

Clawbacks and mandatory rebates in Europe: implications for pharmaceutical companies

Lucy Forrester, Christel Jansen, Vincenzo Straccia, Erin Haney, Herve Lilliu
Inbeeo, 14 Bedford Square, London WC1 3JA



Objective

The objective of this research is to explore the effects of clawbacks and mandatory rebates on the pharmaceutical industry in Europe. It focuses on effects in terms of the revenue impact as well as access, pricing and policy responses.

Introduction

Cost containment measures are applied by policymakers to control pharmaceutical and healthcare budget overspend. Two product-agnostic tools used across Europe are mandatory rebates and clawback schemes. Manufacturers are required to pay mandatory rebates irrespective of a product's value or to pay back a share of their revenue if a pre-specified budget ceiling for pharmaceutical expenditure is exceeded.¹

Often implemented following times of economic downturn (post-COVID, post-global financial crisis), these temporary measures subsequently have not been removed.²

Companies can respond to high clawback levels within an industry in different ways. Notably, two companies have withdrawn from the clawback voluntary pricing scheme in the UK.³ This raises the question around responses currently adopted by companies and the future industry actions.

Methodology

A combination of secondary research and an online survey were used to answer the following questions:

- What is the overall size of the clawbacks in United Kingdom (UK), Germany (DE), France (FR), Italy (IT) and Greece (GR)?
- What is the financial impact of clawbacks at the individual company level?
- What is the awareness of clawbacks within companies?
- How are pharmaceutical companies responding to mitigate the impact of clawbacks, at present and in the future?

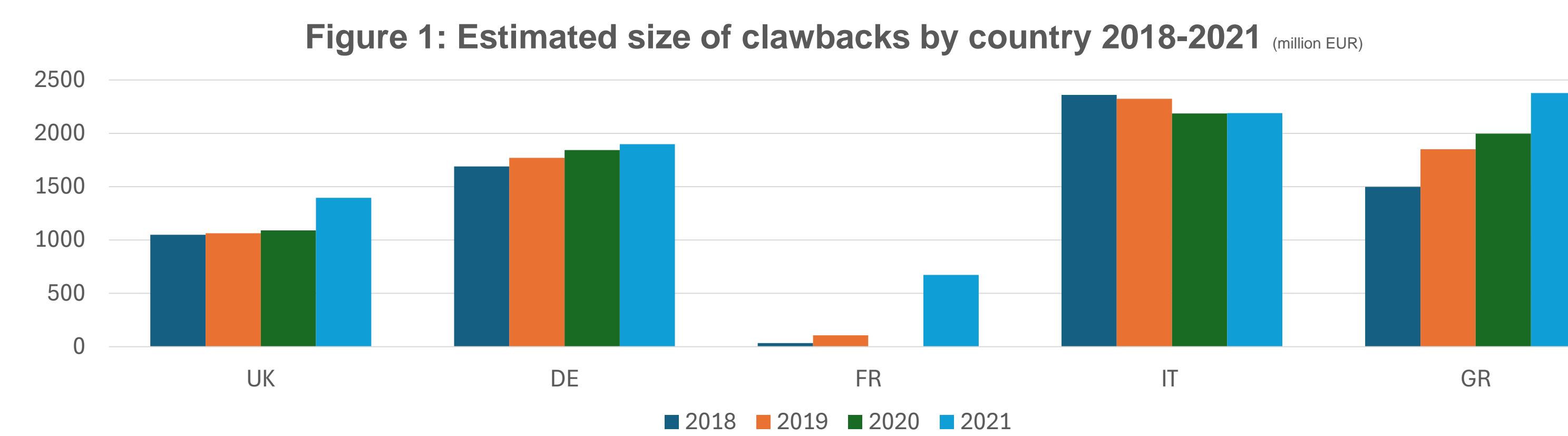
The secondary research focused on major European markets that apply clawbacks or mandatory rebates (France, Germany, Italy, and United Kingdom) and one market implementing particularly high levels of clawbacks and mandatory rebates (Greece). Pharmaceutical expenditure and clawback levels were determined using national authority data. Company level analysis was based on pharmaceutical sales for two companies with different levels of revenue (global annual revenue > USD 30 billion; and < USD 6 billion). Using company annual report data, each company's share of clawback payments was estimated based on their European market share.⁴

To further support the research, a survey for relevant pharmaceutical company representatives was shared via email, LinkedIn, and a European industry body. Survey questions covered levels of awareness as well as current and future actions of pharmaceutical companies in response to clawbacks.

