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Pharmaceutical Prices: The Impact of the Launch Strategy

An Analysis of German Data

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ABSTRACT

PHARMACEUTICAL PRICES: THE IMPACT OF THE LAUNCH STRATEGY

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This paper reports the results from a statistical analysis of pharmaceutical price negotiations in Germany, where the pricing system was changed in 2011 in order to tie prices more to the benefits of the pharmaceuticals. A multiple linear regression of 187 pharmaceuticals which were assessed from 2011 to 2017 suggests that, despite the change, the manufacturers' launch strategy (freely chosen first year price) still has a major impact on pricing while the impact of the additional benefit remains comparably small. Moreover, the data suggest that the assessment of the Federal Joint Committee - while not yet existing at the point - best explains the manufacturer's launch strategy, indicating that manufacturers know more than they reveal.

Keywords: AMNOG, early benefit assessment, pharmaceuticals

JEL classification: I10

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1. INTRODUCTION

Average health spending worldwide corresponds to 8.31% (median: 8.28%) of the country's gross domestic product; and 16.75% (median: 14.67%) of this derives from pharmaceuticals (OECD, 2019a, 2019b). However, pharmaceutical prices are a notoriously contentious topic (see, for example, Steele, 1962, 1964; Scherer, 2004; or Stiglitz and Jayadev, 2010).[1] While effective drugs are in high demand, national health care systems often struggle with the question of what appropriate prices would be. Naturally, there is a social desire for prices to be low while firms have an incentive to overrate benefits as well as development costs and to exert their partial monopoly power derived from patent rights. As a consequence, pharmaceutical prices have become a major topic of political discussion worldwide, resulting in the World Health Organization hosting its second Fair Pricing Forum calling for more transparency on medicine prices in April 2019 (t' Hoen, 2019).

With the present paper, we aim to contribute to this discussion by analysing the pricing process for new pharmaceuticals in Germany, a reference market for the European Union (cf. Vogler and Martikainen, 2015). The focus on Germany is made not only because of its wider relevance, though, but also because a new procedure to determine pharmaceutical prices was introduced in 2011. In particular, in order to tie prices closer to benefits, a negotiation between the pharmaceutical manufacturer and the National Association of Statutory Health Insurance Funds was introduced which is based on an early benefit assessment of the respective drug's additional benefit (Henke, 2014). According to the new procedure, manufacturers now are able to freely price their new product only in the first year while the negotiated price applies for future years (Federal Ministry of Health, 2016). The procedure, however, remains being criticised for still granting small to no influence to fundamentals, most of all the additional benefit (Aerztezeitung, 2014).

The aim of this study is to shed some light on the potential substance of this claim.[2] In order to do so, we collected data on those pharmaceuticals which have been assessed from 2011 to 2017.[3] In line with the critics, the statistical analysis, indeed, finds that the launch strategy - the premium on the comparator's cost chosen by the manufacturer before the negotiation - has a major impact on the negotiated premium ($p < 0.001$, adj. $R2 = 93.5\%$). Yet, the data also suggest a tangible - albeit smaller - influence of the drug's additional benefit on the negotiation ($R2 = 13.3\%$; $p < 0.01$).

Moreover, we find that renegotiations, due to a reassessment or an extension to a new indication, have a positive effect on prices ($p < 0.001$). Focussing only on first assessments does not change results, though. Also, adding further covariates (e.g. therapeutic area, manufacturer's experience and budget impact) results remain unchanged. Regarding benefit assessments,

[1] *See Parker-Lue, Santoro, and Koski (2015) for a review of different theories; see Frakt (2019) for a recent discussion in the media.*

[2] *Previous studies indeed come to the conclusion that the additional benefit and other factors such as therapeutic area, orphan drug status and appropriate comparative therapy alone do not fully explain the negotiated reimbursement price, for instance (Lauenroth and Stargardt, 2017) or (Theidel and von der Schulenburg, 2016).*

[3] *Of 327 in total 187 were eligible for our analysis. See Section 2 for details.*

however, our analysis shows an interesting pattern. While benefits are assessed both by the manufacturer, the Institute for Quality and Efficiency in Health Care, and the Federal Joint Committee, it is that assessment of the latter which best explains the manufacturers' first year pricing. As we also find evidence for manufacturers' assessments to be systematically more positive, we take this result as suggesting that manufacturers indeed know more that they reveal when setting prices – as theory would predict.

