to the comparators, more than 30% of the products had a price-volume agreement. Almost 28% of the devices had at least one lower price in Germany, UK, Italy or Spain.

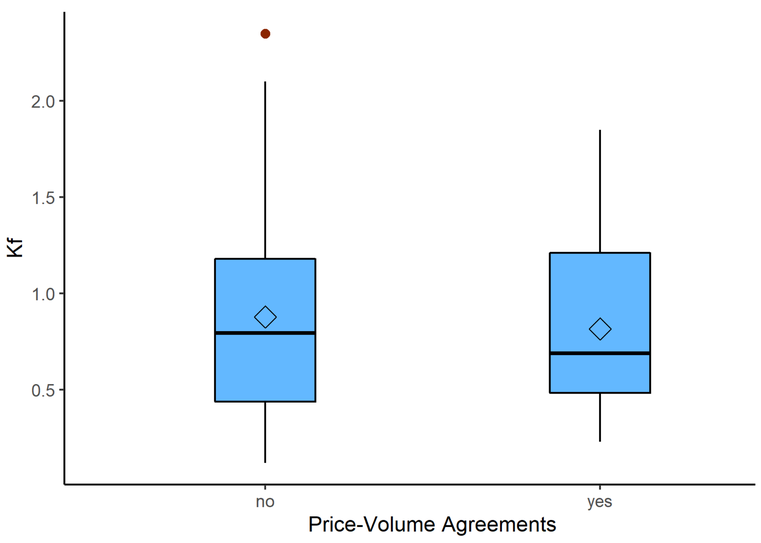

Fig. 2: Boxplot of the **Kf** index depending on the presence of a volume price agreement

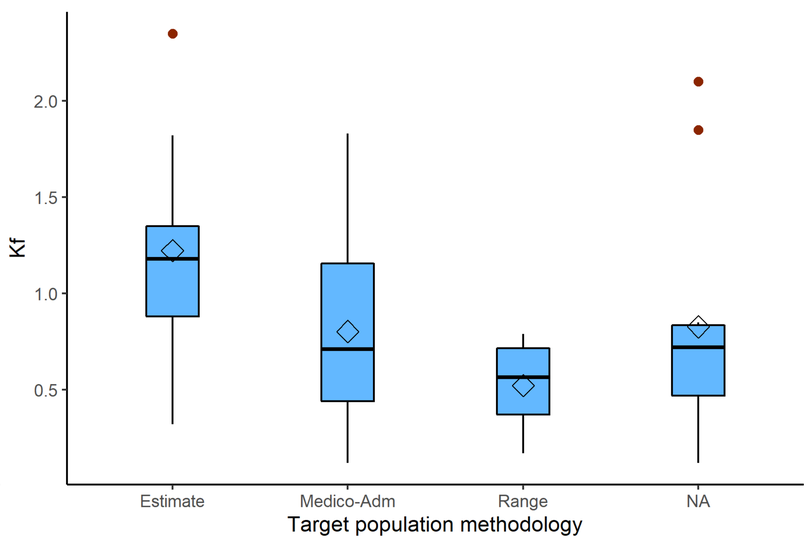

Fig. 3: Boxplot of the **Kf** index according to the methodology used to determine the target population

Table 2: Univariate analysis between the kf score and different variables of interest

VARIABLES	P-VALUE	TEST
Incremental Added Benefit	**NS** (0.26)	Wilcoxon
Therapeutic area	**NS** (0.46)	Kruskal-Wallis
Price – volume agreements	**NS** (0.84)	Wilcoxon
Target population	**NS** (0.07)	Kruskal-Wallis
Time from reimbursement (y)	**NS** (0.18)	Kendall correlation
External Reference Pricing	**NS** (0.77)	Wilcoxon
Annual Budget Impact	**NS** (0.22)	Kendall correlation
Target population methodology	**NS** (0.07)	Kruskal-Wallis

Figures 2 and 3 show visually the absence of correlation between Kf and the presence of a price-volume agreement (figure 2) or the methodology used to determine the target population (figure 3).

Table 2 shows the results of the univariate statistical tests performed between the Kf score and the variables of interest. Non-parametric tests were used: the Kendall correlation test when the variable was quantitative, the Wilcoxon test when the variable was dichotomous qualitative and the Kruskal-Wallis test when the variable was polytomous qualitative.

None of the variables tested showed any correlation with the Kf score. Other variables were tested but were also non-significant, such as the arrival of a comparable medical device during the analysis period (p-value = 0.54).

CONCLUSION

This study shows that the economic dossiers of manufacturers seem to **overestimate** sales forecasts by **nearly 16%.** Among the variables analyzed, none seem to correlate with our sales data accuracy index kf.

None of the variables analyzed showed any correlation, so it seems impossible at this stage to build a predictive model to correct the forecasts. France frequently uses discounts in the form of a price-volume agreement. These discounts are based both on the target population determined by the French HTA and on sales forecasts. Moreover, in the sample analyzed, more than 30% of medical devices were covered by a price-volume agreement.

It may be difficult to make sales forecasts, particularly to take into account the arrival of a new competitor. Thus a correlation with this variable was expected but finally no correlation was found (p-value = 0.54).

Similarly, no correlation was found (p-value = 0.84) between the presence of a price-volume agreement and the accuracy of the sales data. However, a significant economic constraint associated with this type of agreement could have led to a greater difference with the actual reimbursement data observed.

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