Macroeconomic Regulation of Drug Expenditures in Europe : Lessons of the French Safeguard Clause From a Scoping review

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CONTEXT / RESEARCH OBJECTIVES

The regulation of drug expenditures is a key concern in many European countries. **In France, this is managed through various instruments, including the safeguard clause, a collective regulatory tool applied *a posteriori* when expenditures exceed a certain threshold.** Introduced in 1999 and reformed multiple times since 2010, the contributions required from pharmaceutical companies under this clause have surged, **reaching 1 billion euros in 2023.**

Despite its significance, **little is known about similar *a posteriori* regulatory mechanism in European countries.**

THIS STUDY AIMS TO :

Identify and analyze **comparable models of "Safeguard clause"** used in **other European countries.**

Derive **lessons** for the **French system**.

METHODS

A **scoping review** was conducted to explore **macroeconomic levers for healthcare expenditure regulation used by European governments**. The review targeted mechanisms like France's safeguard clause, involving collective and retrospective regulation of drug expenditures. Then, **semi structured interviews were conducted to clarify information found in the scoping review and collect experience from French stakeholders** to identify areas for improvement for the French Safeguard Clause.

Scoping review conducted to identify **countries** of interest
2 independent reviewers + 1 external reviewer

1. Algorithms were applied to search resources
PubMed
Ovid

Algorithm key words
Drugs
Cost containment
European countries

2. Comprehensive review of grey literature
Data sources → posters, Academic reports, legal documents

Semi-structured interviews were conducted via a **thematic grid**

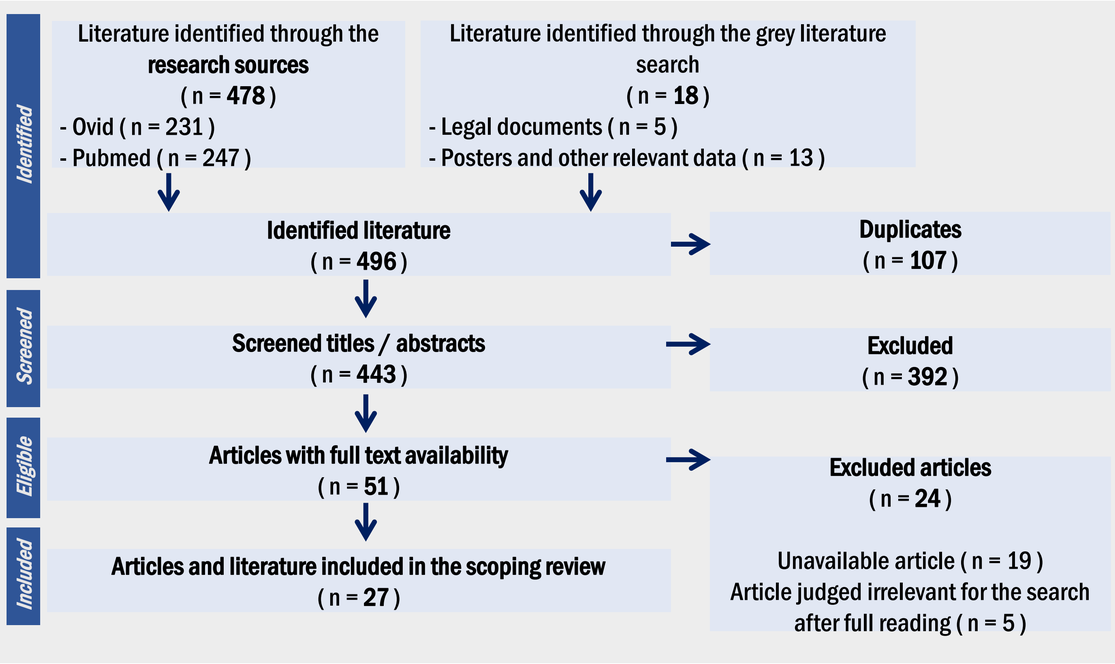
Areas for improvement for the French Safeguard Clause
8 questions

Interviewed profiles
Pharma Industry
French government
French pharma trade union

RESULTS Scoping review

Through the scoping review **27 relevant sources** were identified, including 9 articles from PubMed and Ovid databases, 13 grey literature pieces, and 5 official regulatory documents (Figure 1).