The rest of the paper is structured as follows. Section 2 describes the data set used. The results of the analysis are provided in Section 3. Section 4 concludes with some general comments.

2. DATA DESCRIPTION

From January 1st, 2011 to December 31st, 2017 the Federal Joint Committee (2019a) conducted 327 early benefit assessments – henceforth EBAs for short which are the basis of our dataset. For various technical reasons only 187 EBAs were eligible for our analysis (see Figure 1). For example, EBAs with no successful negotiation were excluded (these are non-complete EBAs, pharmaceuticals classified as fitting for a reference price group and EBAs in which the pharmaceutical manufacturer made use of its right to opt-out). Moreover we excluded EBAs with missing information about treatment costs (annual therapy costs and annual comparator costs, e.g. orphan drugs) and EBAs for which no information on patient group size was available; see Figure 1 for a summary.

Data regarding the early benefit assessment were extracted from the publicly available website of the Federal Joint Committee (Federal Joint Committee, 2019b). These data contain extend and certainty of the additional benefit as assessed by the manufacturer, the Institute for Quality and Efficiency in Health Care (IQWiG) and the Federal Joint Committee, as well as the annual costs of therapy per patient, the patient group size and the appropriate comparator. Moreover, pharmaceutical prices before and after the negotiation were extracted from the official German price database Lauer-Taxe (Lauer-Taxe, 2019). Publicly available information on financial data, in turn, was gathered from the ifo Business Climate Index (ifo Institute, 2019) and finanzen.net (Finanzen.net GmbH, 2019).[4]

Regarding the preparation of the data, it is important to note that in some cases we had to aggregate the available data in order to make them amenable to statistical analysis. In particular, for each pharmaceutical one price is negotiated. Yet, for the benefit assessments they may be divided into different patient groups, leading each to a different outcome, patient group size and comparator cost. For the analysis, the respective variables – additional benefit, annual cost of therapy per patient (also for comparator), price premium – therefore are weighted by the population size of the respective patient group as defined by the Federal Joint Committee for the corresponding EBA.

Moreover, in order to aggregate the data as described above ordinal benefit assessments had to be transferred into a cardinal point scale (see Table 1 and 2 for details). As especially the translation of "non quantifiable" is not without problems, we also conducted various sensitivity

[4] *In organising the data, we greatly benefited from Blankart and Stargardt who kindly provided a reference data set (Blankart and Stargardt, 2017).*

analyses with a total of seven regression models. The core results remain the same for all models; see Appendix A.1.

Figure 1: Reasons for excluding certain EBAs from the dataset eligible for analysis