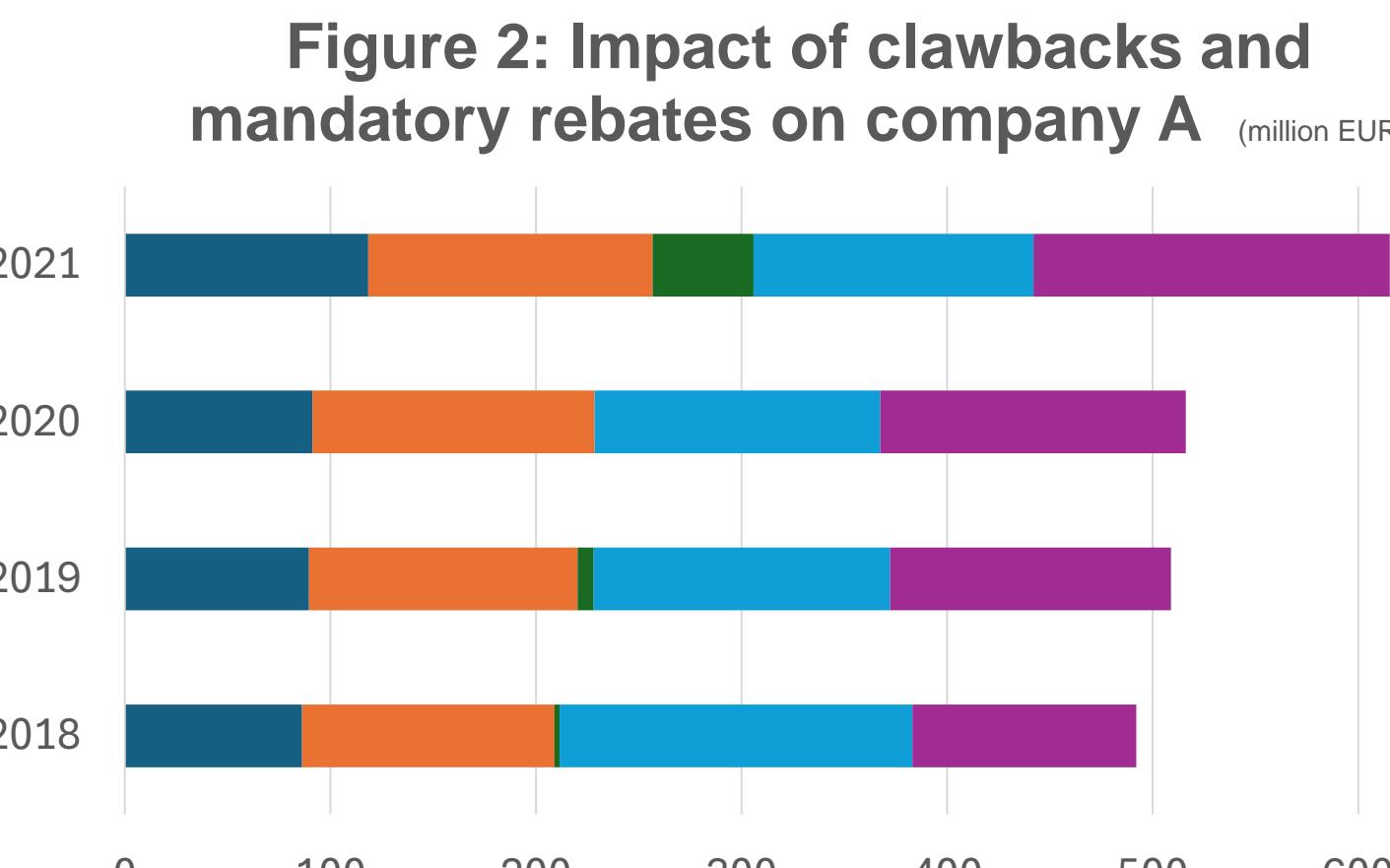
Results

Secondary research results

The estimated payback by companies due to clawbacks and mandatory rebates across markets increased between 2018 and 2021:



