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Article - Version of Record

Suggested Citation:
Kranich, C., Möller, D., & Dintsios, C.-M. (2025). The impact of the new ‘guard rails’ for price negotiations on pharmaceutical expenditure in Germany: A simulation exercise and retrospective analysis. Health Policy, 165, Article 105537. https://doi.org/10.1016/j.healthpol.2025.105537

Health policy 165 (2026) 105537

Contents lists available at ScienceDirect

Health policy

journal homepage: www.elsevier.com/locate/healthpol

The impact of the new 'guard rails' for price negotiations on pharmaceutical expenditure in Germany: A simulation exercise and retrospective analysis

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ARTICLE INFO

Keywords:
Statutory health insurance financial stabilization act
Pharmaceutical price regulation
AMNOG
Budget impact analysis
Simulation

ABSTRACT

Background: Due to increasing pharmaceutical expenditures, Germany implemented 'guardrails' for price negotiations at the end of 2022, as part of the 'Statutory Health Insurance Financial Stabilization Act'. They regulate the pricing of benefit-assessed pharmaceuticals with comparators under data exclusivity, to generate savings
Objective: We aimed at quantifying the targeted savings from a payer perspective.
Methods: A retrospective implementation of the 'guard rails' for new benefit-assessed pharmaceuticals in the period 2020 – 2022 on a subpopulation basis after application of specific exclusion criteria was chosen to estimate their potential savings by means of a simulated budget impact analysis. Comprehensive prescription data and pharmaceutical retail prices were utilized to ensure comparability over time.
Results: The analysis included 38 products with 82 subpopulations encompassing approximately 870,000 patients. The difference between negotiated prices and those regulated by the 'guard rails' in terms of annual therapeutic costs was statistically significant (p=0.01, CI95%: €1145,925.47 – €8914,501.69). If the 'guard rails' had been implemented earlier, pharmaceutical expenditure for the assessed subpopulations could have been reduced by €191.14 million, with oncological products accounting for €117.20 million (61.3% of total savings) in the examined period.
Conclusions: Despite the significant potential savings identified in this analysis, the actual annual savings are inconsistent and challenging to predict as they largely depend on the number of new product launches and the extent of their added benefit demonstrated. The application of the 'guard rails' remains rather complex and legally ambiguous, suggesting that further contentious discussions are likely in the future.

1. Background

1.1. Early benefit assessment and price negotiations

High payer deficits led to the introduction of the 'Act to Reorganize the Pharmaceutical Market in the Statutory Health Insurance System' (AMNOG) in 2010 [1,2], resulting in a paradigm shift in market access for new pharmaceuticals in Germany. Following market launch, new pharmaceuticals are subject to an early benefit assessment (EBA) [3] based on patient-relevant outcomes [4] to prove an added benefit on a subpopulation-basis [5] compared to the appropriate comparative therapy (hereafter referred to as 'comparator'). The extent of added benefit can be categorised as major, considerable, and minor or not quantifiable (in cases of a non-determinable added benefit). The Federal Joint Committee (FJC) decides on the categorisation based on the assessment conducted by the Institute for Quality and Efficiency in Health Care (IQWiG) [6]) (orphan drugs are assessed directly by the FJC). The EBA serves as the basis for subsequent price negotiations between payers and manufacturers. Detailed descriptions of the EBA [7–10], methods applied [11,12], price negotiations [13–17], and the procedural sequence [18] have been published earlier. For orphan drugs (ODs) an added benefit is granted by law and the FJC decides only on its extent in the absence of a defined comparator [10,15]. This legal incentive (given added benefit for ODs) is repealed if a specific turnover

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https://doi.org/10.1016/j.healthpol.2025.105537
Received 28 January 2025; Received in revised form 4 October 2025; Accepted 5 December 2025
Available online 6 December 2025

limit has been exceeded within the previous 12 months of marketing (currently 30 million €) [19]. The price negotiations are conducted according to the framework agreement [17], signed by the National Association of Statutory Health Insurance (SHI) Funds and the relevant pharmaceutical associations. The main points to consider are: the annual therapy costs per patient of the comparator, the extent of added benefit, comparable pharmaceuticals within the same indication, and European prices in the referenced countries [17,20]. With the Medical Research Act (MFG) passed in September 2024, European prices will no longer be considered after 2025 [21]. If no agreement is reached during the negotiations, an arbitration board is called [16].