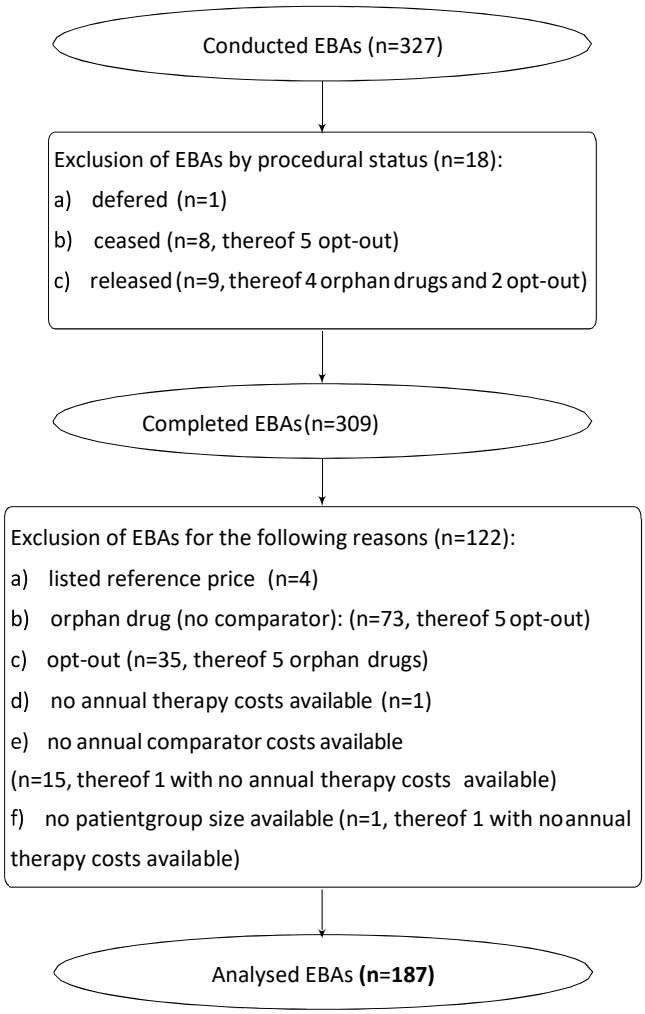


Table 1: Transformation of the extend of the additional benefit into point score.

extend benefit	M1: points
major	6
considerable	5
minor	3
non quantifiable	4
no added benefit	2
lesser benefit	1

Table 2: Transformation of the certainty of the additional benefit into point score.

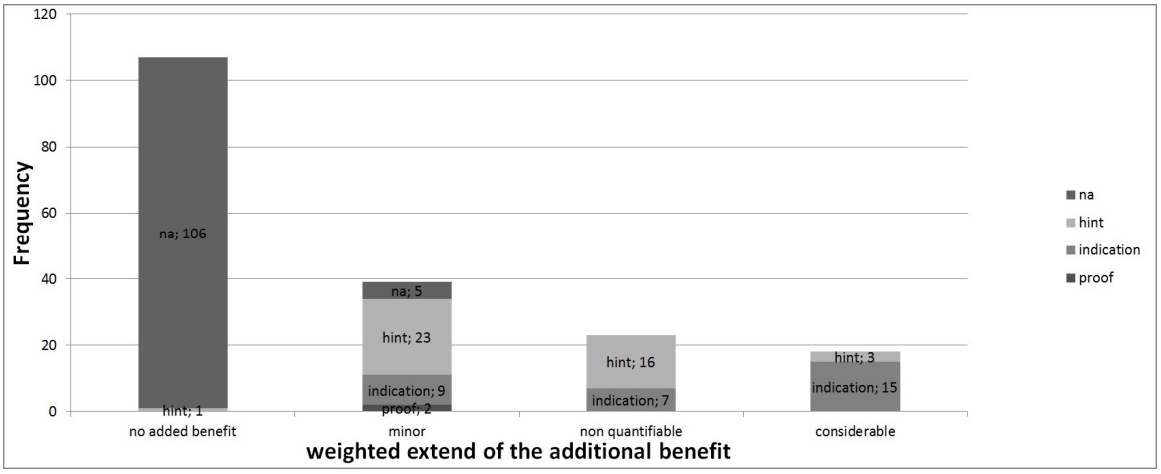
certainty benefit	M1: points
proof	4
indication	3
hint	2
na	1

3. ANALYSES AND RESULTS

3.1 DESCRIPTIVE ANALYSES

From 2011 to 2017 187 EBAs were submitted by 53 manufacturers (average: 3.53, median: 1; min: 1, max: 19) with more than half of the manufacturers (N = 28) having submitted only one EBA. Moreover, the EBAs are dominated by pharmaceuticals with the therapeutic area of oncological diseases (N = 68). In fact, the top three therapeutic areas make up for 65% of the EBAs. The 187 analysed EBA's additional benefit as granted by the Federal Joint Committee is shown in Figure 2.

