Price-Volume Regulation in France: Alignment Between Negotiated Thresholds with the French Economic Committee for Health Products (CEPS) and Real-World Observations

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 # HPR165

BACKGROUND

Thresholds or lump sum envelopes (SLE) are a type of price-volume regulation used by the CEPS to regulate healthcare expenditures. While their budgetary impact is expected, the efficiency of their calibration in real-life settings remains underexplored.

OBJECTIVE

The aim was to assess whether reference volumes (RV), from either sales forecast or target population, in these agreements reflect real-world use by comparing targeted and observed treatment costs (TTC vs OTC).

METHODS

We selected drugs for which a threshold was implemented by CEPS from 2020 to 2022 (study period), allowing 3-year follow-up, as thresholds are often based on year-3 forecasts. Inclusion was restricted to price-volume regulation (restricted to agreements with a marginal payback rate exceeding 80%). Two samples were constituted. The first sample included all incident price-volume regulation as defined above on the study period (n=34) as also those identified in 2023. The second sample was bases only on the study period defined above and needed exclusions to make analyses feasible. From the 34 identified drugs, those with price-volume agreement, with indication extensions during the 3-year period, with a different recording method for sales and/or with missing data were excluded, resulting in a final sample of 28 drugs. For each product, the TTC was based on the assumptions underlying the threshold construction, while the OTC was calculated using observed volumes from Group for the Elaboration and Realization of Statistics (GERS), applying the same posology and population assumptions.

RESULTS

LUMP-SUM ENVELOPES INCIDENCE

Respectively for years 2020, 2021, 2022 and 2023, the incidence of new lump-sum envelopes concerns 16%, 16%, 17% and 14% among the drugs listed for reimbursement in the same year (figure 1). If comparing these data with the total of lump-sum envelopes one year among all the regulated drugs, their weight follows the same trend. For the four same years, the prevalence of lump-sum envelopes concerns 15%, 18%, 19% and 20% (figure 2).These macro analyses are based on sample 1.

Figure 1. Lump-sum envelopes in Terms of Number of New Products (incidence)

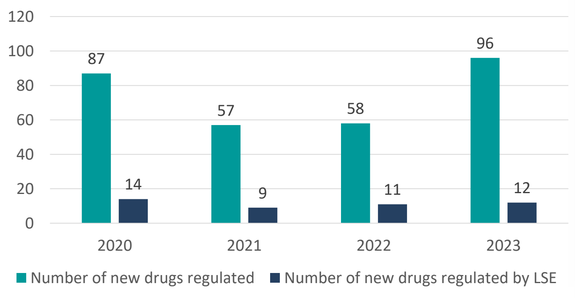


Figure 2. Total lump sum envelopes (prevalence) among regulated drugs

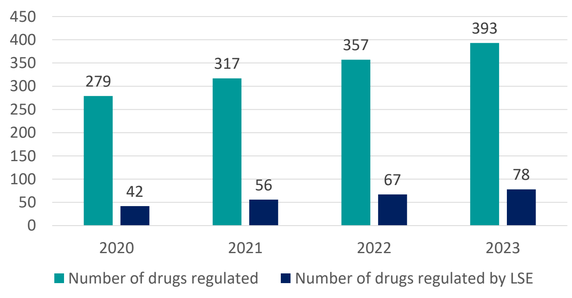
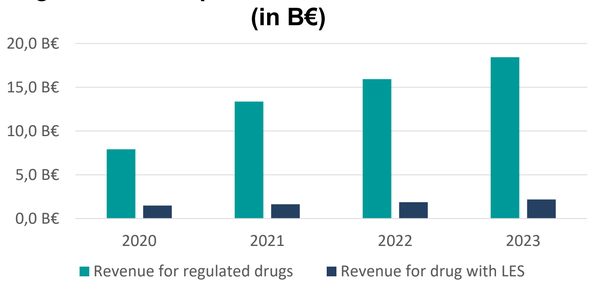


Figure 3. The impact of LSE in terms of revenue (in B€)

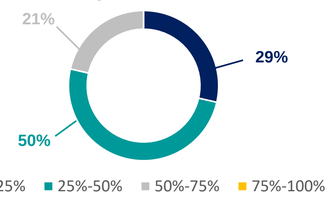


- Revenue for total regulated drugs increase each year, as well as the revenue for drugs having a LSE agreement.
- Although the incidence is slightly increasing, the proportion of revenue is tending to decrease, with a proportion of 19% in 2020 and 12% in 2021, 2022 and 2023.

ACHIEVEMENT OF THE REGULATION WITH LUMP-SUM ENVELOPES

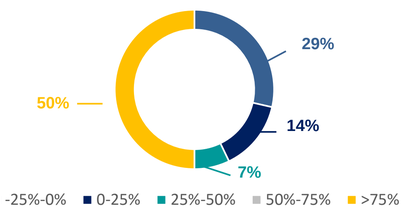
Each category of LSE has its own objective, therefore the analysis was conducted separately for security LSE (Figure 6) and regulatory LSE (Figures 7 and 8). For security LSE, revenues were compared with the threshold level. For regulatory LSE, target and observed treatment costs were compared to assess whether the expected regulation was achieved (Figure 7). Figure 8 summarises the share of products falling above or below the target treatment cost.