1.2. Statutory health insurance financial stabilization act

Whereas in case of an added benefit a price premium over the comparator had to be agreed until the end of 2022, pharmaceuticals without an added benefit were priced with the price of the comparator at maximum or assigned to a reference price group, if available. However, only very few reference price groups were applicable to innovative pharmaceuticals. This framework changed with the implementation of 'Statutory Health Insurance Financial Stabilization Act' (GKV-FinStG), at the end of 2022 [19]. The act was prompted by the substantial increase in pharmaceutical expenditure, which rose by approximately €11.2 billion between 2017 and 2022, accounting for around 17 % of total SHI expenditure (Suppl. Fig. 1) [22]. The act introduced additional guidelines for price negotiations, referred to in German as 'Leitplanken' (translated as 'guard rails'). These 'guard rails' are based on the added benefit and the data exclusivity status of the comparator. For new pharmaceuticals that do not demonstrate an added benefit and whose comparator is still under data exclusivity, a negotiated price must ensure annual therapy costs that are at least 10 % below those of the comparator. In cases where the FJC acknowledges a non-quantifiable or minor added benefit and the comparator is under data exclusivity, the reimbursement cannot exceed the annual therapy costs of the comparator (Fig. 1).

If several alternatives with data exclusivity are determined by the FJC as comparator (comparator-basket), the most economical one is considered. Furthermore, the law includes a special regulation in case of a comparator under data exclusivity or comparable pharmaceutical that has not undergone an EBA: a 15 % deduction is applied to the annual turnover of this pharmaceutical. The case of a mixed comparator-basket containing pharmaceuticals under data exclusivity and with expired data exclusivity remains unregulated by the new legislation.

The aim of the 'guard rails' is to limit the price for new pharmaceuticals depending on the added benefit and to strengthen the negotiating position of the National Association of SHI Funds. Additionally, they are intended to incentivize the development of innovative pharmaceuticals with greater added benefits. According to the legislator, the 'guard rails' are expected to lead to medium-term savings of €250 – 300 million annually [23].

1.3. Hypothesis testing

The GKV-FinStG is expected to bring significant changes in the future. The 'guard rails' are primarily aimed at indications characterized by step innovations, such as oncological pharmaceuticals, which often are granted a minor or not-quantifiable added benefit. In this context, the main hypothesis to be tested is as follows: *The new 'guard rails' for price negotiations will have a strong impact on pharmaceuticals' expenditures in Germany.* To test this hypothesis, additional hypotheses are derived: (1) The SHI expenditures on pharmaceuticals will be significantly lower after the implementation of the 'guard rails' compared to those based on negotiated prices, and (2) the savings generated in oncology will be significantly higher than those in other therapeutic areas. In addition, we tested the hypothesis that there is a significant correlation between therapeutic areas and the extent of the added benefit, expecting that potential savings based on the extent of granted added benefit consequently differ amongst therapeutic areas.