The amount both Company A and B were required to payback increased between 2018 and 2021:

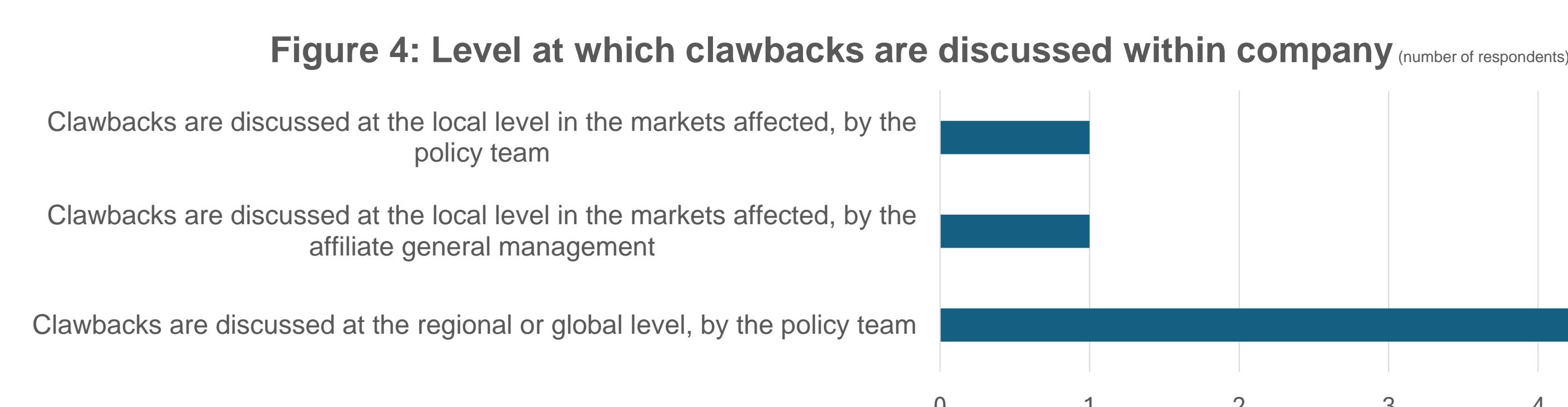


Company A had a European market share of ~7% in 2021.

The combined impact of the clawbacks across markets (the UK, France, Germany, Italy, and Greece) for company A was €597 million in 2021. Between 2018 and 2021, clawbacks represented around 3% of European and 1% of global sales.

Online survey results

The survey captured a total of seven responses. One respondent represented a pharmaceutical company with annual global revenue between USD 6-12 billion; six respondents represented companies with annual global revenues < USD 1 billion.



The perceived impact of clawbacks varied from "minimal to no impact" and "high impact." With one respondent indicating "not being aware" of the level of impact. The majority of respondents (5/7) reported that clawbacks are now being discussed within their company at the above market (regional or global) level.

In terms of company response to clawbacks, the most reported action was related to launch- or launch sequencing decisions. Four respondents have already made changes to launch- or launch sequencing decisions; with two respondents planning to do so.

Conclusion

The total amount of clawbacks paid at both company and industry level increased between 2018 and 2021 in the European countries of interest. This research, despite its small sample size, suggests that pharmaceutical companies are discussing European clawbacks above the individual market level. From results captured by the survey, pharmaceutical company responses are mainly affecting product launches and launch sequencing. If clawbacks continue to grow at the current rate, the response from the pharmaceutical industry is likely to intensify.

As a result, clawbacks may have the unintended consequence of affecting patient access to innovative medicines. Further research is needed to identify and mitigate the potential unintended consequences of clawbacks and mandatory rebates for patients, health systems and economies.

Footnote and references

- UK data is estimated from the difference between gross and net pharmaceutical spend presented in UK Health Accounts⁵; DE data is the value of the statutory rebate owed by companies per year⁶; FR data is the size of the payback attributed to the spending above "Montant M", this data was unavailable for 2020⁷; IT data is the difference between gross and net spending⁸; GR data is all discounts within country⁹
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