Figure 6. Quartile distribution for security LSE based on the proportion of the LSE represented by the revenue



**Intervals show the percentage of the threshold reached by observed revenue (e.g., 30–50% = revenue covers 30–50% of the threshold).*

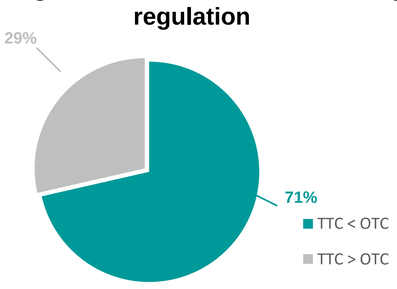
Figure 7. Quintile distribution for regulatory LSE based on the spread between TTC and OTC



**Intervals show the percentage deviation between TTC and OTC: positive values mean TTC is higher than OTC (e.g., +25% = 25% above), negative values mean TTC is lower (e.g., −25% = 25% below).*

- None of the security LSE reached the threshold, neither exceeded 80% of the initial LSE. In addition, more than half of them remained below 50%.
- For most of the drugs having a regulatory LSE, the latter is not reached. Moreover, for none of the regulatory threshold is the target cost achieved.

Figure 8. Distribution of the regulatory LSE depending on the achievement of the required regulation



LUMP-SUM ENVELOPES CATEGORY: REPARTITION AND ACTIVATION

Two categories of LSE can be defined according to their objective. A LSE can be introduced for regulatory purposes (envelope is set aside to treat a defined number of patients (mainly orphans)), or for security purposes, mostly to prevent off-label prescribing. Most of the new LSE introduced are designed to enhance security. The analyses presented in the figure is based on sample 1.

Figure 4. Repartition of LSE by category (total incident LSE on study period)

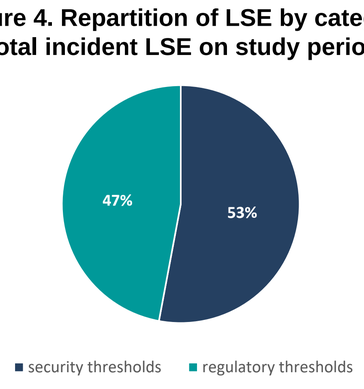
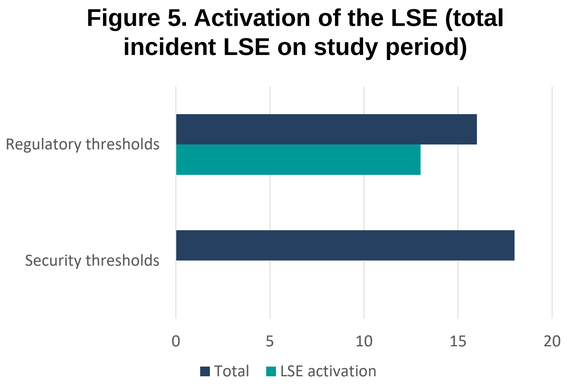


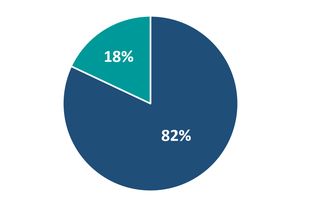
Figure 5. Activation of the LSE (total incident LSE on study period)



Activation occurs only in regulatory LSE. The absence of activation for the security LSE could be the result of either an overly broad calibration of the envelope or proper use of the medication.

The comparison was replicated on the volume, to compare observed volume versus forecasted volume.

Figure 9. Observed vs forecasted volumes (% of products)



- Observed volumes were predominantly below reference, suggesting that forecast assumptions may have been overestimated.

Table 1. Deviation between observed and RV

Interval*	Security LSE	Regulatory LSE
< −75%	36%	7%
-75% to ≤ -50%	21%	36%
-50% to ≤ -25%	21%	21%
−25% to ≤ 0%	14%	7%
0% to ≤ +25%	7%	7%
+25 % to ≤ +50%	0 %	21%
> +50%	0%	0%

**Intervals show the percentage deviation between observed and forecasted volumes relative to the forecasted value, with negative values indicating underperformance and positive values overperformance.*

- Deviations were mostly negative for both thresholds, though less pronounced under regulatory thresholds.

Table 2. Regression results

Parameter	Estimate	Std. Error	t-stat	p-value
Constant (Security CAP)	0.526	0.08	6.6	<0.001
CAP type (Regulation vs Security)	-0.074	0.10	-0.76	0.45

A linear regression model was used to assess the association between thresholds type (regulation vs security) and variation. Mean variation was slightly lower for regulation thresholds (−0.07), but the difference was not statistically significant ($p = 0.45$, $R^2 = 0.02$).

CONCLUSION

Thresholds offer a tool for expenditure predictability by fixing a maximum revenue for the company. For regulatory LSE, this maximum aimed to be reached in the objective to directly obtain the targeted annual treatment cost by patient thanks to the LSE. For security LSE, targeted treatment cost is obtained with another regulation mechanism, the LSE being constructed in order to avoid off-label treatment or misuse. However, real-world use may diverge from initial forecasts, possibly due to differences in posology, target population, or the introduction of new therapeutic alternatives. In particular, this research demonstrates that in regulatory capping, if the threshold is triggered, it does not do so sufficiently for the desired regulation to take effect. The main reason appears to be the discrepancy between company reference volumes and market reality. Since capping regulation is mainly driven by orphan drugs, one may question whether reference volume are overestimated by manufacturers. This highlights the need for ongoing monitoring and better calibration methods.

Abbreviations: CEPS: French healthcare product pricing committee; LSE: lump-sum envelope ; RV: reference volume ; OTC: observed treatment cost ; TTC: targeted treatment cost

ISPOR 28th Annual European Congress, Glasgow, Scotland, 11 to 13 November 2025