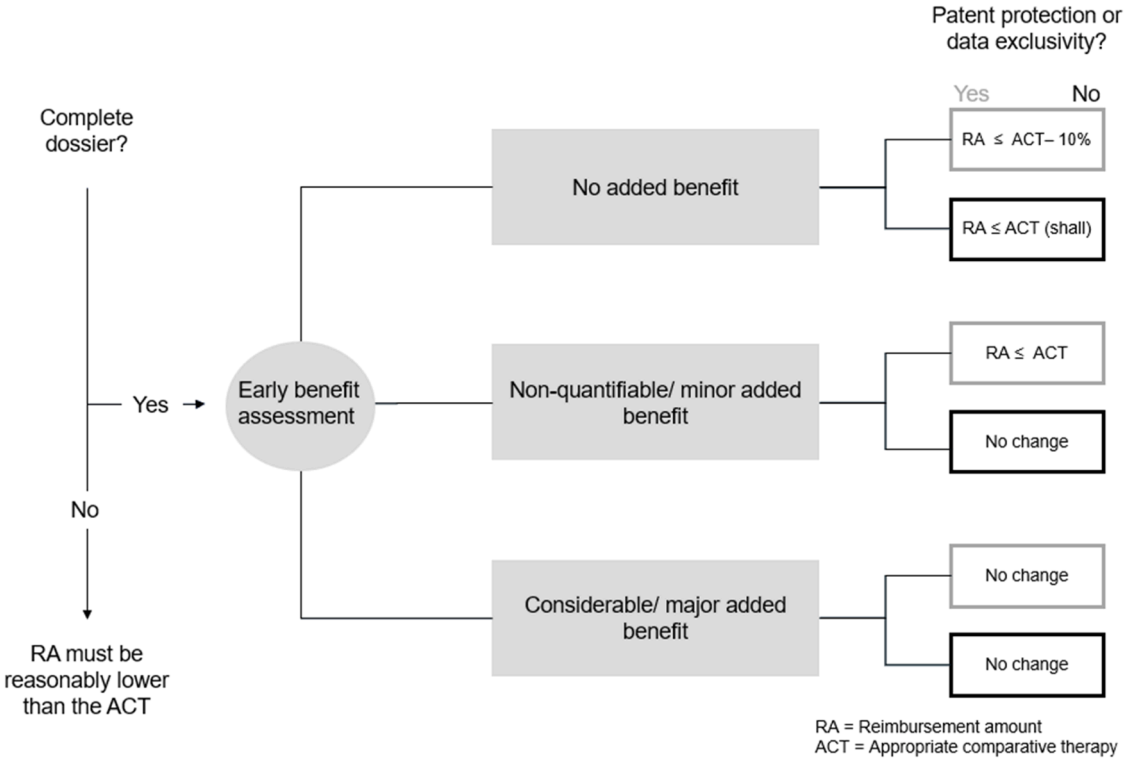

Fig. 1. New 'guard rails' for price negotiations
Legend: the figure presents the 'guard rail' algorithm for price restrictions depending on added benefit and (most cost-effectiv) Appropriate Comparative Therapy under data exclusivity.

2. Methods

2.1. Retrospective budget impact analysis and exclusion criteria

A retrospective application of the 'guard rails' to new pharmaceuticals in the period of 2020 to 2022 was conducted to estimate their effects by means of a Budget Impact Analysis (BIA). This period reflects current data on the uptake of the pharmaceuticals. The analysis followed a multistage approach comprising four steps: (1) Based on the decision of the FJC for these pharmaceuticals, we extracted the following data: indication, (sub-)population size, intervention, comparator, subpopulation-specific added benefit, date of the decision, annual therapy costs of the new pharmaceutical, annual therapy costs of the comparator, and costs for additional SHI services when applying the pharmaceuticals. (2) In addition, since the prices are not kept confidential, based on the German Drug Directory, we calculated the changes of the annual therapy costs as the result of the price negotiations for each dosage and package referred to in the FJC decisions. (3) To estimate the real SHI sales volume at a product level until May 2023, we used the IQVIA PADDS DatabaseViewer version 7.9.5., which documents the invoiced SHI prescriptions. (4) We considered only pharmaceuticals for which the new regulations can be applied across all subpopulations. The following exclusion criteria were defined at subpopulation level: no dossier for EBA submitted, unclear data exclusivity status of comparator, pharmaceuticals assigned to a reference price group, inappropriate subpopulation definitions, hospital pharmaceuticals (these are mainly mapped through diagnosis-related groups, making individual tracking of their use impossible) [24], pharmaceuticals withdrawn from the market [25], pharmaceuticals currently subject of arbitration, and pharmaceuticals with comparators for which no information regarding the annual therapy costs is provided by the FJC.

2.2. Budget impact simulation

At subpopulation level the impact on pharmaceuticals expenditure is analysed as if 'guard rails' regulations would have been applied earlier to the corresponding annual therapy costs per patient and offset against the annual patient numbers (eq. 1, where AnTC stands for annual therapy costs).

$$\sum \left\{ \left(\text{AnTC}_{(\text{negotiated})} - \text{AnTC}_{(\text{'guard rails'})} \right) \text{x N Patients}_{(\text{annually})} \right\} = \text{SHI Savings (annually)} \quad (1)$$

To enable comparability, the information must be given as the pharmacy retail price reduced by the statutory discounts (pharmacy discount and manufacturer discount). There are pharmaceuticals for which several EBAs exist. To be able to utilise the sales volume, which is only recorded at product level, it is essential to determine the annual therapy costs at a product level. First, the patient shares are calculated based on the number of patients per EBA. Second, the weighting and addition is done according to the patient shares at EBA level. For combinations of two or more active substances constituting a comparator, the data exclusivity status of the combination is considered accordingly. The annual therapy costs of the comparator are often provided as a price range per patient. To obtain an average cost basis, a mean value was calculated in this case. The 15 % discount on pharmaceuticals with comparable drugs under data exclusivity that did not undergo an EBA is neglected, since potential comparable drugs are not explicitly stated in the FJC decision. Their definition is part of the confidential negotiations between manufacturers and payers. Similarly, European prices are kept confidential and are not considered in the present simulation. The annual number of patients treated with each pharmaceutical is derived from the corresponding sales volume. A distinction is made between total and annual savings. Total savings refer to the data covering a one-year period, from May 2022 to May 2023 as the 'guard rails' are based on annual saving targets. This period is aligned with available prescription data. Annual savings relate to the individual years (2021, 2022 and 2023), based on FJC decisions published in the prior year (e.g., FJC decisions from 2020 are used to calculate savings for 2021, and so on).