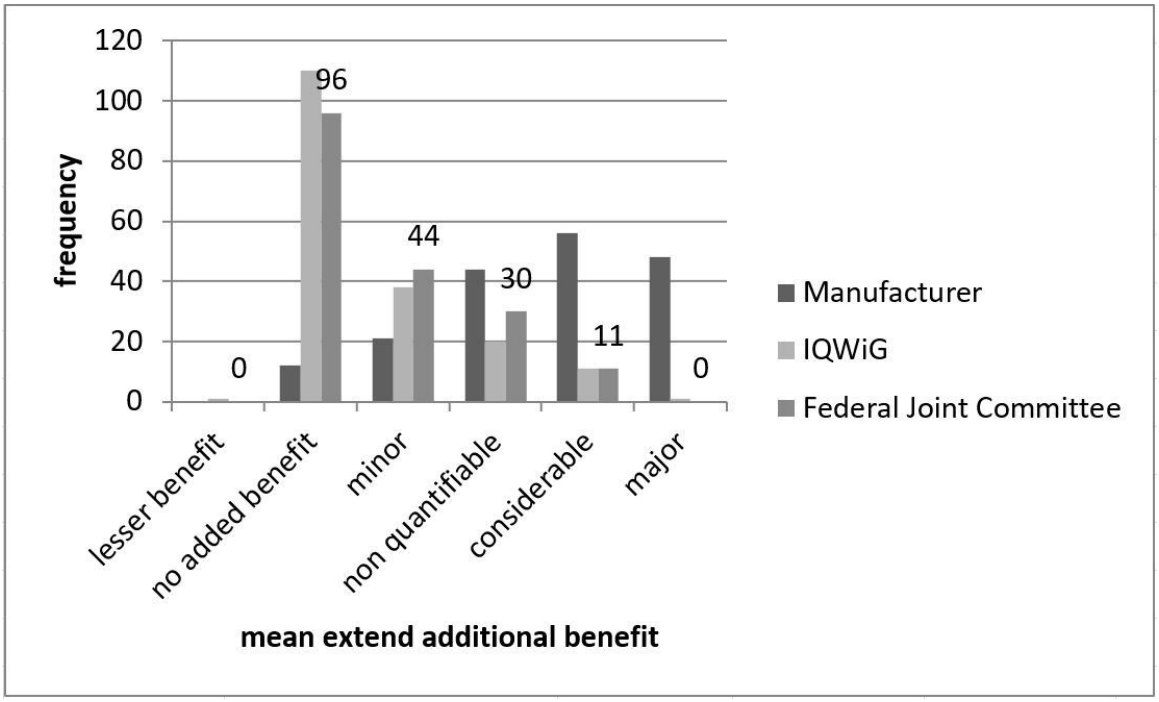
Figure 2: Frequency of EBAs with a certain extend and certainty of the additional benefit weighted by the population size.



Furthermore, the data reveal a conspicuous difference between the manufacturers' stated expectation about the assessment and the assessments made by IQWiG and the Federal Joint Committee; see Figure 3 for illustration, see Fischer and Stargardt (2014) for a more detailed discussion of the topic.

Regarding the actual pricing, we find that the mean premium on the comparator's costs weighted by the population size before the negotiation is 526.4%. During the negotiations, this gets reduced to approximately 80.3% of the initial premium (mean final premium: 422.7%). These values are strongly influenced by some outliers, though. In fact, the median launch price premium is 195.2% and the median final premium after the negotiations is 151.8%.

Figure 3: Discrepancy between the extend of the additional benefit assessed by the manufacturer, IQWiG and the Federal Joint Committee.



3.1 REGRESSION ANALYSES

As the dependent variable for our regression analysis, we use the negotiated premium on the comparator price – henceforth referred to as premium – which is defined as the relation between the new pharmaceutical's annual costs of therapy per patient and the comparator's annual costs of therapy per patient.[5]

$$premium = \frac{pharmaceutical's\ annual\ costs\ per\ patient\ after\ the\ negotiation}{comparator's\ annual\ costs\ per\ patient} \qquad (1)$$

Similarly, we normalised the manufacturer's launch strategy – henceforth referred to as launch.

$$launch = \frac{pharmaceutical's\ annual\ costs\ per\ patient\ before\ the\ negotiation}{comparator's\ annual\ costs\ per\ patient} \qquad (2)$$

