In 2011 a major health care reform has taken place in Germany, also known as AMNOG (German law on reorganization of the pharmaceutical market). This act aims to close the gap of clinically relevant patient benefit and appropriate drug pricing for the German statutory health insurance (which covers around 90% of the German health care market). Newly approved compounds or indication extensions for a drug therefore have to demonstrate an additional benefit compared to their appropriate comparator treatment to the Federal Joint Committee (G-BA) in order to avoid reference group pricing. To do so the pharmaceutical manufacturer has to submit a dossier to the G-BA, containing all evidence available, to prove an additional benefit versus the appropriate comparative therapy. For more than 4 years AMNOG and the related pricing procedure for drugs is enforced now. Since its introduction until April 2015 there have already 124 assessments been finished. Rebates have been assigned following 83 price negotiations. Following 8 withdrawals, drugs from 75 assessments remained on the market.

The objective of this analysis is to review these 124 assessments based on the dossiers and G-BA decisions and its effect on drug pricing in Germany. Of particular interest were correlations between additional benefit, as determined by the G-BA, and negotiated rebate on the manufacturer free price (set by the manufacturer) following negotiations between the National Association of Statutory Health Insurance Funds (GKV-SV) and the pharmaceutical industry.

### Results (cont.)

Only 2 dossiers earned a Figure 1. Evidence & Benefit not quantifiable benefit (with a hint), and proofs was only found for 5 drugs, 3 times to be considerable and 2 times to be of minor benefit (Figure 1). Mean rebate of all 61 dossiers was found to be 17%. Across the different groups of benefit no significant variation of rebate could be found (Figure 2).

### Background & Objectives

In 2011 a major health care reform has taken place in Germany, also known as AMNOG (German law on reorganization of the pharmaceutical market). This act aims to close the gap of clinically relevant patient benefit and appropriate drug pricing for the German statutory health insurance (which covers around 90% of the German health care market). Newly approved compounds or indication extensions for a drug therefore have to demonstrate an additional benefit compared to their appropriate comparator treatment to the Federal Joint Committee (G-BA) in order to avoid reference group pricing. To do so the pharmaceutical manufacturer has to submit a dossier to the G-BA, containing all evidence available, to prove an additional benefit versus the appropriate comparative therapy. For more than 4 years AMNOG and the related pricing procedure for drugs is enforced now. Since its introduction until April 2015 there have already 124 assessments been finished. Rebates have been assigned following 83 price negotiations. Following 8 withdrawals, drugs from 75 assessments remained on the market.

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### Methods

**Review of Outcomes:** All n=124 finished and available decisions from the benefit assessment by the G-BA until April 4th 2015, were reviewed for relevant information and analyzed with regard to the outcome of price negotiations. Prices and rebates were obtained using the Laufer-Taxe database, the German drug pricing database.

**Evaluation of Information:** We identified n=75 marketed drugs with finished price negotiations and rebates. Of those n=61 were incorporated in our primary analysis (n=13 orphan drugs and n=1 decision by the arbitration board were excluded).

**Data Analysis:**

1. **Data:** Data were extracted from the G-BA decisions, GKV-SV reports and the Laufer-Taxe database in April 2014.
2. **Rebates in %** were calculated from selling price of pharmacies in EUR, derived from G-BA decision and absolute rebates in EUR, derived from the Laufer-Taxe database.
3. **Potential rebate related factors were explored.**

**Considered Factors:**

- **Rebate**
- **Best benefit rating**
- **Best evidence rating**
- **Indication**

**Understanding the dimensions of benefit and evidence rating by the G-BA and the Institute for Quality and Efficiency in Health Care (IQWiG):**

Additional benefit is determined by quantitative statements according to the IQWiG methods not quantifiable, minor, considerable or major (least to greatest benefit). Evidence is also defined according to the IQWiG methods: indication; hint; proof (least to greatest evidence). For orphan drugs any evidence is recognized as sufficient for reimbursement, therefore these dossiers usually don’t have an evidence rating.

**Results**

Evidence & Benefit: According to the G-BA, 36% (n=22) of the dossiers included in our analysis could not show evidence for additional benefit. The majority though (52.5%; n=32) achieved minor to considerable benefit with evidence levels from indication to hint. Other rankings being the exceptions (11.5%; n=7).

### Discussion

**Dossier:** Succeeding with the AMNOG process despite its massive requirements is crucial. Since in Germany the statutory health insurance covers 90% of the population, mandatory assessment for an additional benefit is the only way to enter into price negotiations with the GKV-SV which is required for reimbursement beyond reference pricing for this important market.

**Negotiation:** Seven out of eight of the manufacturers that underwent a decision made by the arbitration board are no longer selling their products in Germany. On the other hand, out of 75 successful negotiations only 1 drug is no longer available in Germany today. Therefore we conclude that succeeding in price negotiations with the Statutory Health Insurance Funds seem to lead to acceptable rebates for most pharmaceuticals, while arbitration board decisions tend to signal withdrawal from the market.

**Outcome:** Despite our thorough analysis no significant correlation between rebate and the evaluated factors could be identified. Based on the data it has to be assumed that much more complex interrelations for determining rebates exist and are not reflected in yearly therapy and comparator costs.

### References

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