2.3. Statistical analysis

Normal distribution of continuous variables is tested by the Shapiro-Wilk test. Costs with and without implemented 'guard rails' are tested by a paired t-test. The t-test is applied irrespective of the distributions, as it is robust to violations of the normal distribution assumption [26]. The savings of pharmaceuticals in oncology and in other therapeutic areas are tested for variance equality using the Levene test. The t-test is then calculated on independent samples. The chi-square test is used to test the correlation between therapeutic areas and added benefit.

IBM SPSS Version 29.0 (IBM CORP. 2023) is used for statistical analyses and precision is presented with 95 % confidence intervals. Due to limited access to some data sources used (German Drug Directory and IQVIA PADDS DatabaseViewer), full replication of the presented analysis is not possible.

3. Results

3.1. Data basis

397 products with 1645 subpopulations were assessed from the introduction of EBA in 2011 (Suppl. Fig. 2). In the period of interest (2020 – 2022), the number of subpopulations is reduced to 556. As only initial assessments are included in our simulation, the cases are reduced to 226 subpopulations. Disregarding the orphan drugs because they are assessed without a comparator, reduces the cases by a further 56 subpopulations. As only subpopulations affected by the new law are relevant, the number amounts to 70 products with 143 subpopulations. Applying further single exclusion criteria leads to a reduction to 38 products with 82 relevant subpopulations (72 with no added benefit and 10 with minor added benefit). The number of subpopulations per product varies between one and eight (average around two subpopulations). Oncology is the most frequently represented indication area with nine products and 15 subpopulations followed by infectious diseases with six products without any subpopulations.

3.2. Budget impact analysis

The concrete detailed steps of the BIA for each considered product are illustrated using the example of Acalabrutinib (Calquence®) in Supplement 1 (the different analysis levels are delineated in Supplement 2).

3.2.1. Changes in annual therapy costs

Fig. 2 shows a comparison of the negotiated annual therapy costs and annual therapy costs with applied 'guard rails' per patient for all 38 products included in the analysis. The average negotiated price for the pharmaceuticals considered here is about €48,270 (€15,600 – €476,110). The average price under application of the 'guard rails' is about €38,980 (€11,630 – €421,750).