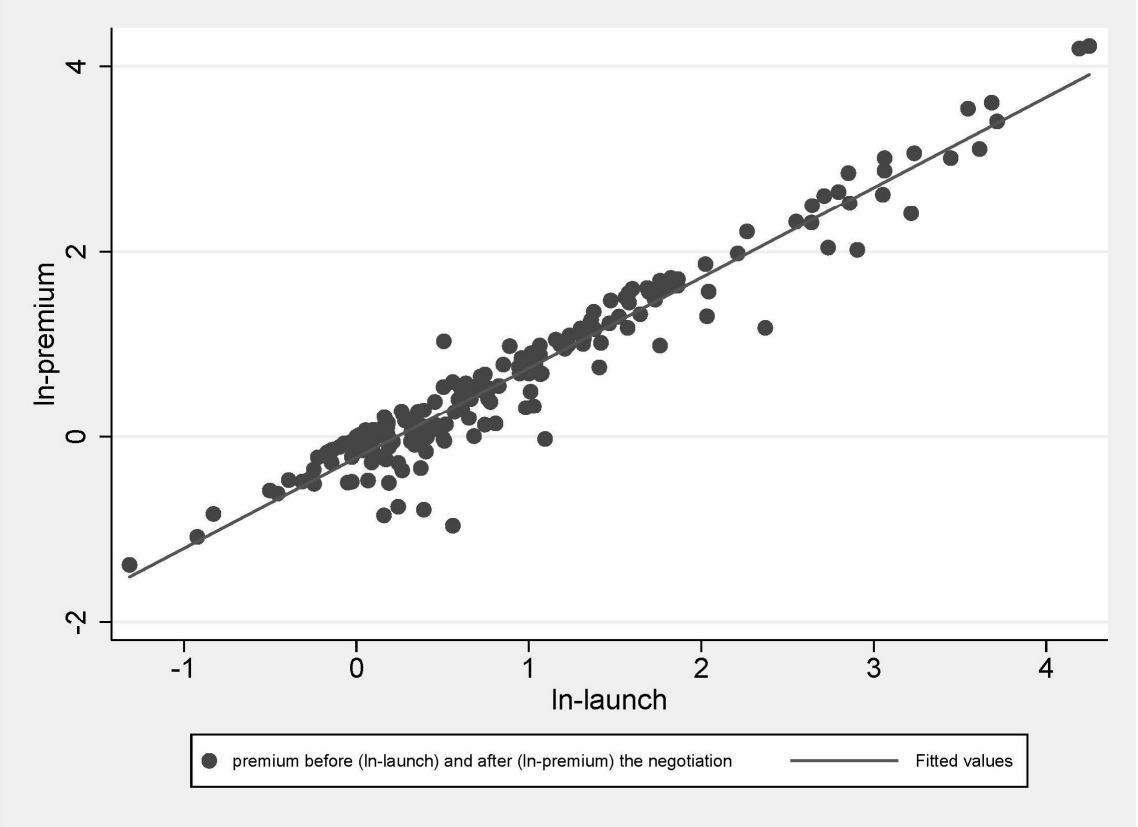
[5] *This approach is consistent with the intention of the German Pharmaceutical Restructuring Act (AMNOG), creating a reimbursement price representing the additional benefit assessed over the appropriate comparator (Social Security Code V (SGB V), 2012).*

For the regression analysis, we conducted a log ordinary least squares model. The main results of our analysis are presented as Model 1 (M1) in the sequel. A second model (M13) containing all 35 available control variables as well as a description of all variables can be found in the Appendix (Appendix A.2).

As a first result, we find a strong correlation between the launch price and the price premium after the negotiations (cf. Figure 4). This first impression is also confirmed by various regressions; see Table 3. For example, Model 2 illustrates the sole influence of the launch strategy on the negotiated premium. Note in particular, that the goodness of fit for M2 is 93.5%, suggesting that the launch price explains a large share of the eventual premium. By contrast, model M3, which only considers variables regarding the value added by the new drug – here we take the assessments by the Federal Joint Committee as variables[6] - has only a goodness of fit of 13.3% - despite the extend of the benefit having a highly significant impact. Once we take the launch price and the additional benefit into account (as well as the assessed certainty of the benefit, an interaction term and a variable accounting for whether the EBA is a renegotiation), however, the variable "extend of benefit" loses impact both in terms of parameter size and statistical significance ($p < 0.05$, see M1 in Table 3); this result is also robust to adding various further control variables (cf. Appendix A.2).

