Pharmaceutical spending caps across Europe: an overview of the current national policies

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INTRODUCTION

- As healthcare expenditure continues to grow worldwide, policymakers have increasingly adopted **control mechanisms** to ensure the **sustainability** of healthcare systems.
- Among these, **pharma spending caps** and the relevant payback/clawback models represent a widely used yet **highly heterogeneous policy** tool, varying substantially in their design, scope, and enforcement across countries.

⇨ Such mechanisms can **influence market attractiveness, firms' revenue expectations** and, ultimately, **incentives for pharma innovation and Research & Development (R&D) investment**.

OBJECTIVE

- Evidence on the characteristics of spending cap policies remains **fragmented**.

⇨ Our study aims at filling this gap, providing a **comprehensive cross-country assessment** to better understand the current policy landscape in **seven European countries** (UK, Germany, France, Italy, Spain, Portugal and Greece).

METHOD

Information was gathered through:

- **grey literature** (e.g., national Agencies, normative sources);
- **academic articles** (when more updated).

Semi-structured interviews directed to **local experts** currently in place, to validate previously collected information and integrate it with additional evidence not retrievable online.

RESULTS

- The overview highlights the **presence of caps** either on the overall spending level or on its growth rate for **all the selected countries (except Germany)**.
- The main drivers of such thresholds are:
  - **historical** pharma **spending** (France);
  - pharma **spending expected growth rate** (UK, Greece, Portugal);
  - **percentage** of national **GDP** (Greece);
  - **GDP growth rate** (France, Spain);
  - NHS funds **expected growth rate** (UK) or **percentage** of the **NHS Funds** (Italy).
- **Payback systems** on pharmaceutical firms are heterogeneous as well, but mainly depend on **firms' overall turnover** (France, Portugal) or on their **market shares** (UK, Italy, Greece). Some countries allow mechanisms for firms to **partially reduce the payback/contribution** due (France, Greece, Spain), also in function of their local R&D investments.
- Many systems allow some sort of **dialogue between governments and firms** –typically through national industrial associations– to **enhance the predictability of future paybacks.**

Table 1. Evidence on budget caps: cross-country overview

Country	Presence of caps	Main caps' determinants	Companies' payback	Companies' involvement / statements
France	✓	Historical pharma spending + GDP growth + political & macroeconomic factors	Collective payback mechanism based on companies' overall turnover (Safeguard Clause)	-
Germany	x	-	-	-
Greece	✓	1% of GDP + expected pharma spending growth rate	Payback redistribution according to the 90-10 formula (90% based on the final company market share + 10% based on its growth share).	Industrial association discusses with Ministries/EOPYY possible framework agreements to make clawbacks more predictable. Since 2019, companies can offset part of their pending clawback, by investing in R&D or in manufacturing in the country.
Italy	✓	% of NHS Funds (8.7% for drugs procured by hospitals and 6.85% by community pharmacies)	Payback allocation according to the final company market share (with the exclusion of innovative and orphan drugs)	Undergoing Parliament hearings on the pharmaceutical legislation reform: industry calls for overcoming the payback system.
Portugal	✓	Pharma spending growth rate	Reimbursement of 50% of the difference between actual expenditure and the cap; distribution proportional to the company turnover.	Interaction between APIFARMA and the Government to estimate the pharma spending growth rate.
Spain	✓	GDP growth rate	Payment of quarterly contributions of 1.5-2% depending on sales volumes. 5 to 25% (+ additional 10%) reductions according to Profarma Plan	Farmaindustria involved by the Government/Ministry of Finance to plan policies on pharma caps.
UK	✓	NHS Funds and pharma spending growth rate	Reimbursement of a percentage of the total spending exceeding the growth rate; distribution proportional to the company market shares (both for VPAG and the Statutory Scheme).	VPAG negotiated by Department of Health and Social Care and ABPI. Companies and industry associations are raising concerns about payback negative impact on UK's reduced attractiveness for R&D.

ABPI: Asosciation of the British Pharmaceutical Industry. **EOPYY:** Ethnikos Organismos Parochis Ypiresion Ygeias. **GDP:** Gross Domestic Product. **NHS:** National Health Service. **VPAG:** Voluntary scheme for branded medicines Pricing, Access and Growth.

CONCLUSIONS

- While pharma spending caps have become a common tool to support healthcare sustainability, considerable **cross-country variation** remains in their operationalization.
- Since these mechanisms can affect expected revenues and market attractiveness, their design may have **implications extending beyond budget control**.
- Furthermore, spending caps reflect a **silos budgeting approach**, disregarding the impact of medicines on other healthcare spending items.
- The evidence generated by this study can support policymakers in evaluating the **trade-offs** between **expenditure** containment, regulatory **predictability**, and **incentives** for pharma **innovation** and **investment**.

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