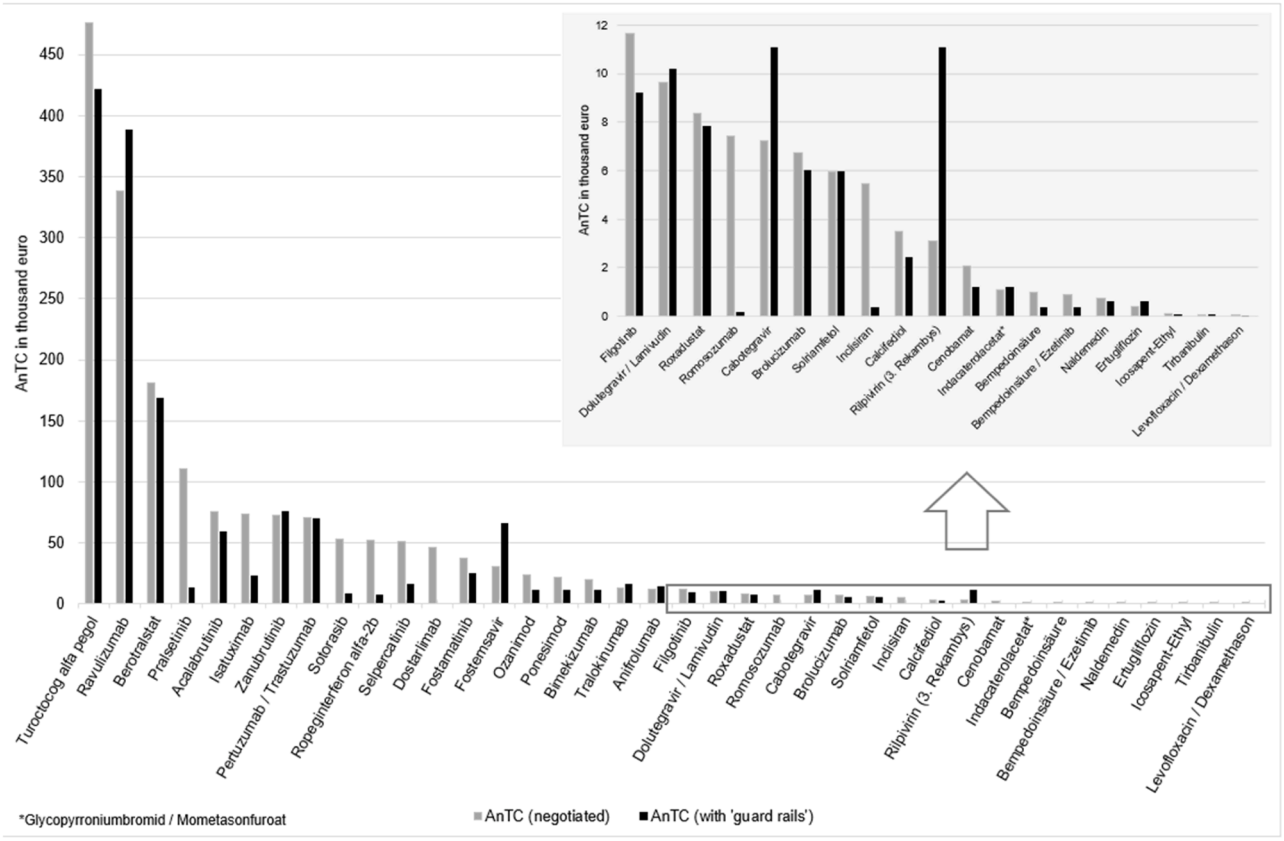

Fig. 2. Negotiated annual therapy costs versus annual therapy costs with 'guard rails' Legend: The figure shows the negotiated annual therapeutic costs compared to the annual therapeutic costs after application of the 'guard rails' of the products included in the analysis.

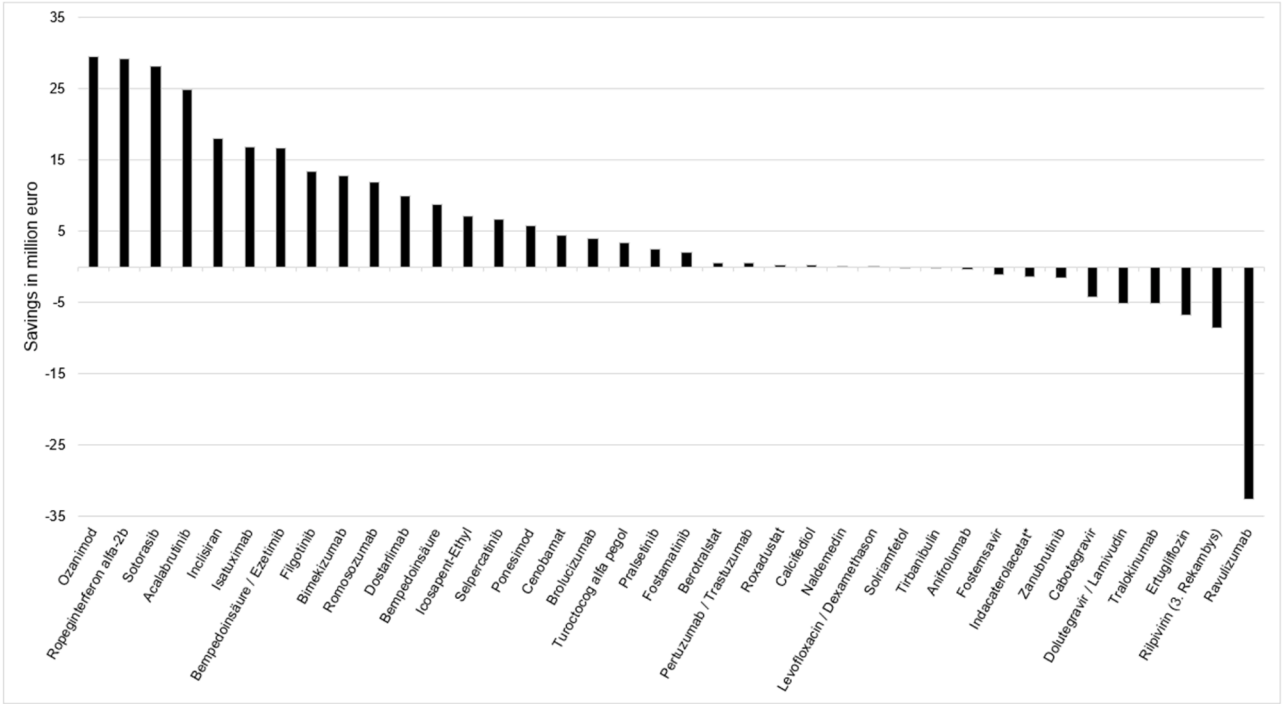

Fig. 3. Savings per product
Legend: The figure depicts the savings per product applying the guardrails for the period May 2022 – May 2023.