[6] *The results are robust to taking either of the available assessments.*

Figure 4: Log OLS of the premium before and after the negotiation.



A factor of particular importance, which is taken up also in Model M1, is the effect of renegotiations (e.g. due to a reassessment or an extension to a new indication). However, an additional analysis taking only the first assessment of each pharmaceutical into account (N = 118) and therefore excluding 69 renegotiated EBAs also provides no change in results (see Appendix A.3).

Thus, while the data confirm a small but tangible dependence of eventual price premiums on the actual benefit of the respective pharmaceutical, they also provide support for the claim that eventual prices are only weakly tied to fundamentals (i.e. actual quality of the drug).

Result 1 *Both launch price and benefit added by the new drug have a statistically significant influence on the negotiated eventual premium. The impact of the launch price is far stronger, though, both in terms of parameter size and level of statistical significance.*

Table 3: Regression results of M1-M5; Factors influencing the negotiated premium; * p < 0.05; ** p < 0.01; *** p < 0.001.

Variable	M1	M2	M3	M4	M5
	final	launch strategy	benefit only	launch strategy and benefit	interaction term
lnlaunch	0.954***	0.973***		0.955***	0.954***
extend	0.154*		0.358**	0.066	0.170*
certainty	0.140		0.050	-0.015	0.119
extend*certainty	-0.051				-0.048
renegotiation	0.198***				
Constant	-0.671***	-0.226***	-0.373	-0.366***	-0.620***
N	187	187	187	187	187
adj. R^2	0.946	0.935	0.133	0.937	0.938

A further question we were interested in is in how far manufacturers actually provide all available information. While the data naturally do not allow any direct inferences about this question, we do find some indirect evidence that they indeed do not.

In particular, while we find no statistically significant indifference in the benefit assessments of the pharmaceuticals by the manufacturer, the IQWiG and the Federal Joint Committee, we find that the assessment of the Federal Joint Committee actually shows the highest explanatory power regarding launch prices (cf. Table 4). Note however, that the assessment of the Federal Joint Committee is made only after the launch price, which in itself has a very high explanatory power, is set.

Moreover, the discrepancy between the three assessments of the additional benefit (cf. Figure 3) let us to analyse whether there is overstatement by the manufacturer. Results suggest that manufacturers systematically provide more favourable assessments of their products than the Federal Joint Committee. Taken together, this suggests that manufacturers indeed tend to overrate their products.

Table 4: Influence of the extend of the additional benefit granted by the manufacturer, the IQWiG and the Federal Joint Committee on the launch strategy; p < 0.05; ** p < 0.01; *** p < 0.001.

Variable	Manufacturer	IQWiG	Federal Joint Committee
benefit	0.254***	0.259***	0.383***
Constant	-0.362	0.127	-0.256
N	181	182	187
adj. R^2	0.091	0.059	0.133

Result 2 *A comparison of the benefit assessments of the manufacturers, the IQWiG and the Federal Joint Committee and their explanatory power regarding launch prices suggest that manufacturers systematically overrate the quality of their pharmaceuticals.*

4. CONCLUDING REMARKS

In this paper, we have presented the results from an analysis of the pricing process of 187 innovative pharmaceuticals in Germany, introduced between 2011 and 2017. As we have seen, the results of our analysis show that eventual price premia mostly depend on the launch price set by the manufacturer. While the actual benefit as well as a parameter measuring whether the drug is actually reintroduced so that prices are renegotiated, also show a statistically significant impact, their explanatory power remains far smaller. Of course, we can only speculate about reasons at this point. Yet, a natural guess to us seems to be that manufacturers exploit what is known as the anchoring effect (Tversky and Kahneman, 1974) when setting prices for the first year - i.e. before the actual negotiations start.