Figure 1 : Flowchart of the scoping review



Countries identified

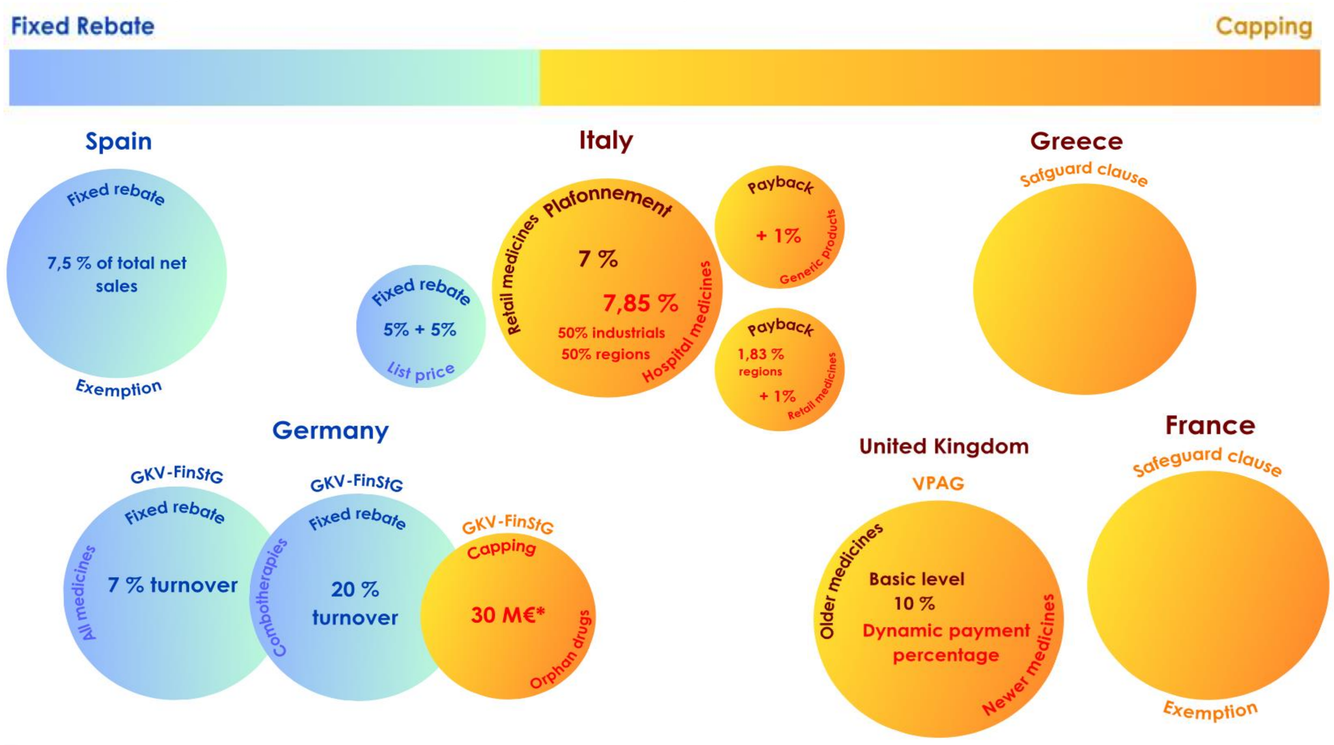
Through the scoping review, **six countries** of interest were identified : **France, Germany, Greece, Italy, Spain, United Kingdom**.`

Three categories of macroeconomic regulation emerged:

1. **Threshold-based models** where expenditures beyond a certain limit are not fully covered by national health insurance (*France, Greece*)
2. **Models imposing fixed rebates** on all pharmaceutical industries based on revenue (*Spain*)
3. **Mixed models** incorporating both thresholds and fixed rebates (*Italy, Germany, United Kingdom*).

Figure 2 shows the macroeconomic levers for healthcare expenditure regulation used in each European country of interest. The color of the circle represents the type of mechanism used (fixed rebate or capping), whereas the size of each circle estimates the economic impact of each mechanism in a certain country if the country uses a combination of mechanisms.

Figure 2 : Type of macroeconomic levers in each identified country



DISCUSSION

1 Collective drug expenditure regulation varies significantly across Europe. In France, the safeguard clause retroactively controls spending beyond a set threshold**. Other countries, like the UK or Germany, however, uses a collective dynamic contribution or mix model** for "new drugs" or "combination therapies" allowing targeted regulation of high-cost drugs. **This differentiation approach enables countries to manage high-cost pharmaceutical innovations individually rather than through a pooled mechanism**. Such disparities underscore the need to explore a posteriori mechanisms across countries to better address the economic impact of pharmaceutical innovation.

2 **Semi-structured interviews highlighted ways to improve the French clause :**

- Add **predictability** to the clause by **multiplying debates** between governments and pharma industries
- **Demutualize** the clause to allow a **better repartition** of it
- Add **visibility** to the amount to pay by **transforming** the clause into rebates

CONCLUSION

The increasing financial contributions required from pharmaceutical companies, through rebates or revenue caps, are leading to frequent regulatory changes. While no single approach guarantees long-term expenditure control, these evolving mechanisms demonstrate a strong governmental resolve to manage drug expenditures. Insights from this comparison can inform improvements in the French safeguard clause system.

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