3.2.2. Target populations

The product with the largest target population is Icosapent-Ethyl for the treatment of metabolic diseases (154,860 patients) and the oncological product Pralsetinib is that with the smallest number (26 patients). The average number of patients per product is 10,860. Suppl. Table 1 contains the patient numbers for the years 2021, 2022 and 2023.

3.2.3. Total cost savings

When aggregating the savings achieved by the 'guard rails' for all 38 products appraised by the FJC from 2020 to 2022, they lead to an absolute cost reduction of €191.14 million from May 2022 to May 2023 (Suppl. Fig. 3). The mean savings per product amount to €5.03 million (€-32.54 million – €29.56 million) and cover a range of €62.10 million. The highest difference in savings is achieved in the positive area by Rilpivirine at 254 % and in the negative area by Dostarlimab at -98 %. Tirbanibulin shows no change (Fig. 3).

The annual therapy costs after implementation of the 'guard rails' and the negotiated annual therapy costs are not normally distributed (Shapiro-Wilk test, $p < 0.05$). The first are lower (€22,418,467.64 ± €44,157,929.31) than the second (€27,448,681.22 ± €40,642,998.76). The paired samples t-test shows that this difference is statistically significant [$t(37) = 2.62$, $p = 0.01$, $CI_{95\%}$: €1,145,925.47 – €8,914,501.69].

Nine products had oncological indications. A further 29 products are used in other therapeutic areas. The potential saving per oncological product from May 2022 to May 2023 ranges roughly from €-1.5 million to €30 million (mean €13 million). For products used in other therapeutic areas, the saving ranges from €-32 million to €30 million (mean € 2.5 million) (Suppl. Figure 4). Overall, oncological products account for 61.3 % (€117.20 million) of the total savings. The Levene test shows no significant result ($p > 0.05$) and thus the null hypothesis of homogeneity of variance cannot be rejected. Against the background of the directed hypothesis, the p-value is below 0.05 and rejects the null hypothesis of the t-test of equal means. Oncological pharmaceuticals show with $t(36) = 2.48$ ($p = 0.02$, $d = 1.95$) a statistically significantly higher mean saving (€13,021,592.74 ± €12,114,703.52) compared to pharmaceuticals in other therapeutic areas (€2550,130.39 ± €10,756,788.64). According to Cohen [27], this difference is considered large. Interestingly, the therapeutic areas do not differ regarding the extent of the added benefit ($Chi^2 = 0.17$, $p = 0.68$) and thus there is no statistically significant correlation between the therapeutic areas and the extent of the added benefit.

3.2.4. Cost savings per year

The implementation of the 'guard rails' would have reduced the expenditure on assessed pharmaceuticals with a FJC decision in 2021 by €1.71 million (€-24.59 million to €16.28 million), in 2022 by €130.96 million (€ -8.36 million to €23.9 million), and in 2023 €5.86 million (€-7.64 million to €16.37 million) (Suppl. Fig. 5).

3.3. Hypothesis testing

The costs applying the 'guard rails' differ significantly from the actual negotiated annual therapy costs. Hypothesis 1 can therefore be accepted. The savings generated by oncological pharmaceuticals are significantly higher than the savings generated in other therapeutic areas. Thus, hypothesis 2 can be accepted. There is no significant correlation between the therapeutic area and the extent of the added benefit and thus the last hypothesis must be rejected.

4. Discussion

Based on the simulated BIA, it is shown that expenditure on assessed pharmaceuticals would have been reduced by €191.14 million between May 2022 and May 2023 if the GKV-FinStG had been implemented earlier. The government estimated expected savings at approximately €250 – 300 million per year [23]. If the 'guard rails' would have been consistently applied to all benefit-assessed drugs since 2011 – provided they meet the relevant criteria – the savings shown here for 2020 to 2022 would roughly account for around a quarter of the total potential savings over the period from 2011 to 2022.

The AMNOG Report 2023 [28] also addresses the GKV-FinStG and simulates the 'guard rails' effects based on the data from 2019 to 2021. The authors arrive at savings of €179 million for new approvals in 2019 and 2020 within the first year following the FJC decision. Based on these results, the report assumes that the annual savings quantified by the legislator can be exceeded by the application of the 'guard rails'. These findings reinforce the results of the present analysis.