Moreover, our analysis provides some tentative indirect evidence that manufacturers systematically overrate the quality of their newly introduced pharmaceuticals. While in itself not entirely surprising, this result, to us, still seems relevant from a policy perspective. If firms use overly positive reports on their pharmaceuticals in their motivating their launch prices and if these are what effectively determines later prices, further regulation or at least a less lenient bargaining strategy of official institutions might be justified or even called for.

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Appendices

A.1 Sensitivity Analyses

Four groups of sensitivity analyses.
In addition to the main analysis, we conducted seven sensitivity analyses clustered into four different groups. Further information regarding the groups can be found below. The results of the sensitivity analyses (M6-M12) are provided in Table A.1.2. For all models, there is no change in the main results compared to our primary model M1 presented in the main body of the text. In M11, however, the variable measuring the extend of the additional benefit becomes statistically insignificant. This only strengthens the point made in the paper.

Group 1: Three additional versions of the point score for the extend of the additional benefit (see Table A.1.1) were analysed in models M6 to M8.

Group 2: Two analyses using dummy variables were conducted. M9 uses a binary variable for the existence of a weighted additional benefit (extend and certainty) while M10 tests whether the indication / patient group has an additional benefit (extend / certainty) which is weighted by the population size afterwards. A point score at and above 0.5 is defined as an added benefit.

Group 3: M11 displays the results of using data of the ebaindicationpatientgroupID with the highest extend of the additional benefit granted by the Federal Joint Committee for the corresponding EBA.

Group 4: Here we consider a model without outliers, excluding 8 EBAs with a Cook's that exceeds the threshold of 4/n from M1 in a separate sensitivity analysis in M12 (Bollen and Jackman, 1985).

Table A.1.1: Sensitivity analyses. Transformation of the extend of the additional benefit into point scores.

extend benefit	M1: points	M6: points	M7: points	M8: points
major	6	6	6	6
considerable	5	5	4	5
minor	3	4	3	2
non quantifiable	4	3	5	4
no added benefit	2	2	2	1
lesser benefit	1	1	1	0

Table A.1.2: Sensitivity analyses. Comparison of M1 (final model) to seven sensitivity analyses models; * p < 0.05; ** p < 0.01; *** p < 0.001.

Variable	M1	M6	M7	M8	M9	M10	M11	M12
	final	minor > non quantifiable	non quantifiable > considerable	non quantifiable >> minor	dummy weighted extend benefit	dummy extend benefit	highest extend	Cook's D
lnlaunch	0.954***	0.952***	0.952***	0.954***	0.955***	0.957***		0.964***
extend	0.154*							0.115
certainty	0.140	0.131	0.155	0.080				0.128
extend*certainty	-0.051							-0.042
renegotiation	0.198***	0.199***	0.195***	0.193***	0.201***	0.203***	0.196***	0.177***
extendV2		0.149*						
extend*certaintyV2		-0.047						
extendV3			0.161					
extend*certaintyV3			-0.055					
extendV4				0.123*				
extend*certaintyV4				-0.041				
addedbenefitcertainty					0.093*			
addedbenefitcertainty2						0.087*		
lnlaunchhigh							0.981***	
extendhigh							0.029	
certaintyhigh							0.027	
extend*certaintyhigh							-0.002	
Constant	-0.671***	-0.664***	-0.691***	-0.487***	-0.320***	-0.317***	-0.433**	-0.573***
N	187	187	187	187	187	187	183	179
adj. R^2	0.946	0.946	0.946	0.946	0.946	0.945	0.962	0.965

A.2 Explanation of 15 controls and regression analyses

In addition to our main model M1, we tested for a total of 35 available control variables clustered into 15 control groups. Our initial interpretation remains unchanged. Full results are presented below.