Twelve products show no savings following the application of the 'guard rails', instead they exhibit increased annual therapy costs (Fig. 3)., This outcome can be attributed to the fact that, in addition to the added benefit, other criteria – such as the selling price in other EU countries and the annual therapy costs of comparable drugs – are also considered in the price negotiations but are not included into the present analysis.

Savings fluctuate significantly over the years and depend largely on various factors, including the number of products to which the 'guard rails' can be applied, the therapeutic area in which they are used, and the extent of the added benefit. For example, the number of oncological pharmaceuticals plays a significant role in overall expenditure, leading to high savings in years when more such products are launched. Approximately 85 % of the subpopulations that have undergone EBA since 2011 would hypothetically be affected by the 'guard rails'. Due to this extensive influence, the long-term effects of the policy should not be overlooked. Engelke and Kiss [29] highlight the relevance for the international reference price system. If the German prices fall significantly below the international price range because of the new legislation, this could have far-reaching effects on the global prices, since Germany is included in price baskets of different countries as a high-priced reference country. Consequently, manufacturers might alter their launch sequence if Germany becomes a lower-priced reference country (market access in Germany is averagely 45 days after authorization [30]) or may even choose not to launch their products in Germany at all. A new evaluation of the measures of the GKV-FinStG, initiated by the Federal Ministry of Health for the period from the end of 2022 to 2024, concluded that no definitive assessment could yet be made. Especially with regard to the 'guard rails', it was stated that quantifications of actual savings are not yet available and therefore they cannot be evaluated [31]. The present work offers simulated estimates of potential savings. The recently enacted 'Medical Research Act' (MFG) passed on September 27, 2024, did not repeal the 'guard rails' but modified some of the conditions: the 'guard rails' are suspended if 5 % of the study participants are recruited from German study centres [21]. It remains to be seen to what extent this change will incentivize clinical research in Germany and what proportion of products will benefit from this regulation.

Finally, the 'guard rails' deviate from a pure value-based pricing as the chosen methodological approach for the AMNOG price regulation, as they do not stipulate anymore a premium for some of the extents of added benefit and sanction no added benefit [32]. Thus they implicitly trigger, except in cases of considerable or major added benefit, a legally intended staircase effect with decreasing prices.

4.1. Strengths and limitations

The impact of the simulation approach and assumptions made on the expected 'guard rails' effects is described in Table 1. The BIA simulation is based on a short period after the GKV-FinStG was passed and is therefore only an excerpt that does not cover the entire past of the AMNOG. In addition, only subpopulations with an initial assessment are considered (226/556) and not such originating from an indication extension or a re-assessment (59.3 %). Furthermore, the focus is on the outpatient sector. However, the development of the inpatient sector should not be ignored, as the importance of assessed pharmaceuticals in

Table 1
Impact of calculation approach and assumptions made on the expected 'guard rail' effects.

Calculation approach or assumption	Impact on expected effects	Extent
• The BIA simulation is based on a short period after the GKV-FinStG	• The simulation does not cover the entire past of the AMNOG	↓↓
• Inclusion of subpopulations with an initial assessment	• This leads to an underestimation of the expected 'guard rails' effects, as indication extensions and reassessments are not included	↓
• Only consideration of the outpatient sector	• Underestimation of potential savings due to exclusion of the hospital pharmaceutical expenditure	↓
• Products for which the annual therapy costs are not recognizable in the FJC decision are excluded	• This can lead to an underestimation of the effects	↓
• Assumption that substances with loss of data exclusivity are subject to generic competition.	• This assumption can represent a bias in both directions (overestimation or underestimation of the results).	↑↓
• 15 % discount on pharmaceuticals that were launched before 2011 and have not undergone an EBA is not considered	• This aspect only represents a slight underestimation without a significant scope.	↔
• The price for pharmaceuticals without added benefit is to be reduced by at least 10 % compared to the most economical comparator under data exclusivity	• This minimum discount is assumed in the calculation and may represent an underestimation of the savings.	↓
• For pharmaceuticals with a non-quantifiable or minor added benefit, the price should be less than or equal to the price of the most economical comparator under data exclusivity	• Equal prices to the prices of the most economical comparator under data exclusivity are assumed	↓
• Pharmaceuticals that have been assigned a mixed comparator basket by the FJC have a special status	• The assumption that the most economical comparator represents the price is only speculative leading potentially to over- or underestimation of the savings	↑↓
• Linear extrapolation for the sales volumes of the second half of the year 2023	• This may both underestimate or overestimate reality	↑↓

Table 1 (*continued*)