Table A.2.1: Explanation of 15 controls and the variables used.

controls	variable	detail
1: launch strategy	lnlaunch	launch strategy
2: extend benefit	extend	extend of the additional benefit granted by the Federal Joint Committee weighted by the population size per EBA
3: certainty benefit	certainty	certainty of the additional benefit granted by the Federal Joint Committee weighted by the population size per EBA
4: interaction benefit	extend*certainty	interaction term (extend * certainty)
5: therapeutic area	eyes	eye diseases
5: therapeutic area	skin	skin diseases
5: therapeutic area	heart	cardiovascular disease
5: therapeutic area	infectious	infectious diseases
5: therapeutic area	respiratory	diseases of the respiratory system
5: therapeutic area	blood	diseases of the blood and the blood-forming organs
5: therapeutic area	muscle	diseases of the musculoskeletal system
5: therapeutic area	nervous	diseases of the nervous system
5: therapeutic area	uro	diseases of the genitourinary system
5: therapeutic area	gastro	diseases of the digestive system
5: therapeutic area	oncology	oncological diseases
5: therapeutic area	psych	mental illness
5: therapeutic area	metabolic	metabolic diseases
5: therapeutic area	miscellaneous	miscellaneous
6: home bias and experience	headquarter	manufacturer's headquarter located in Germany (y/n)
6: home bias and experience	headquarterparent	parent's headquarter located in Germany (y/n)

controls	variable	detail
6: home bias and experience	totalassetsparent	parent's total assets
6: home bias and experience	experienceprocess	number of AMNOG processes conducted before
6: home bias and experience	experienceneg	number of AMNOG negotiations conducted before
7: planning insecurity	limit	Federal Joint Committee decision limited
8: arbitration board	arbitration	decision made by arbitration board (y/n)
9: previous behavior	optouts	number of previous opt-outs
10: anchor	comparatorcost	comparator's annual costs of therapy per patient in Euro weighted by the population size per EBA
11: patent	offpatent	comparator off patent weighted by the population size per EBA (y/n)
12: budgeting	groupsize	sum of population sizes per EBA
12: budgeting	cost	annual costs of therapy per patient defined by the Federal Joint Committee weighted by the population size per EBA
12: budgeting	budgetimpact	population size * annual costs of therapy
12: budgeting	ifoyear	ifo businees clima index in the year of the negotiaion
13: importance	hearingparticipants	number of hearing participants
14: value perception	discrepancy	discrepancy between the mean extend assessed by the Federal Joint Committee and the manufacturer
15: strategy	renegotiation	renegotiation due to a reassessment or an extension to a new indication

Table A.2.2: Comparison of M1(final model) to M13 (15 controls); * p < 0.05; ** p < 0.01; *** p < 0.001.

Variable	M1	M13
lnlaunch	0.954***	0.967***
extend	0.154*	0.154*
certainty	0.140	0.104
extend*certainty	-0.051	-0.046
renegotiation	0.198***	0.206***
eyes		-0.288
skin		-0.385
heart		-0.480
infectious		-0.332
respiratory		-0.182
blood		(omitted)
muscle		-0.360
nervous		-0.492
uro		-0.251
gastro		-0.383
oncology		-0.312
psych		-0.399
miscellaneous		-0.550
metabolic		-0.356
headquarter		(omitted)
headquarterparent		0.001
totalassetsparent		-0.000
experienceprocess		0.005
experienceneg		0.001
limit		-0.020
arbitration		-0.076
optouts		-0.037
comparatorcost		0.000
offpatent		0.052
groupsize		-0.000
budgetimpact		0.000
hearingparticipants		0.005
cost		-0.000*
ifoyear		0.006
discrepancy		-0.005
Constant	-0.671***	-0.923
N	187	177
adj. R^2	0.946	0.957

A.3 Renegotiation

In order to test in how far renegotiations influence our results, we excluded all 69 renegotiated EBAs leaving 118 EBAs eligible for analysis. Again, all main results remain unchanged; cf. Table A.3.

Table A.3: Comparison of M1(final model) to M14 (excluding renegotiated EBAs); * p < 0.05; ** p < 0.01; *** p < 0.001.

Variable	M1	M14
launch	0.954***	0.941***
extend	0.154*	0.256*
certainty	0.140	0.280*
edextend*certainty	-0.051	-0.090
renegotiation	0.198***	(omitted)
Constant	-0.671***	-0.960***
N	187	118
adj. R^2	0.946	0.931