Calculation approach or assumption	Impact on expected effects	Extent
↑	Overestimation of the expected 'guard rails' effects	
↑↑	Strong overestimation of the expected 'guard rails' effects	
↓	Underestimation of the expected 'guard rails' effects	
↓↓	Strong underestimation of the expected 'guard rails' effects	
↑↓	Overestimation or Underestimation of the expected 'guard rails' effects possible	
↔	Marginal impact on the expected 'guard rails' effects	

hospitals has risen sharply in recent years. It is not possible to clearly track pharmaceutical costs in the inpatient sector. According to a rough estimate, inpatient pharmaceutical expenditure in Germany reached €3.36 billion in 2023 of which €1.2 billion (36 %) were spent for benefit-assessed pharmaceuticals [33]. Moreover, products are excluded for which the annual therapy costs are not recognizable in the FJC decision. The lawmaker has not yet specified how such scenarios will be dealt with in future. Therefore, it is necessary to await future developments and adjust the model calculation accordingly.

In the calculation we postulate that active ingredients in the German Drug Directory marked as having lost the data exclusivity are subject to generic competition. But there are products where this is not the case. This may be due to the unattractiveness of the indication or the difficulty in manufacturing the active ingredients. One example is interferon beta-1a. Another point worth mentioning is the neglect of the 15 % discount on pharmaceuticals that were launched before 2011 and have not undergone an EBA. On the one hand, this legal amendment promotes products for which the FJC designates a comparator under data exclusivity. On the other hand, it applies to pharmaceuticals that are considered as comparable drugs. However, pharmaceuticals have an average market exclusivity of around 12 years. In view of the EBA introduction in 2011, almost all products launched before 2011 have passed this 12-year period.

According to the GKV-FinStG, the price for pharmaceuticals the FJC did not grant an added benefit is to be reduced by at least 10 % compared to the most economical comparator under data exclusivity. For pharmaceuticals that receive a non-quantifiable or minor added benefit, the price should be less than or equal to the price of the most economical comparator under data exclusivity. In the present analysis, the assumption was made that the price for drugs with this extent of added benefit corresponds to the price of the most economical comparator under data exclusivity. In addition, the available data referred to sales volumes up to May 2023, meaning that the sales volume for 2023 is calculated based on the first five months. The sales volumes used for 2023 are based on a static linear extrapolation. This approach was chosen, as dynamic predictions of the uptake of newly introduced drugs are very vague.

In contrast to publications referring to data from individual SHI funds [28] or reflecting only the expectations of manufacturers [34,35], this simulation of the consequences of the 'guard rails' is based on a complete survey of prescription data of the entire SHI for the drugs included and evaluates the therapeutic areas separately. The study pursues an approach with explicit inclusion of subpopulations, the consideration of which is indispensable in the context of the mixed-calculation approach to price negotiations. This is also in alignment with the systematic literature review on guidelines on BIA of Chugh et al. [32], which highlights differences in contextual factors pertaining to health system organisation, operating financing mechanisms and different modes of healthcare.

5. Conclusion

Initial estimates regarding the effects of the retrospectively applied 'guard rails' introduced by the 'Statutory Health Insurance Financial Stabilization Act' on the expenditure of benefit-assessed pharmaceuticals can be derived. Considering new pharmaceuticals that were assessed in the years 2020 – 2022, the expenditure on these pharmaceuticals would have been reduced by €191 million between May 2022 and May 2023. The savings could even quadruple if 'guard rails' were implemented from the very beginning of early benefit assessment in 2011. These hypothetical savings demonstrate the potential scope of the 'guard rails' primarily in the oncological therapeutic area where step innovations are common. However, due to the cumulative effect of the 'guard rails' the expected annually increasing savings are inconsistent and difficult to predict. They are heavily dependent on the number of new pharmaceuticals launched and the extent of their added benefit. The application of the 'guard rails' is rather complex and legally ambiguous, so that further controversial discussions can be expected in the future. Since real savings achieved so far by the 'guard rails' have not yet been quantified, simulations still provide valuable estimates of potential savings.

Funding

No funding was received for this study.

Availability of data and materials

Price data were gathered from the German Drug Directory (Lauer-Taxe). IQVIA PADDS DatabaseViewer served as the source for invoiced SHI prescriptions from the pharmacy data centres. Both databanks are not publicly available but can be accessed for academic purposes.

Ethics approval

Not applicable.

CRediT authorship contribution statement

C. Kranich: Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **D. Möller:** Writing – review & editing. **C.M. Dintsios:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Declaration of competing interest

CMD is next to his academic affiliation employed by Bayer Vital GmbH in Leverkusen, Germany. CK and DM have no conflicts of interest.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.healthpol.2025.105537.

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